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Note

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LEGAL IMPLICATIONS OF PRESCRIBING ANTIPSYCHOTIC MEDICATIONS TO INDIVIDUALS WITH DEVELOPMENTAL AND INTELLECTUAL DISABILITIES: FILLING IN THE GAPS OF THE MASSACHUSETTS SUBSTITUTED JUDGMENT DOCTRINE

Introduction

Antipsychotic medications are prescribed to individuals with developmental and intellectual disabilities at a skyrocketing rate, yet minimal information is available on the safety and efficacy of these medications in addressing the symptoms or conditions they are purported to treat.¹ In a six-year Canadian study, fifty-six percent of nearly fifty-two thousand adults with developmental and intellectual disabilities living in group homes received antipsychotic medications.² According to the Canadian study, almost one-third of the group home residents receiving antipsychotic medications did not have a psychiatric diagnosis.³ Furthermore, despite recent publicity about the excessive uses of antipsychotic medications and their severe side effects, the rate of prescribing these medications is not decelerating.⁴

*518 Despite a rapid increase in prescribing atypical antipsychotics for non-psychiatric indications, clinical studies are sparse in explaining the efficacy, safety, and tolerability of these medications.⁵ Foster care children are frequently prescribed antipsychotic medications for “aggression,” a practice that is highly scrutinized due to minimal empirical data supporting aggression as an appropriate indication.⁶ Although the FDA approved antipsychotics for limited non-psychosis indications, clinicians are responsible for explaining their own careful analysis of potential risks and benefits during the process of obtaining informed consent from their patients.⁷

Part I of this note will describe the history of first-generation antipsychotics and the subsequent development of second-generation antipsychotics associated with a rapid expansion of prescribed uses.⁸ This part will also discuss the history of federal legislation involving antipsychotics in nursing homes and the background of informed consent issues relating to children and individuals of all ages with mental illness.⁹ Part II will discuss concerns with prescribing antipsychotics to individuals with disabilities.¹⁰ Part II will also address regulatory mechanisms to obtain informed consent and reduce chemical restraints among children, nursing home residents, and individuals with developmental and intellectual disabilities.¹¹ Part III will analyze the effectiveness of existing efforts to reduce *519 antipsychotic use for developmental and intellectual disabilities and advocate for the implementation of medication review teams.¹²

I. History of Antipsychotic Medication

A. History of Development, Use, and Expansion of Antipsychotic Medications

In 1952, Henri Laborit, a French army surgeon, was researching drugs to supplement anesthetics when he noticed patients developed a type of quiet euphoria after taking one of these drugs.¹³ Following the discovery, scientists continued to develop various theories until the mid 1970s when Jacques Van Rossum suggested antipsychotics target the brain's dopamine receptors.¹⁴ During the same decade, a Toronto laboratory found that it took a much lower concentration of another antipsychotic, haloperidol, to reach an “active” state.¹⁵ Today, the medical literature reveals that typical antipsychotics work as dopamine antagonists, a mechanism that increases the chance of developing serious movement disorders.¹⁶ Two frequently occurring antipsychotic-induced movement disorders are Parkinson-type movements and tardive dyskinesia.¹⁷

Prompted by the desire to find drugs with a lower incidence of movement disorders, scientists discovered clozapine and claimed that it produced fewer side effects than other antipsychotic medications.¹⁸ Drug companies rushed to market what came to be known *520 as “atypical antipsychotics,” touting their uses for refractory schizophrenia and their supposedly low incidence of tardive dyskinesia.¹⁹ Theoretically, atypical antipsychotics, also known as second-generation antipsychotics, have a lower risk of causing irreversible movement disorders.²⁰ Physicians continue prescribing atypical antipsychotic medications at high rates, especially to children in foster care, elderly patients, and people with developmental and intellectual disabilities.²¹

The practice of prescribing atypical antipsychotics off-label for non-psychotic symptoms rapidly shifted in 2006, when the Food and Drug Administration (“FDA”) approved risperidone for irritability associated with autism.²² Autism spectrum disorder (“ASD”) is a type of developmental disorder with symptoms typically consisting of difficulty communicating and interacting with others, repetitive behaviors, and minimal or no eye contact with other people.²³ In 2009, the FDA approved aripiprazole (“Abilify”), another type of atypical antipsychotic, for treating irritability associated with *521 autistic spectrum disorder.²⁴ Pharmacologists hypothesize that risperidone and aripiprazole treat “irritability” by blocking specific dopamine and serotonin neurotransmitter receptors.²⁵

B. History of Federal Regulation and Oversight of Antipsychotic Medications

While physicians and healthcare facilities prescribed antipsychotic medications more frequently, federal agencies started advocating for the enhanced monitoring of the usage and effect of antipsychotic medications on vulnerable populations.²⁶ In 1978, the FDA took a significant step by requiring physicians to include precaution statements on antipsychotic drug labels warning patients of the potential risk of breast cancer.²⁷ In 1986, the Institute of Medicine (“IoM”) released an extensive report on the quality of care in *522 nursing homes, categorizing the excessive use of antipsychotic medications as indicative of poor quality of care.²⁸

The IoM report explained that “key indicators of inadequate care are prima facie evidence of a problem” that prompted further investigation into the etiology of the problem.²⁹ The investigation resulted in a “bill of rights” for nursing home residents, addressing chemical and physical restraints as part of the Omnibus Budget Reconciliation Act of 1987 (“OBRA”).³⁰ Other than two exceptions, nursing homes are prohibited from imposing chemical or physical restraints if they are used mainly for the purpose of convenience or discipline.³¹


Despite this apparently significant stride in nursing home reform, a myriad of medical and policy reports continued to express concerns over the care of, and civil rights issues relating to, nursing home residents.³² In 1992, the Health Care Financing Administration (“HCFA”) proposed a regulation requiring long-term care facilities to complete a specialized assessment of residents taking psychotropic medications, including *523 antipsychotics.³³ Facilities performed assessments when residents exhibited a combination of “triggers” that would indicate a need to lower the dose or stop the psychotropic medication

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treatment.³⁴ The proposed law became implemented in practice as the Resident Assessment Instrument, guided by the Center for Medicare and Medicaid Services (“CMS”).³⁵

In addition, a string of U.S. Supreme Court cases reflected the elephant in the room: the forcible administration of antipsychotic medications resulted in depriving patients of their rights to informed consent.³⁶ In 1990, the U.S. Supreme Court held a forensic hospital's policy of forcibly administering antipsychotic drugs to an inmate did not violate the inmate's due process rights where the inmate was dangerous and the use of antipsychotics was consistent with medical opinion.³⁷ In *Olmstead v. L.C.*, the U.S. *524 Supreme Court held that people with disabilities must receive treatment in the most integrated environment as possible, so long as it does not fundamentally alter the state's services for disabilities.³⁸ Even with increasing pressure for change, the United States continues to allow the misguided and harmful prescribing of antipsychotic medications to infringe upon individuals' human rights.³⁹

C. History of Informed Consent with Antipsychotic Medications? Problems Unique to Children and Individuals with Disabilities

Informed consent for medications among vulnerable individuals-- children, elderly, and people with disabilities--is a human rights issue with a rich history of legislation.⁴⁰ The legal concept of “informed consent” was first applied in a 1914 New York case where the court found that the removal of a fibroid tumor without the patient's consent constituted medical battery.⁴¹ In 1982, the International Ethical Guidelines for Research Involving Human Subjects established specific requirements to obtain informed consent prior to enrolling human subjects in research studies.⁴² Prison inmates with mental illness *525 who were forcibly administered antipsychotic medications have successfully brought civil actions for the deprivation of their rights, under  42 United States Code, Section 1983.⁴³

Prescribers of psychotropic medications to a child must obtain informed consent from the child's parent or guardian.⁴⁴ The prescribing clinician must explain the medication's purpose for the patient's condition, the potential risks of the medication, unknown risks, a treatment description, and alternative treatments.⁴⁵ With the proliferation of non-psychosis indications for prescribing antipsychotic medications to foster care children, enforcing informed consent is critical.⁴⁶ Antipsychotic medications are commonly prescribed for attention deficit hyperactivity disorder (“ADHD”), oppositional defiant disorder, and conduct disorder, all conditions involving challenging behavior.⁴⁷

In a 2008 congressional hearing, a panel of medical and legal professionals testified about the dangers of prescribing psychotropic medications to foster care children, mainly *526 due to the children's deficiencies in continuity of care.⁴⁸ The panel suggested implementing a “clinical education team” consisting of psychopharmacologists and looking at states that improved, to help minimize interstate variation in prescribing practices.⁴⁹ The Office of the Inspector General (“OIG”) under the U.S. Department of Health and Human Services (“HHS”) recommended regulation to monitor the use of antipsychotic medications among children without psychiatric diagnoses.⁵⁰ An OIG investigation found that sixty-seven percent of Medicaid-paid claims had quality-of-care concerns based on the psychiatrists' reviews of children's medical records.⁵¹

Whereas continuity of care is a major issue for foster care children's' medical treatment, the prejudice of the psychiatric field regarding adults with mental illness is a major preclusion to achieving higher quality of care for this vulnerable population.⁵² In Massachusetts, several Supreme Judicial Court (“SJC”) decisions involved the rights of individuals with mental illness to refuse antipsychotic medications.⁵³ Massachusetts requires that individuals with mental illness receive an adjudicatory hearing to determine whether they may be administered antipsychotic medications in non-emergency situations.⁵⁴

*527 The SJC developed a five-factor test to determine when administering antipsychotic medications to incompetent individuals with mental illness requires a court order.⁵⁵ The court considers: (1) intrusiveness of the proposed treatment, (2)

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chances of experiencing negative side effects, (3) whether an emergency exists, (4) prior judicial involvement, and (5) potential conflicting interests.⁵⁶ In addition, the substituted treatment plan must evaluate the individual's current competency.⁵⁷ The purpose of the procedure is to protect patients from abandoning their rights to refuse medications once they are committed to a mental health facility or are under guardianship.⁵⁸

II. Prescribing Antipsychotic Medications to Individuals with Developmental and Intellectual Disabilities

A 2009 medical claims study found that sixty-two percent of adolescents and sixty-seven percent of young adults were prescribed antipsychotics without a psychiatric diagnosis.⁵⁹ A United Kingdom ("U.K.") study of 9,135 individuals found that seventy-one percent of people prescribed antipsychotic medication were not diagnosed with a severe mental illness.⁶⁰ People within the group lacking mental illness diagnoses were *528 most commonly prescribed antipsychotics for "problematic behaviors."⁶¹ A Canadian study found that thirty-nine percent of adults with developmental or intellectual disabilities were given antipsychotic medications.⁶²

The advent of atypical antipsychotics, with their allegedly reduced risk of movement disorders, catalyzed the increased prescribing to individuals with intellectual or developmental disabilities.⁶³ Amidst the excitement to prescribe these "miracle" drugs, other doctors and psychologists criticized the lack of adequate scientific evidence on the drugs' long-term side effects, such as tardive dyskinesia.⁶⁴

A. Antipsychotic Drugs and the Danger of Chemical Restraints

A chemical restraint is "a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition."⁶⁵ Antipsychotics are more likely to be used to control behavior when they are either administered as PRNs or substituted for behavioral *529 management programs.⁶⁶ In order to avoid prescribing drugs for inappropriate indications, physicians should perform a differential diagnosis of the patient's underlying conditions and determine how severely the behavior impacts the patient's daily functioning.⁶⁷ Physicians who fail to perform thorough assessments tend to prescribe antipsychotics to control challenging behaviors, thereby using them as chemical restraints.⁶⁸ When prescribing Risperdal and Abilify, drugs that are FDA-approved for irritability associated with autism, physicians must limit prescribing to children between five years old and seventeen years old in order to remain within the FDA-approved age indication.⁶⁹

As an attempt to curtail the use of psychotropic medications as chemical restraints, the Royal College of Psychiatrists of the U.K. ("Royal College") created a faculty report setting out a comprehensive set of guidelines for treating patients with intellectual disability.⁷⁰ The Royal College issued the faculty report in response to two significant concerns: (1) physicians and healthcare institutions were inadequately monitoring for adverse effects of psychotropic medications; and (2) physicians were performing *530 substandard diagnostic assessments prior to prescribing psychotropic medications.⁷¹ The Royal College regards "challenging behaviors" as a cluster of socially constructed symptoms rather than a medical diagnosis, making it crucial to identify underlying causes of the behavior.⁷² The main prescribing standards are: (1) providing the indications and rationale for prescribing the psychotropic medication, (2) obtaining and documenting consent, (3) monitoring side effects every three to six months, and (4) reviewing and evaluating the need to continue the psychotropic drug every three to six months.⁷³

Although not as comprehensive as the U.K. guidelines, Australia and the Netherlands are asserting the critical need for monitoring antipsychotic use among individuals with intellectual and developmental disabilities.⁷⁴ The Netherlands proposed a law that would make the prescription of antipsychotic medications to individuals with intellectual disabilities a presumptively coercive measure.⁷⁵ Unlike the U.K. and other countries in *531 the process of establishing uniform guidelines, the U.S. lacks consistent, federal laws and regulations despite multiple government agency reports revealing substandard prescribing

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practices.⁷⁶ Despite codifying regulations for individuals living in prison,⁷⁷ long-term care facilities,⁷⁸ homes for veterans, and children covered under Medicaid programs, the Code of Federal Regulations is silent about psychotropic medications for individuals with developmental and intellectual disabilities.⁷⁹ The Developmental Disabilities Assistance *532 and Bill of Rights Act of 2000 provides minimal guidance on “sufficient medical and dental services,” and does not include information regarding psychotropic medications.⁸⁰

Washington, Illinois, Georgia, and Washington D.C. have some regulations or statutes regarding the prescriptions of psychotropic medications for individuals with developmental or intellectual disabilities.⁸¹ California recently revised its code to mandate the Medical Board of California to give priority to disciplinary investigations for inappropriate prescribing of psychotropic medications to minors.⁸² Georgia prohibits the use of chemical restraints for all students in its public schools and educational programs and for all individuals receiving treatment in crisis stabilization units.⁸³ Illinois and *533 Massachusetts require an authorized physician to order chemical restraints, document the reasons necessitating the restraint, and explain how the restraint is the least restrictive and most appropriate alternative.⁸⁴ While Massachusetts' laws limit the use of chemical restraints among individuals with developmental and intellectual disabilities, it lacks the oversight and infrastructure necessary to ensure compliance with these laws.⁸⁵

B. Informed Consent and Monitoring for Side Effects of Antipsychotic Medications

Initially, the pharmaceutical companies enjoyed wide acceptance in marketing atypical antipsychotic drugs for people with autism and other developmental and intellectual disabilities.⁸⁶ Public outcry erupted when the FDA discovered that Janssen Pharmaceuticals had concealed some of Risperdal's serious side effects.⁸⁷ A majority of the lawsuits asserted that the concealed effects caused an increase of prolactin production, *534 which caused a condition known as gynecomastia.⁸⁸ The Joint Commission suggests that physicians inform patients of the “nature, risks, and alternatives of a medical procedure or treatment” to obtain informed consent.⁸⁹ Recently, a Pennsylvania jury found Janssen Pharmaceuticals negligent for failing to warn the plaintiff's prescribing physician about the prevalence of gynecomastia in children and thus, failing to inform the plaintiff's mother of an adverse effect.⁹⁰ As a result of his physician prescribing him Risperdal, the plaintiff took the medication as instructed and subsequently developed gynecomastia.⁹¹ The plaintiff's mother asserted that if she were properly informed of Risperdal's statistically significant risk of causing gynecomastia, she would not have consented to her son taking Risperdal.⁹²

The other under-reported side effect of atypical antipsychotic medications is tardive dyskinesia.⁹³ In an Illinois medical malpractice case, Dr. Peter Breggin, a child psychiatrist, testified that the plaintiff's doctor failed to obtain informed consent to administer risperidone and failed to monitor the plaintiff for early signs of tardive *535 dyskinesia.⁹⁴ He added that informed consent requires physicians to provide detailed information to enable the parent, caretaker, or the patient to recognize and describe manifestations if and when they observe side effects.⁹⁵

Individuals with developmental and intellectual disabilities may have a physiological hypersensitivity to antipsychotic medications, and consequentially prescribers should be especially cautious to monitor for side effects.⁹⁶ In fact, physicians tend to overlook physical symptoms in this population because they assume the intellectual or developmental disability is the cause of abnormal movements.⁹⁷ The result is a phenomenon called “diagnostic overshadowing” because the physician evaluating the individual misses the actual condition by misattributing the physical symptoms to the person's disability.⁹⁸ A U.S. Government Accountability Office report revealed that nearly half of physicians did not adequately monitor patients for adverse effects and only one-quarter of physicians obtained informed consent.⁹⁹

*536 For long-term care residents, Massachusetts defines informed consent as a three-part process, requiring the prescriber to explain the purpose for administering the drug, “the prescribed dosage,” and “any known effect or side effect of the psychotropic medication.”¹⁰⁰ In order to clarify informed consent requirement for long-term care facility residents, Massachusetts recently

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implemented revisions to its prescribing guidelines.¹⁰¹ The revised guidelines specify that antipsychotic drugs may be prescribed, so long as the individual's *Rogers* rights are maintained.¹⁰²

The administration of antipsychotic medication is considered a type of “extraordinary treatment.”¹⁰³ If a physician, parent, or other involved person believes that an adult lacks competency to make medical decisions, then he or she must petition for a *Rogers* guardianship with the probate and family court.¹⁰⁴ In a *Rogers* procedure, the court first determines whether the individual lacks competency to provide informed consent.¹⁰⁵ If the answer is affirmative, the court applies a substituted judgment standard to decide whether the individual would choose to accept the antipsychotic treatment if he or she *537 were competent to make this decision.¹⁰⁶ If the court determines that the individual would receive treatment, it will appoint a *Rogers* guardian.¹⁰⁷ The *Rogers* Guardian's role is to ensure that the individual's physician and care team are prescribing and administering the antipsychotic medication in accordance with the court-approved treatment plan.¹⁰⁸ The *Rogers* order must be periodically reviewed to determine if the individual's condition and circumstances have substantially changed.¹⁰⁹

Before 2009, Massachusetts lacked any codification of the substituted judgment proceeding for treatment with antipsychotic medications for individuals declared incompetent for reasons other than mental illness.¹¹⁰ Instead of providing a concise statute for prescribing antipsychotic medications, Massachusetts separated its antipsychotic guidelines depending on the type of school or medical facility where the individual resides.¹¹¹ The implementation of Article V of the original Uniform Probate *538 Code (“UPC”) added some clarification to this dilemma.¹¹² Article V codified the Massachusetts extraordinary treatment doctrine by requiring the guardian of an incapacitated person to submit a petition for substituted judgment to the court in order to administer a prescription of antipsychotic medication to the incapacitated person.¹¹³

Some attempts to regulate the use of antipsychotic medication to protect the rights of individuals with developmental and intellectual disabilities have resulted in action, and other attempts have expressed insightful ideas.¹¹⁴ Nevertheless, recent medical studies and government agency reports demonstrate that a substantial amount of work remains for policymakers, legislators, healthcare professionals, and legal advocates to curb the misuse of antipsychotic medications.¹¹⁵

III. Filling the Gap of Substituted Judgment Proceedings with the Implementation of a Medical Review Team

The excessive and inappropriate prescribing of antipsychotic medications to individuals with developmental and intellectual disabilities contradicts both human rights principles and the Supreme Court decision in *Olmstead*, which emphasized the rights of *539 individuals with disabilities to live in the least restrictive environment.¹¹⁶ The multifaceted issue behind inappropriate medication use involves physicians' failure to perform comprehensive assessments, failure to identify target behaviors caused by an underlying condition, and subsequent misprescribing of antipsychotic medications as chemical restraints.¹¹⁷

A. Poor Informed Consent Compliance Among Prescribers of Antipsychotic Medications

If Massachusetts better regulates informed consent for prescribing antipsychotic drugs through medical record audits, then the rate of inappropriate prescribing of medications will decrease.¹¹⁸ Despite a recent history of reform for individuals in institutions, Medicaid recipients, and nursing home residents, Massachusetts allows individuals with developmental and intellectual disabilities to undergo ineffective and potentially harmful medical treatment.¹¹⁹ Although substituted judgment is a well-intended belief, reality demonstrates overbooked family and probate court judges are left *540 with unfettered discretion to make life-altering decisions about an individual's body.¹²⁰ The illusion of progressive judicial protection hides an overarching theme that society accepts the widespread use of antipsychotics to control individuals with behaviors of unknown causes, which require a “quick fix.”¹²¹

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By lacking stringent documentation and monitoring requirements, informed consent laws allow physicians to pervasively evade obtaining informed consent from their patients or patients' guardians when prescribing antipsychotic medications.¹²² Despite detailed analyses provided in both *Roe* and *Rogers*, the Massachusetts Supreme Judicial Court has *541 inconsistently applied the substituted judgment standard.¹²³ When properly enforced, substituted judgment promotes an individual's autonomy and dignity by carefully considering and periodically reviewing whether the individual can make certain decisions of his or her own.¹²⁴ In practice, substituted judgment has failed to ensure that individuals' wishes are being accurately applied to the decision to treat them with antipsychotic medications.¹²⁵

Just as judges should not make binding decisions about an individual's medical care, prescribers cannot assume a patient is incompetent to make medical decisions, because an individual's inability to provide consent must be determined through a court hearing *542 and requires due process safeguards.¹²⁶ Numerous government agency reports show that physicians fail to obtain informed consent from vulnerable groups of people.¹²⁷ Therefore, regulatory agencies need to be especially attentive in monitoring physician's compliance in prescribing antipsychotic medications to individuals with developmental and intellectual disabilities.¹²⁸ By prescribing harmful and ineffective antipsychotic medications, physicians are violating the fourteenth amendment liberty interests of individuals with intellectual and developmental disabilities.¹²⁹

B. The Overuse of Chemical Restraints in Massachusetts

Massachusetts DDS regulations exempt court-ordered antipsychotic medications from being considered “chemical restraints.”¹³⁰ By doing so, DDS haphazardly leaves crucial medical decisions to the ultimate discretion of probate and family courts.¹³¹ Even *543 when appropriately ordered, the administration of antipsychotic medications is problematic when caretakers and guardians lack adequate medical oversight when dispensing antipsychotic medications.¹³² The inappropriate use of antipsychotic medications as chemical restraints is due to both inadequate education and training of caretakers on administering antipsychotics, and lackluster documentation requirements for prescribers.¹³³ Probate and family courts are responsible for overseeing an individual's medication plan, yet in practice, these courts rarely change or overturn a *Rogers* treatment plan to maintain the status quo of the individual's antipsychotic dosage.¹³⁴

The lack of a mandatory documentation system contributes to the widespread over-prescribing of antipsychotic medications by failing to incentivize prescribers to rule out underlying conditions contributing to the target behaviors.¹³⁵ By failing to perform a *544 differential diagnosis, prescribers set up the patient for a potentially indefinite span of presumed incapacity, instead of restoring the patient's capacity by treating an underlying condition.¹³⁶ The popular use of the term “challenging behavior,” as a clinical indication for prescribing antipsychotic medications, exacerbates the harmful practice of diagnostic overshadowing.¹³⁷ Medical organizations and policymakers should eradicate the term “challenging behavior” as a permitted justification for antipsychotic prescriptions because the term is arbitrary and the etiologies of challenging behaviors are poorly understood.¹³⁸

C. The Lack of Federal Guidance in Protecting the Rights of Individuals Receiving Antipsychotic Medications

A uniform and systematic process of documenting the process for prescribing antipsychotic medications is crucial to preserve the autonomy and dignity of individuals with developmental and intellectual disabilities with the capacity to consent to medical treatment.¹³⁹ The National Association of State Directors of Developmental Disability *545 Services (“NASDDDS”) and the Center for Medicare and Medicaid Services (“CMS”) lack a consistent set of guidelines for the safe and effective prescribing of antipsychotic medications to individuals with developmental and intellectual disabilities.¹⁴⁰ Successful prescribing guidelines require both a detailed documentation process for physicians and medication dispensers, and the designation and funding of an agency in each state to receive and verify these documents, such as DDS in Massachusetts.¹⁴¹ To ensure proper monitoring

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of negative and positive effects of antipsychotic medication, a working group of physicians and other healthcare professionals must create a guided documentation list of pre-prescribing evaluation requirements, with an attached detailed checklist.¹⁴²

D. Massachusetts Should Implement Antipsychotic Medication Review Teams to Protect Individuals with Developmental and Intellectual Disabilities from Harmful and Ineffective Treatment

On a state level, Massachusetts needs to fine-tune its regulations on using chemical restraints, and increase oversight of physicians' incentives to perform a comprehensive assessment prior to prescribing antipsychotic medications.¹⁴³ Without clearer guidelines, physicians will continue to misattribute indications for antipsychotic medications to the patient's developmental or intellectual disability.¹⁴⁴ Long-term and ineffective prescribing of antipsychotics will likely exacerbate the individual's underlying condition and could create a permanent mental incapacity in someone who could have improved with the *546 correct treatment.¹⁴⁵ A few states have taken positive initiative by strictly limiting permitted uses of chemical restraints or establishing medication review teams regarding antipsychotics for individuals with intellectual and developmental disabilities.¹⁴⁶

Massachusetts must hold healthcare providers who prescribe antipsychotic medications to individuals with developmental and intellectual disabilities accountable by creating and legally mandating medication review teams.¹⁴⁷ Medication review teams consist of psychiatrists, pharmacists, and various healthcare practitioners who review the individual's medication regimen at defined time intervals, and look for "red flags," such as excessive dosage, inadequate monitoring and adverse effects outweighing the benefits.¹⁴⁸ The medication review process, adopted by the federal government for nursing home residents and by some states for foster care children and individuals with disabilities, would help to fill the gaps of the substituted judgment procedure in five ways.¹⁴⁹

First, medication review teams require at minimum, the participation of a licensed physician other than the prescribing physician.¹⁵⁰ In addition, most medication review *547 teams require a clinical pharmacist or other medical professional to consult alongside the physician.¹⁵¹ In contrast, a judge makes the substituted judgment decision often relying solely on the prescribing physician's testimony regarding the justification for the extraordinary medical treatment.¹⁵² Although the substituted judgment procedure also encourages the involvement of other professionals working with the individual and the individual's family, the judge will give substantial deference to the medical professional's opinion when making a medically based decision.¹⁵³

Second, a medication review team would ensure a thorough and timely re-inspection of the antipsychotic treatment plan, as opposed to the probate and family court only requiring a cursory review of the Rogers treatment plan once a year.¹⁵⁴ The standard for changing the Rogers order is whether circumstances have substantially changed so that if the individual were competent, he or she would no longer consent to treatment.¹⁵⁵ Medication review teams require more frequent checks, typically ranging between one and *548 nine months.¹⁵⁶ The reviews are detailed and straightforward; they often include a presumed dose reduction of the antipsychotic medication unless clinically contraindicated.¹⁵⁷

Third, there are factors in common between substituted judgment decisions and medication review teams, including the intrusiveness of the proposed treatment and the chance of experiencing negative side effects.¹⁵⁸ Medication review teams bolster the substituted judgment protocol by: (1) requiring the prescriber to either obtain recent records of a differential diagnosis or perform one upon prescribing the medication, and (2) mandating a plan for gradually tapering the antipsychotic medication.¹⁵⁹

Furthermore, only the Rogers monitor or Rogers guardian is relied upon to ensure that the individual is taking antipsychotics in accordance with the court ordered treatment plan.¹⁶⁰ Nevertheless, neither Rogers monitors nor guardians are required to attend medical training that would better equip them to recognize potential warning signs for *549 adverse reactions to

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antipsychotic medications.¹⁶¹ Conversely, medication review teams consist of independent physicians and other professionals with specialized medical training who can act as a peer review to the prescribing physician's decision.¹⁶² Lastly, the clinician's affidavit and report, required for extending or amending a substituted judgment plan, leaves a small blank space inquiring about side effects.¹⁶³ Medication review teams include a checklist of monitoring requirements, such as labs, electrocardiograms, and movement disorder scales.¹⁶⁴

If Massachusetts mandates physicians to obtain all medical and psychiatric records prior to prescribing antipsychotic medications to individuals with developmental and intellectual disabilities, physicians will be likely to perform a thorough assessment of whether the individual actually requires antipsychotic medication.¹⁶⁵ This way, physicians will be more attuned to co-occurring conditions that provide triggers for ordering additional monitoring tests.¹⁶⁶ If DDS and the Board of Registration in Medicine *550 collaborate to co-investigate and sanction physicians who inappropriately prescribe antipsychotic medications to individuals with developmental and intellectual disabilities.¹⁶⁷ This way, courts will only need to hold hearings if the medication review team is unable to address concerns of improper prescribing of antipsychotics with the individual's prescribing physician.¹⁶⁸

IV. Conclusion

The use and regulation of antipsychotic medications have expanded tremendously since the 1950s. Nursing home advocate groups and U.S. Supreme Court cases led to the recognition that "treatment" with antipsychotic medications was often infringing upon an individual's right to live in the least restrictive environment, with the environment including one's body and brain. The Massachusetts substituted judgment doctrine defined in *Roe* and *Rogers* changed the legal system's perception of an individual's right to make choices but did little to eradicate the problem of antipsychotic medications being forced upon people as a mode of controlling poorly understood behaviors. Doctors, families, caretakers, and people with disabilities are concerned about the pervasive prescribing of antipsychotics to individuals with developmental and intellectual disabilities, provided with the growing body of evidence of these drugs' severe and potentially permanent adverse effects.

Despite a series of federal agency investigations and statewide reforms, the federal government has been passive in enforcing accountability and responsibility upon prescribers and monitors of antipsychotic medications. While some physicians are attentive and thorough in their assessments of patients, others continue to prescribe antipsychotic medications for the wrong reasons, to the unacceptable detriment of their patients. Physicians must treat their decisions to prescribe antipsychotic medications as life altering--after all, these medications earned the label "extraordinary medical treatment." Rather than continue to accept the practice of administering drugs to keep individuals with developmental and intellectual disabilities quiet or even make them worse, the medical and legal community must create ways for these individuals to preserve their autonomy through safe and effective treatment.

Footnotes

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¹ See Yona Lunskey et al., *Antipsychotic Use with and Without Comorbid Psychiatric Diagnosis Among Adults with Intellectual and Developmental Disabilities*, 63 CANADIAN J. PSYCHIATRY 361-69 (2017) (studying over 50,000 adults with developmental-intellectual disabilities with and without psychiatric diagnoses).

² See *id.*; see also Lotte Ramerman et al., *Adherence of Clinicians to Guidelines for the Prescription of Antipsychotic Drugs to People with Intellectual Disabilities*, 11 ADVANCES MENTAL HEALTH & INTELLECTUAL DISABILITIES 110 (2017) (finding ninety percent of non-psychotic indications were for problem behaviors).

- 3 See Lunsky et al., *supra* note 1.
- 4 See e.g. Rory Sheehan et al., *Mental Illness, Challenging Behaviour, and Psychotropic Drug Prescribing in People with Intellectual Disability: UK Population Based Cohort Study*, 351 BRIT. MED. J. 342 (2015); Sadira Teeluckdharry et al., *Monitoring Metabolic Side Effects of Atypical Antipsychotics in People with an Intellectual Disability*, 17 J. INTELLECTUAL DISABILITIES 223 (2013) (discussing psychiatrists' challenges in following minimum acceptable standards in prescribing antipsychotics); Emily Anthes, *Widely Used Autism Drug Carries Heavy Risks for Children*, SCI. AM. (May 8, 2014), <https://www.scientificamerican.com/article/widely-used-autism-drug-carries-heavy-risks-for-children/> (describing multiple studies revealing weight gain, involuntary movements, and fatigue from autism drugs); Jacintha S. Cauffield, *[Infographic] Medication Use in Autism Spectrum Disorders: What is the Evidence?* FORMULARY J. (May 1, 2013), <http://formularyjournal.modernmedicine.com/formularyjournal/content/tags/antipsychotics/infographic-medication-use-autism-spectrum-disorders-w> (summarizing various studies on second-generation antipsychotics in individuals with autism).
- 5 See Robert Findling et al., *Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents*, AM. ACADEMY CHILD & ADOLESCENT PSYCHIATRY 8-9 (2011), (discussing limited data on cardiovascular effects, electroencephalogram abnormalities, and cataracts). Limited research has revealed an increase of certain serious side effects among patients with personal or family histories of cardiac problems, diabetes, and seizures. *Id.* at 10. In response, clinicians should carefully identify these factors prior to prescribing atypical antipsychotics. *Id.* An “atypical” label is used to distinguish antipsychotic drugs that are less likely to cause extrapyramidal side effects compared to “typical” antipsychotic drugs. *Id.* at 3. Extrapyramidal side effects are “involuntary movements that occur due to blockade of dopamine receptors in the nigrostriatal pathway of the basal ganglia.” LORING F. CHAPMAN & JOHN W. EVANS, COURTROOM MEDICINE SERIES: HEAD AND BRAIN § 87.03 (Matthew Bender, 2016) [hereinafter COURTROOM MEDICINE]. These side effects most frequently include muscular rigidity, tremor, and feelings of inner restlessness. *Id.*
- 6 Findling et al., *supra* note 5, at 10 (suggesting clinicians conduct more in-depth assessments prior to prescribing atypical antipsychotics); Oriana Linares et al., *Stimulant and Atypical Antipsychotic Medications for Children Placed in Foster Homes*, 8 PLOS ONE 1 (2013) (outlining high metabolic risks for children taking antipsychotics). Antipsychotics are often indicated for children with reactive aggression and impulsivity, and are used frequently in children with attention deficit hyperactivity disorder (“ADHD”). *Id.* at 5. One danger is that antipsychotics (and other psychotropic drugs) are being readily prescribed without a comprehensive diagnostic workup to evaluate the underlying cause of the child's behaviors. *Id.* at 6.
- 7 See Aveekshit Tripathi, *Antipsychotics for Nonpsychotic Illness*, 12 CURRENT PSYCHIATRY 22 (2013) (studying antipsychotic medication uses for insomnia, tics, delirium, and stuttering).
- 8 See *infra* Part I (differentiating between typical and atypical antipsychotic medications).
- 9 See *infra* Part I (explaining the history of antipsychotic medications, their regulation, and emerging issues).
- 10 See *infra* Part II (discussing excessive and inappropriate prescribing of antipsychotic medications to individuals with developmental/intellectual disabilities).
- 11 See *infra* Part II (explaining and comparing other countries' efforts in reducing antipsychotic use).
- 12 See *infra* Part III (analyzing areas needing improvement in Massachusetts as well as identifying potential solutions).
- 13 See Thomas A. Ban, *Fifty Years Chlorpromazine: A Historical Perspective*, 3 NEUROPSYCHIATRIC DISEASE & TREATMENT 495, 495-96 (2007) (discovering first antipsychotic, called chlorpromazine); Bertha A. Madras, *History of the Discovery of the Antipsychotic Dopamine D2 Receptor: A Basis for the Dopamine Hypothesis of Schizophrenia*, 22 J. HISTORY NEUROSCIENCE 62 (2013) (describing one of Laborit's drug's initial uses was to alleviate pain).

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- 14 See Madras, *supra* note 13, at 63. While Van Rossum focused on dopamine nerve pathway hyperactivity, other scientists soon realized that noradrenaline and other neurotransmitters were involved in the mechanism underlying schizophrenia. *See id.* at 64.
- 15 *Id.* at 70.
- 16 See President & Fellows of Harvard College, *How Antipsychotic Drugs Work*, HARVARD MENTAL HEALTH LETTER 4 (Harvard Health Publications ed., Sept. 2002) (acting on limbic system that controls emotions).
- 17 *Id.* Parkinson-type movements and tardive dyskinesia are both types of extrapyramidal effects. COURTROOM MEDICINE, *supra* note 5 (describing extrapyramidal effects). Parkinson-type movements involve muscle stiffness and rigidity, resting tremors, and slowness in starting movement. *See* MASS. GEN. HOSPITAL, *Parkinson's Disease*, http://www.massgeneral.org/conditions/condition.aspx?id=352&display=about_this_condition (last visited Mar. 24, 2019). Tardive dyskinesia is a set of “involuntary movements of the tongue, lips, face, trunk, and extremities that occur in patients treated with long-term dopaminergic antagonist medications.” James R. Brasic & Russell H. Morgan, *Tardive Dyskinesia: Overview*, MEDSCAPE (Apr. 24, 2017), <https://emedicine.medscape.com/article/1151826-overview> (defining tardive dyskinesia).
- 18 See Tim Kendall, *The Rise and Fall of the Atypical Antipsychotics*, 199 BRITISH J. PSYCHIATRY 266, 266-67 (2011) (suggesting claims of improved second generation antipsychotics are due to marketing schemes); *see also* Jeffrey Kerner & Bridget McCoy, ANTIPSYCHOTICS, 26-27 (Peter L. Myers, ed., ABC CLIO LLC 2017) (discussing clozapine's temporary withdrawal from market after concern for life-threatening side effect).
- 19 See Findling, *supra* note 5, at 3 (defining atypical antipsychotics); *see generally* COURTROOM MEDICINE, *supra* note 5 (defining extrapyramidal side effects); *see generally* Kendall, *supra* note 18, at 1 (explaining “smoke and mirrors” marketing scheme of atypical antipsychotics).
- 20 See Findling, *supra* note 5, at 3 (targeting serotonin-5HT₂ at dopamine receptors rather than D₂). According to medical research studies, atypical antipsychotics have a lower affinity for the D₂ receptor, which is key to what would make this class of antipsychotics less likely to cause certain types of movement disorders. *See generally* DG Owens, *Extrapyramidal Side Effects and Tolerability of Risperidone: A Review*, 55 J. CLINICAL PSYCHIATRY SUPPLEMENT. 29 (1994) (finding reduced extrapyramidal effects in risperidone group compared to typical antipsychotic group).
- 21 See Linares et al., *supra* note 6, at 5 (finding six percent increase of prescribing ADHD and antipsychotic medications despite stable rates of co-morbidity); *see also* Lunskey et al., *supra* note 1 (finding increased use of antipsychotics among individuals with developmental and intellectual disabilities), Victoria Sackett, *Antipsychotic Drug Use for Dementia Patients Still Widespread*, AARP (June 26, 2017), <https://www.aarp.org/health/conditions-treatments/info-2017/nursing-homes-antipsychotic-drugs-fd.html> (finding one in six nursing home patients with dementia prescribed antipsychotics despite black box warning). The FDA issued a black box warning for prescribing antipsychotics to individuals with dementia because this population has increased vulnerability to fatal side effects. *Id.*
- 22 See Yael Waknine, *FDA Approvals: Risperdal/Risperdal M-TAB, Travatan Z, Rituxan*, MEDSCAPE (Oct. 24, 2006) [hereinafter Waknine, *Risperdal*], <https://www.medscape.com/viewarticle/546499> (showing significant improvements in target symptoms over eight weeks). The FDA approved Risperdal for irritability associated with autistic spectrum disorder as a result of two placebo-controlled, eight-week studies of subjects between five and sixteen years old with a DSM-IV diagnosis of autistic disorder. *See* FOOD & DRUG ADMIN., LABEL FOR RISPERDAL, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020272s056,020588s044,021346s033,021444s03/1bl.pdf (last visited Mar. 24, 2019). The “irritability” is measured by a fifteen-item scale by the Aberrant Behavioral Checklist, which looks for incidents of the subjects injuring themselves and crying inappropriately among many other factors. *See* Sarah Shea et al., *Risperidone in the Treatment of Disruptive Behavioral Symptoms in Children With Autistic and Other Pervasive Developmental Disorders*, 114 PEDIATRICS e364, e365 (2004). The results demonstrated a 64% improvement in irritability and those given risperidone demonstrated the greatest overall improvement from baseline. *Id.* at e367.

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- 23 See NAT'L INST. MENTAL HEALTH, *Autism Spectrum Disorder* (Mar. 2018), <https://www.nimh.nih.gov/health/topics/autism-spectrum-disorders-asd/index.shtml> (describing symptoms of autism spectrum disorder).
- 24 See FOOD & DRUG ADMIN., APPROVAL PACKAGE FOR ABILIFY, APPLICATION NO. NDA 21-436/S027 (Nov. 19, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/021436Orig1s027.pdf. (verifying approval of aripiprazole for treating irritability). Short-term trials average eight weeks, whereas long-term trials average twenty-six to fifty-two weeks. See *id.* at 36-38. The FDA based Abilify's approval on two placebo-controlled, eight-week studies of subjects with autism who were between six and seventeen years old. See Kelly Blankenship et al., *Aripiprazole for Irritability Associated with Autistic Disorder in Children and Adolescents Aged 6-17 Years*, 4 PEDIATRIC HEALTH 375, 277 (2010). In the first study, the top three reasons for discontinuation were sedation, drooling, and tremor. *Id.*; Yael Waknine, *FDA Approves Aripiprazole to Treat Irritability in Autistic Children*, MEDSCAPE (Nov. 24, 2009) [hereinafter Waknine, *Aripiprazole*], <https://www.medscape.com/viewarticle/713006> (listing the most common reasons for discontinuation); see also Waknine, *Risperidone*, *supra* note 22 (identifying the most commonly reported risperidone-related adverse events).
- 25 See Flavio Guzman, *Mechanism of Action of Risperidone*, PSYCHOPHARM. INST. (Feb. 9, 2018), <https://psychopharmacologyinstitute.com/antipsychotics/risperidone/mechanism-of-action-pharmacodynamics-risperidone/> (explaining how risperidone binds to certain neurotransmitters). Risperidone blocks specifically the D2 and 5-HT_{2A} receptors. *Id.* Aripiprazole functions as a partial agonist at the D2 receptor and serotonin 5HT₂ receptors and an antagonist at another type of serotonin receptor. See *Abilify (Aripiprazole) Is the Only Commercially Available Partial Agonist that Modulates Both Synaptic Dopamine and Serotonin*, FDA, <https://www.fda.gov/downloads/Drugs/UCM443936.pdf> (last visited Mar. 24, 2019) (evidencing the treatment of irritability by blocking dopamine and serotonin receptors).
- 26 See Hollis Turnham, *Federal Nursing Home Reform Act from the Omnibus Budget Reconciliation Act of 1987*, NAT'L CONSUMER VOICE QUALITY LONG-TERM CARE, 3, [http://theconsumervoice.org/uploads/files/family-member/Summary-History-Federal_Nursing-Home_Reform-Act_\(3\).pdf](http://theconsumervoice.org/uploads/files/family-member/Summary-History-Federal_Nursing-Home_Reform-Act_(3).pdf) (last visited Mar. 25, 2019) (discussing federal laws to protect nursing home patients); see also U.S. GOV'T ACCOUNTABILITY OFF., GAO-15-211, ANTIPSYCHOTIC DRUG USE: HHS HAS INITIATIVES TO REDUCE USE AMONG OLDER ADULTS IN NURSING HOMES, BUT SHOULD EXPAND EFFORTS TO OTHER SETTINGS (2015) [hereinafter GAO-15-211], <https://www.gao.gov/assets/670/668221.pdf> (suggesting plan to expand antipsychotic reduction program among older adults living outside nursing homes).
- 27 See [Physician Labeling for Antipsychotic Drugs](http://cdn.loc.gov/service/ll/fedreg/fr043/fr043095/fr043095.pdf), 43 Fed. Reg. 21051, 21051 (May 16, 1978), <http://cdn.loc.gov/service/ll/fedreg/fr043/fr043095/fr043095.pdf> (following recent rodent studies revealing carcinogenic effect of antipsychotic drugs). Although the notice indicated that there were clear physical differences between humans and rodents, the risk to humans had not been ruled out either, so that warning patients was most likely the prudent choice. *Id.*
- 28 INST. OF MED. & COMM. ON NURSING HOME REGULATION, IMPROVING THE QUALITY OF CARE IN NURSING HOMES 378 (Nat'l Acad. of Sci. ed. 1986) [hereinafter QUALITY OF CARE IN NURSING HOMES]. Appendix E of includes examples of key indicators, like medications, ulcers, urinary tract infections, and management of urinary incontinence, already used in differentiating between standards of care at facilities. *Id.* at 378-79.
- 29 *Id.* at 378. Antipsychotics may be used as chemical restraints more often in facilities that have an inadequate number of staff. *Id.* at 54.
- 30 See Krista Maier, Article, *Chemical Restraints and Off-Label Drug Use in Nursing Homes*, 16 MICH. ST. J. MED. & L. 243, 251-52 (2012) (describing nursing home bill of rights under OBRA). A chemical restraint is a “medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.” 42 C.F.R. § 460.114 (2017); see also [Grammer v. John J. Kane Reg'l Ctrs.](#), 570 F.3d 520, 532 (3rd Cir. 2009) (holding OBRA intended to include protection of individual rights).

- 31 See 42 U.S.C.S. § 1396r(c)(1)(A)(ii) (LexisNexis 2017) (excusing use for safety emergencies and physician-written orders). The safety exception allows chemical restraints to be used “to ensure the physical safety of the resident or other residents.” See 42 U.S.C.S. §1396r(c)(1)(A)(ii)(I) (LexisNexis 2017). A written order, when used as an exception, must list the circumstances that would be appropriate for administering the restraint and a specific duration for which the restraint can be used for the individual resident. 42 U.S.C.S. §1396r(c)(1)(A)(ii)(II) (LexisNexis 2017); see, e.g., 42 C.F.R. § 483.45(d)(2017) (“free from unnecessary drugs”); 42 C.F.R. § 483.10(e)(1)(2017) (“free from inappropriate chemical restraints”); 42 C.F.R. § 483.10(c)(2017) (“informed consent for treatment plan”).
- 32 See Judith Garrard et al., *The Impact of the 1987 Federal Regulations on the Use of Psychotropic Drugs in Minnesota Nursing Homes*, 85 AM. J. PUB. HEALTH 771, 774-75 (1995) (questioning whether legislative changes were directly responsible for reduction in antipsychotic use). The authors of this study reasoned that because they studied only the quantifiable difference in psychotropic use, and not any resulting differences in the quality of care, they could not conclude whether the decrease in antipsychotic medications resulted in an improved quality of care for residents. See *id.* at 776; see also U.S. HEALTH & HUMAN SERVS., OFFICE INSPECTOR GEN., OEI-06-96-00080, PRESCRIPTION DRUG USE IN NURSING HOMES (1997) (commenting that despite improvement, still problems inappropriately prescribing psychotropic medications); Jerry Avorn et al., *A Randomized Trial of a Program to Reduce the Use of Psychoactive Drugs in Nursing Homes*, 168 N. ENGL. J. MED. 327 (1992) (proposing educational programs for nursing home medical professionals to reduce psychotropic uses).
- 33 See Medicare and Medicaid; Resident Assessment in Long-Term Care Facilities, 57 Fed. Reg. 61557, 61614 (proposed Dec. 28, 1992) (to be codified at 42 C.F.R. pts. 456 & 483) [hereinafter Resident Assessment in Long-Term Care Facilities].
- 34 See *id.* These triggers were ways of coding for comprehensive assessments of residents and included psychosocial well-being, urinary incontinence, falls, nutritional status and twelve other triggers. *Id.* at 61616.
- 35 See CENTER FOR MEDICARE & MEDICAID SERVS., LONG-TERM CARE FACILITY RESIDENT ASSESSMENT INSTRUMENT 3.0 USER'S MANUAL, VERSION 1.15 N-1 (Oct. 2017) [hereinafter *Resident Assessment Instrument*], <https://downloads.cms.gov/files/MDS-30-RAI-Manual-v115-October-2017.pdf>. The CMS added an antipsychotic medication review as a separate procedure with an additional set of requirements under its most recent revisions to the Residential Assessment Instrument guidelines. See *id.*
- 36 See *Olmstead v. L.C.*, 527 U.S. 581, 587 (1999) (holding public entities must provide community-based services to people with disabilities). Public entities, such as the state, are only obligated to provide these services if the placement is appropriate, the individual with disabilities does not oppose the placement, and the state can reasonably accommodate this placement given its resources. See *id.* at 607; see, e.g., *Mills v. Rogers*, 457 U.S. 291, 298-99 (1982) (questioning whether involuntary committed patients with mental illness had right to refuse antipsychotics); *Cruzan v. Dir., Mo. Dep't Health*, 497 U.S. 261, 280-81(1990) (holding patients have constitutionally protected liberty interests in refusing life-sustaining medical treatment); *Washington v. Harper*, 494 U.S. 210, 227 (1990) (requiring that inmate is dangerous to himself or others and treatment in his best interests); *Sell v. United States*, 539 U.S. 166, 169 (2003) (criticizing lower court's focus solely on defendant's dangerousness and missing additional factors). Although these cases focused on people with mental illness, rather than nursing home patients, they brought up a similar pattern of civil rights implications in administering powerful medications or serious medical interventions to people, who either lacked the capability to understand the medication's effects or were deprived of the opportunity to provide informed consent when they were capable of doing so. See generally, Bruce J. Winick, *The Right to Refuse Mental Health Treatment*, 44 U. MIAMI L. REV. 1 (1989) (discussing cases involving right to refuse treatment).
- 37 See *Washington*, 494 U.S. at 235-36. The petitioner was committed to the Special Offender Center (“SOC”) with a diagnosis of manic-depressive disorder and refused to continue taking his psychiatric medications. *Id.* The petitioner's

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treating psychiatrist sought forcible administration of the medication in accord with SOC policy because the petitioner suffered from a mental disorder and was a danger to others. [Id.](#) at 215-16. The petitioner argued that the psychiatric hospital had to obtain a court-ordered substituted judgment in order to administer psychiatric medication without the petitioner's consent, however, the Supreme Court rejected this argument. *Id.* The Court reasoned that the SOC policy was reasonably related to the legitimate interest of ensuring the safety of SOC staff and other inmates and that the policy provided a rational means because the medication is administered under the psychiatrist's professional medical opinion. [Id.](#) at 225-26.

38

See [Olmstead](#), 527 U.S. at 587. In *Olmstead*, the Court had to decide whether individuals with mental illness had to be placed in community settings rather than institutions in order to comply with Title II of the Americans with Disabilities Act. [Id.](#) at 587. The respondents were two women with both intellectual disabilities and psychiatric disorders. [Id.](#) at 593. Both respondents remained institutionalized despite medical opinions from each institution that the respondents' needs could be met appropriately in a community-based setting. *Id.* The first part to the Court's holding was "unjustified institutional isolation of persons with disabilities is a form of discrimination." [Id.](#) at 600. The second part of the holding was that states have a defense to keeping persons with disabilities in institutionalized settings if the placement can be reasonably accommodated given a state's resources and the needs of other individuals with similar types of disabilities. [Id.](#) at 607.

39

See, e.g., [42 U.S.C.S. §1396r](#) (LEXIS through [Pub. L. No. 115-442](#)) (listing rights of nursing home residents regarding restrictions on chemical restraints); *supra* notes 26, 27 and accompanying text (discussing initiatives by federal agencies and nursing home reform advocates).

40

See generally [Schloendorff v. Soc'y of N.Y. Hospital](#), 105 N.E. 92, 93 (N.Y. 1914) (holding physicians have an obligation to obtain informed consent from patient prior to performing surgery); [Ortiz v. City of Chicago](#), 656 F.3d 523 (7th Cir. 2011) (applying Fourth Amendment rights to denial of arrestee's medical care); Flaherty *infra* note 52 (describing forced antipsychotic treatment as violation of constitutional rights).

41

See [Schloendorff](#), 105 N.E. at 93 (asserting that surgery without patient's consent is assault and battery). The court ultimately, however, affirmed the verdict for the hospital-defendant based on the principle of charitable immunity, where a non-profit hospital is not liable for the medical staff's negligent acts. [Id.](#) at 94-95; see Douglas S.T. Green & Ronald MacKenzie, *Nuances of Informed Consent: The Paradigm of Regional Anesthesia*, 3 HOSPITAL FOR SPECIAL SURGERY 115 (2007) (explaining delay of adopting informed consent into professional medical standards).





42

COUNCIL FOR INT'L ORGS. OF MED. SCIS. & WORLD HEALTH ORG., INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS (Geneva, 4th ed. 2016). There are challenges in obtaining informed consent from children because some argue they should be able to receive information and express their own desired purposes for participating in the research, however, parents are legally required to consent for people under eighteen years old. *Id.* at 65.

43

See [42 U.S.C.S. § 1983](#) (LEXIS through [Pub. L. No. 115-68](#)). A [section 1983](#) action applies to every person who has experienced a "deprivation of any rights, privileges, or immunities secured by the Constitution and laws." *Id.* For example, where a woman was deprived of her thyroid and diabetes medications for sixteen hours while in police custody, the woman's daughter brought a [section 1983](#) claim against the city of Chicago and the police officers. See [Ortiz](#), 656 F.3d at 528-30; see also [Washington v. Harper](#), 494 U.S. 210, 213 (1990) (holding forcible administration to be constitutional). The Court reasoned that the State used rational means to accomplish its legitimate interests in ensuring safety of employees and other prisoners by its policy of administering antipsychotic medications to prisoners by reason of their mental illness and only under the medical instruction of a psychiatrist. [Id.](#) at 225-26.



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- 44 See generally *Prescription Psychotropic Drug Use Among Children in Foster Care: Hearing Before the Subcomm. Income Security & Family Support of the H. Comm. on Ways & Means*, 110th Cong. 4, 49-50 (2008) [hereinafter *Committee on Ways & Means*] (prepared statement of Christopher Bellonci, M.D., Medical Director, The Walker School) (explaining requirements of informed consent related to foster care children).
- 45 See  [Harnish v. Children's Hospital Med. Ctr.](#), 439 N.E.2d 240, 243 (Mass. 1982) (discussing informed consent for a person undergoing surgery).
- 46 See Linares et al., *supra* note 6, at 5 (discussing characteristics in children that indicate antipsychotics should be used).
- 47 See Lauren Vanderwerker et al., *Foster Care, Externalizing Disorders, and Antipsychotic Use Among Medicaid-Enrolled Youth*, 65 PSYCH. SERV. 1281, 1283 (2014); see also U.S. GOV'T ACCOUNTABILITY OFF., GAO-14-362, ADDITIONAL FEDERAL GUIDANCE COULD HELP STATES BETTER PLAN FOR OVERSIGHT OF PSYCHOTROPIC MEDICATIONS ADMINISTERED BY MANAGED-CARE ORGANIZATIONS (2014) [hereinafter GAO-14-362]. Physicians prescribing antipsychotic medications for a variety of non-FDA approved conditions for the reason of reducing problematic behaviors is problematic because these medications are actually being used as chemical restraints. *Id.* ADHD is a cluster of symptoms including inattention, impulsivity, hyperactivity, difficulty following through with tasks, and frequently interrupting other people. See *Attention-deficit/Hyperactivity Disorder (ADHD) in Children*, MAYO CLINIC (Aug. 16, 2017), <https://www.mayoclinic.org/diseases-conditions/adhd/symptoms-causes/syc-20350889>. Children with conduct disorder tend to be aggressive, deceitful, and disrespect social norms. Jennifer Theule et al., *Conduct Disorder/Oppositional Defiant Disorder and Attachment: A Meta-Analysis*, 2 J. DEV. LIFE COURSE CRIMINOLOGY 232, 233 (2016). People with oppositional defiant disorder “struggle with respecting authority and often display animosity, noncompliance, and negativity towards those in authority.” *Id.*
- 48 See generally *Committee on Ways & Means*, *supra* note 44, at 4 (suggesting medication review process, continuity of medical records, and expanded treatment options).
- 49 *Id.* at 12 (statement of Julie M. Zito, PhD., Professor of Pharmacy and Psychiatry, University of Maryland) (explaining safety concerns specific to pediatric use and adverse effects). Dr. Zito suggested that the federal government implement a national research base to document effectiveness of psychotropic medications across the states and assure that these medications are being prescribed for clinically appropriate reasons and not as a means of simply controlling challenging behavior. *Id.* at 7.
- 50 See generally Daniel R. Levinson, *Second-Generation Antipsychotic Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns*, OFF. INSPECTOR GEN. (2015), <https://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf> (evaluating six hundred eighty-seven claims of children across five states). The Office of the Inspector General study's methodology consisted of seven criteria, culminated from a variety of guidance and literature, to evaluate the quality of care in children treated with second-generation antipsychotics. *Id.* at 6.
- 51 *Id.* at 9 (finding poor monitoring and wrong treatment top reasons for concerns). The psychiatrists had specialty training in child and adolescent psychiatry. *Id.* at 7.
- 52 See generally Michael R. Flaherty, *Nonconsensual Treatment of Involuntarily Committed Mentally Ill Persons with Neuroleptic or Antipsychotic Drugs as Violative of State Constitutional Guaranty*, 74 A.L.R. 4th ed. 1099 (1989) (concluding most states hold that involuntarily hospitalized patients have right to refuse medication).
- 53 See, e.g.,  [In re Guardianship of Roe](#), 421 N.E.2d 40 (Mass. 1981) (establishing five factors determining whether court order required prior to medical treatment of incapacitated individual);  [Rogers v. Comm'r of Dep't of Mental Health](#), 458 N.E.2d 308 (Mass. 1983) (holding mentally ill committed patients must be adjudicated incompetent before enforcing substituted judgment); see also  MASS. ANN. LAWS ch. 123, § 8B (LexisNexis, 2017) (administering antipsychotics to people committed to mental health facilities when unable to give informed consent).

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- 54 See [Roe](#), 421 N.E.2d at 42; [Rogers](#), 458 N.E.2d at 310. The *Roe* holding applies to individuals who are not institutionalized and are already under guardianship by reason of incapacitation. See [Roe](#), 421 N.E.2d at 42. In contrast, *Rogers* applies to institutionalized individuals on whether they are under guardianship, so that they may still have the capacity to make their own informed medical decisions. See [Rogers](#), 458 N.E.2d at 310.
- 55 See [Roe](#), 421 N.E.2d at 52; see also [MASS. ANN. LAWS ch. 190B, § 5-306A](#) (LexisNexis 2018) (requesting guardian petitions for substitute judgment proceeding to involuntarily administer antipsychotics). This proceeding has to be authorized and performed through the probate and family court. *Id.* The five-factor test is currently applied and is cited in Massachusetts statutes related to both mental health and guardianship. [MASS. ANN. LAWS ch. 123, §§ 1, 12](#) (LexisNexis 2018); [MASS. ANN. LAWS ch. 190B, §§ 5-303, 5-308](#) (LexisNexis 2018). The test is also codified in the Department of Children and Families regulations. [110 MASS. CODE REGS. 11.17\(1\)](#) (LexisNexis 2018) (applying to whether medical treatment is considered extraordinary).
- 56 See [Roe](#), 421 N.E.2d at 52.
- 57 See *Guardianship of Pamela*, 519 N.E.2d 1335, 1337 (Mass. 1988) (encouraging evidence of ward's current medical condition in determining ability to provide informed consent). *But see* Pamela B. Teaster et al., Article, *Wards of the State: A National Study of Public Guardianship*, 37 STETSON L. REV. 193, 233-34 (2007) (reporting courts rarely utilize limited guardianships).
- 58 See generally [Roe](#), 421 N.E.2d 40 (clarifying that preponderance of the evidence standard applied to guardianship proceedings); [Rogers](#), 458 N.E.2d 308 (discussing person's protected interest in being free from invasion of bodily integrity).
- 59 See Mark Olfson et al., *Treatment of Young People with Antipsychotic Medications in the United States*, 72 JAMA 867, 872 (2015) (finding most people given antipsychotics did not have mental disorder diagnosis); see also Meredith Matone et al., *The Relationship Between Mental Health Diagnosis and Treatment with Second-Generation Antipsychotics over Time: A National Study of U.S. Medicaid-Enrolled Children*, 47 HEALTH SERVS. RES. 1836, 1852 (2012) (finding twenty-two percent increase in use of second-generation antipsychotics among children with developmental disabilities). When measured by frequency of prescribing per given diagnosis, children between twelve and eighteen years old with developmental disabilities had the highest rate of increase in second-generation antipsychotics ("SGAs") between 2002 and 2007. *Id.* at 1852-53. SGAs are another term for atypical antipsychotics. Findling et al., *supra* note 5; see also Michael D. Jibson et al., *Second-Generation Antipsychotic Medications: Pharmacology, Administration, and Side Effects*, UPTODATE (last updated May 15, 2017), <https://www.uptodate.com/contents/second-generation-antipsychotic-medications-pharmacology-administration-and-side-effects> (stating SGAs are synonymous with atypical antipsychotics).
- 60 See Sara Reardon, *Intellectually Disabled Often Get Antipsychotics in Absence of Mental Illness*, NATURE (Sept. 1, 2015), <https://www.nature.com/news/intellectually-disabled-often-get-antipsychotics-in-absence-of-mental-illness-1.18281> (adding that antipsychotics may produce placebo effect reducing aggressive behavior for individuals with intellectual disabilities).
- 61 *Id.*; Peter Tyrer et al., *Risperidone, Haloperidol, and Placebo in the Treatment of Aggressive Challenging Behaviour in Patients with Intellectual Disability: A Randomised Controlled Trial*, 371 LANCET 57, 61-62 (2008) (finding antipsychotics showed same reduction of aggressive behavior compared to placebo); Jennifer Wild, *Cheap Drugs Against Aggression Don't Work*, NATURE (Jan. 3, 2008), <https://www.nature.com/news/2008/080103/full/news.2007.404.html> (describing study comparing effects on individuals taking haloperidol, risperidone, or placebo). The study of eighty-six people with intellectual disabilities found similar effects between all three groups when measured after twelve weeks, suggesting antipsychotics were acting as placebo in their reduction of aggressive symptoms. *Id.*

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- 62 Megan Brooks, *Antipsychotics Overused in Intellectually Disabled Adults*, MEDSCAPE (Aug. 24, 2017), <http://www.medscape.com/viewarticle/884657> (citing *Yunsky et al.*, *supra* note 1). About twenty-eight percent of the adults did not have a psychiatric diagnosis, the predominant indication for prescribing antipsychotics to individuals. *Id.* Medical researchers are concerned that this overuse stems from the practice of using antipsychotics as chemical restraints, rather than using them as a result of a comprehensive medical assessment. *Id.* The United States is deplete of studies on this critical issue. *Id.* at 2. Studying the actual reasons why antipsychotics are prescribed to this population will likely incentivize physicians to perform more accurate diagnoses of the underlying problems, rather than automatically prescribe these powerful medications for any behavioral challenges that come their way. *Id.*
- 63 See Andrew S. Levitas & Anne D. Hurley, *The History Behind the Use of Antipsychotic Medications in Persons with Intellectual Disability: Part II*, 9 MENTAL HEALTH ASPECTS DEV. DISABILITIES 1, 2 (2006). One of the long-term effects of atypical antipsychotics is tardive dyskinesia, which usually appears once patients are *taken off of* antipsychotic medications. *Id.* at 1. Dr. Levitas criticized the studies on atypical antipsychotic medication, such as risperidone, because they did not specifically measure the difference in effectiveness between those receiving risperidone for the symptom of aggression and those receiving behavioral therapy for the symptom of aggression. *Id.* at 4. The atypical antipsychotic studies may be glorified because the medical community generally views them as an improvement to the more frequently occurring and serious side effects of first-generation antipsychotics due to pressure to come up with a better, “quick fix.” *Id.* at 5-6.
- 64 See *id.* at 3 (including tardive dyskinesia among long-term side effects).
- 65 42 C.F.R. § 460.114(a)(2) (2017) (pertaining to programs of all-inclusive care for the elderly).
- 66 See *infra* note 78 (describing process for long-term care facilities when prescribing psychotropic medications), see e.g.,  *Sabo v. O'Bannon*, 586 F. Supp. 1132, 1140 (Pa. D & C.3d, 1984) (explaining patient's interest in right to be free from being given antipsychotics as chemical restraints);  *Thomas v. Flaherty*, 699 F. Supp. 1178, 1188 (W. Dist. N.C., 1988) (presuming antipsychotics administered as PRNs to be chemical restraints). “PRN” indicates a medication that is given to the patient “on an as needed basis.” 42 C.F.R. § 418.110(n)(5).
- 67 See Kelly McGuire et al., *Irritability and Problem Behavior in Autism Spectrum Disorder: A Practice Pathway for Pediatric Primary Care*, 137 PEDIATRICS S136, S140-41 (2016) (emphasizing importance of comprehensive diagnostic assessment prior to deciding to prescribe atypical antipsychotics). This assessment includes a thorough review of the patient's medical, psychiatric, and developmental history, creating a detailed timeline including when the behaviors began and the presence of any precipitating environmental factors. *Id.* at S141. Since individuals with autism are especially sensitive to psychotropic medication side effects and often have difficulty communicating, it is crucial to review the possibility that antipsychotic medications are causing or exacerbating the problem behaviors prior to adding a new medication or increasing the dosage of the current medication. *Id.* at S142.
- 68 See Brooks, *supra* note 62, at 2 (urging close monitoring of both positive and negative effects of medications).
- 69 LABEL FOR RISPERDAL, *supra* note 22, at 31-32. Off-label prescribing is a legal practice that is common among physicians and includes prescribing medications that have an FDA-approved indication but are prescribed to an individual of a different age group or at a different dosage than specified in the FDA approval. Christopher M. Wittich et al., *Ten Common Questions (and their Answers) About Off-Label Drug Use*, 87 MAYO CLINIC PROC. 982 (2012) (explaining recent expansion of off-label psychiatric medication prescriptions).
- 70 See generally FACULTY OF PSYCHIATRY OF INTELLECTUAL DISABILITY, PSYCHOTROPIC DRUG PRESCRIBING FOR PEOPLE WITH INTELLECTUAL DISABILITY, MENTAL HEALTH PROBLEMS AND/OR BEHAVIOURS THAT CHALLENGE: PRACTICE GUIDELINES, 1 (Royal College of Psychiatrists, Apr. 2016) [hereinafter PRACTICE GUIDELINES], https://www.rcpsych.ac.uk/pdf/FR_ID_09_for_website.pdf. The Royal College of Psychiatrists is an independent organization composed of medical professionals, that educates psychiatrists in the U.K., sets medical practice standards, and advocates for patients and their families. ROYAL COLL.

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OF PSYCHIATRISTS, *About the College* (2017), http://www.rcpsych.ac.uk/aboutthecollege.aspx#What_we_do (last visited Mar. 24, 2019).

- 71 See PRACTICE GUIDELINES, *supra* note 70, at 5 (explaining how individual's difficulty explaining symptoms is contributor to inadequate monitoring). The practice of recording "challenging behaviors" as a clinical indication for prescribing antipsychotics, a type of psychotropic medication, is insufficient. *Id.* Instead, prescribing physicians should follow one of the specified prescribing standards outlined in the psychiatry faculty report. *Id.* at 6.
- 72 *Id.* at 9 (explaining communication difficulties impair diagnosis of underlying conditions). The detailed recording of the psychotropic drug's medical indication, its targeted symptoms, and the presence or lack of improvement within a specified time frame will decrease the rate of inappropriate prescribing. PRACTICE GUIDELINES, *supra* note 70, at 11.
- 73 See *id.* at 14. The report details the pre-prescribing diagnostic assessment that includes, but is not limited to, the cause of the disability, co-morbid mental illness and medical conditions, underlying medical causes of the disability, and the types of challenging behaviors that the medication is intended to treat. *Id.* at 10. In cases of off-label prescribing, the prescriber needs to pay careful attention to documenting the informed consent of the individual or the individual's parents and caretakers. *Id.* at 12. The U.K.'s General Medical Council mandates that prescribers identify the likely cause of the patient's condition, explain the risks, benefits, and likely duration of the treatment, provide aids for people with disabilities to better understand the information, and provide the patient's caretakers with information about the medication if the patient lacks the capacity to consent and if this is in the patient's best interests. GEN. MEDICAL COUNCIL, *Good Practice in Prescribing and Managing Medicines and Devices* (last updated Mar. 2013), https://www.gmc-uk.org/-/media/documents/prescribing-guidance_pdf-59055247.pdf.
- 74 See NAT'L PRESCRIBING SERV., *Antipsychotic Monitoring Tool: Monitoring for Patients Taking Antipsychotics Long Term* (Aug. 2011), http://www.qcidd.com.au/images/content/GPS/Antipsychotic_Monitoring_Tool.pdf (Australia) (including electrocardiogram, weight, fasting blood glucose, extrapyramidal symptoms, and other adverse effects); THERAPEUTIC GUIDELINES LTD., *MANAGEMENT GUIDELINES: DEVELOPMENTAL DISABILITY 32-33* (3d ed. 2012), https://tgdcdp.tg.org.au/fulltext/quicklinks/management_guideline.pdf (listing purposes for investigating underlying causes before prescribing psychotropic drugs) (Australia); G. de Kujiper et al., *Use of Antipsychotic Drugs in Individuals with Intellectual Disability (ID) in the Netherlands: Prevalence and Reasons for Prescription*, 54 J. INTEL. DISABILITY RES. 659, 659-61 (2010) (describing lack of systematic evaluation of long-term use of antipsychotic drugs).
- 75 See 31.966 *Wet zorg end wang psychogeriatrische en verstandelijk gehandicapte cliënten [Care and Coercion Law for Psychogeriatric and Mentally Disabled Act]*, EERSTE KAMER DER STATEN-GENERAAL, https://www.eerstekamer.nl/wetsvoorstel/31996_wet_zorg_en_dwang (awaiting final decision of the proposed legislation by the Senate in 2018) (Neth.). The proposed law allows a rebuttal to the presumption of coercion if the prescribing clinician specifically documents the prescription's non-coercive uses. *Id.*; S. Kapitein & J. Weiland, *The New Draft Law on Care and Coercion: Concerning the Use and Reduction of Antipsychotics Without a Valid Indication in People with Intellectual Disabilities*, 56 TIJDSCHR PSYCHIATRY 807, 809 (2014) (Netherlands) (explaining nonclinical reasons for physicians prescribing antipsychotics, such as nagging behavior).
- 76 See GAO-15-211, *supra* note 26, at 21-23 (finding antipsychotics prescribed more often for residents with aggression or agitation); Todd Kates, *Rights Review*, DMR HUMAN RIGHTS ADVISORY COMMITTEE NEWSLETTER May 2015, at 1, 3 (describing data-monitoring system for psychotropic medication in people with developmental disabilities); *What Does NCI Tell Us About Adults with Intellectual and Developmental Disabilities Who Are Taking Prescribed Medications for Anxiety, Behavioral Challenges, Mood Disorders, or Psychotic Disorders?* NCI DATA BRIEF, Dec. 2012, at 8-9 (Dec. 2012) [hereinafter NCI DATA BRIEF], http://www.nasdds.org/uploads/documents/Psych_NCI_Data_Brief_final_1.pdf; Post-Trial Brief for Petitioner at 136, *United States v. Arkansas*, (No. 4:09-CV-33-JLH) (E.D. Ark. Feb. 10, 2011), https://www.ada.gov/olmstead/documents/arkansas_post_trial.pdf (describing developmental disability center's inappropriate use of chemical restraints). The Department of Justice ("DOJ") attributed the developmental center's high rate of psychotropic prescriptions to their substandard behavioral intervention treatment plans. *Id.* Instead of making all reasonable efforts to address the underlying behavioral or medical cause of the challenging behaviors, the center's psychiatrists prematurely prescribed psychotropic medications as chemical restraints.

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Id. at 173. See generally NHS ENGLAND, *Stopping Over Medication of People with a Learning Disability, Autism, or Both (STOMP)*, <https://www.england.nhs.uk/learning-disabilities/improving-health/stomp/> (last visited Mar. 24, 2019); Kapitein & Weiland, *supra* note 75, at 807 (forcing psychiatrists in the Netherlands to re-assess individuals for use of antipsychotic medications).

77 See 28 C.F.R. § 549.46(a) (2017) (describing four requirements for psychiatrists to involuntarily administer antipsychotic medication). The Bureau of Prisons' requirements include providing twenty-four hour written notice to the inmate, informing the inmate of his or her rights to participate in the hearing with a staff representative, and a psychiatrist's evaluation and determination of whether the involuntary administration of antipsychotic medication is necessary due to a serious safety risk. *Id.* The psychiatrist must specify that the inmate poses a serious risk as a result of his or her mental illness. *Id.*

78 See 42 C.F.R. § 483.45(c) (2017) (including antipsychotics under psychotropic drug reviews). When prescribing antipsychotic medications to long-term care residents, facilities must provide gradual dose reductions unless contraindicated, establish a specific clinical indication in the resident's medical record, and limit antipsychotic PRN orders to 14 days. *Id.* at § 483.45(e). Prescribers seeking to extend the PRN order "should document their rationale in the resident's medical record and indicate the duration for the PRN order." *Id.* Civilly committed patients and criminal defendants awaiting competency evaluations are entitled to a civil action for the deprivation of rights if they are forcefully administered antipsychotic medications. 42 U.S.C.S. § 1983 (2017). There is no specific provision for individuals with intellectual or developmental disabilities who are not involuntarily committed to bring a civil action for the deprivation of rights to medical treatment. *Id.*

79 See 38 C.F.R. § 51.120(m)(vi)(2) (2017) (requiring gradual dose reductions of antipsychotics unless specifically contraindicated). Similar to other federal provisions, the facility management at a state home for veterans must first ensure the antipsychotic is being prescribed to treat a specific condition that is added to the resident's medical record. *Id.* The only federal entity to oversee the treatment of individuals with developmental and intellectual disabilities is NASDDDS, the National Association of State Directors of Developmental Disability Services, which actually assists all fifty states and the District of Columbia in managing their own disability agencies. NASDDDS, *About NASDDDS*, <http://www.nasddds.org/about-nasddds/> (last visited Mar. 24, 2019). Federal law mandates that each state has a protection and advocacy organization for individuals with disabilities, however, these are run at the state level. *State Protection and Advocacy Systems*, ADMIN. FOR COMMUNITY LIVING, <https://www.acl.gov/programs/aging-and-disability-networks/state-protection-advocacy-systems> (last updated Sept. 6, 2017); MEDICAID, *A Review of State Medicaid Approaches on Child Antipsychotic Monitoring Programs*, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/state-medicaid-dur-summaries.pdf> (last visited Mar. 24, 2019).

80 42 U.S.C. § 15009(a)(3) (2000) (holding federal government and states obligated to provide appropriately suited treatment and habilitation services).

81 See D.C. CODE § 7-1305.06c (2018) (detailing procedure to prescribe psychotropic medications to individuals with intellectual disabilities); GOV'T D.C., DEP'T DISABILITY SERVS., *Behavioral Health: Team Review of Psychotropic Medication*, [hereinafter *D.C. Team Review*] https://dds.dc.gov/sites/default/files/dc/sites/dds/publication/attachments/Psychotropic%20Medication%20Review%20Form_0.pdf (last visited Mar. 24, 2019) (including health services report, behavioral support, and physician's report as part of psychotropic medication review); GA. COMP. R. & REGS. 160-5-1.35 (2017); GA. COMP. R. & REGS. 82-3-1.13(5)(b) (2017); 405 ILL. CODE. R. 5/2-107.1 (2017) (requiring clear and convincing evidence for court order authorizing psychotropic medication to incapacitated individuals); WASH. ST. DEP'T SOC. & HEALTH SERVS., ADMINISTRATION OF PSYCHOACTIVE MEDICATIONS FOR BEHAVIOR SUPPORT OR TREATMENT OF MENTAL ILLNESS: POLICY 9.02 (2012) [hereinafter WASH. ST. DEP'T SOC. & HEALTH SERVS.], <https://www.dshs.wa.gov/sites/default/files/DDA/dda/documents/policy/policy9.02.pdf>.

82 CAL. BUS. & PROF. CODE § 2220.05 (Deering, LEXIS through 2019 Sess.) (adding physician's repeated prescribing of psychotropic medications without good faith prior examination to priority basis); Medi-Cal: Children: Prescribing

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Patterns: Psychotropic, Sen. B. 1174, 2016, Medications (Cal. 2016) (requiring California Medical Board to receive data on psychotropic prescribing patterns from human services departments); CAL. DEP'T SOC. SERVS. & DEP'T HEALTH CARE SERVS., CALIFORNIA GUIDELINES FOR THE USE OF PSYCHOTROPIC MEDICATION WITH CHILDREN AND YOUTH IN FOSTER CARE, 1, 10 [hereinafter *California Guidelines*], http://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/QIP_Guidelines_18.pdf (last visited Mar. 24, 2019).

- 83 *See* GA. COMP. R. & REGS. 160-5-1-.35 (2017); GA. COMP. R. & REGS. 82-3-1-.13(5)(b) (2017) (prohibiting use of chemical restraints by crisis stabilization units). Georgia applies the Code of Federal Regulations' definition of chemical restraints. GA. COMP. R. & REGS. 82-3-1-.12; (2017); 42 C.F.R. § 460.114 (2018); *supra* note 65 and accompanying text. Interestingly, Georgia performed a quality analysis of individuals with intellectual and developmental disabilities who transitioned from institutions to community settings (either group homes or with families and support services). *See generally* GA. QUALITY MGMT SYS., PSYCHOTROPIC & ANTICONVULSANT MEDICATION PREVALENCE AND AVERAGE UTILIZATION RATES FOR INDIVIDUALS RECENTLY TRANSITIONED TO THE COMMUNITY FROM AN INSTITUTION 1 (2013), https://dbhdd.georgia.gov/sites/dbhdd.georgia.gov/files/related_files/document/Attachment%205-Psychotropic%20medication%20C20QI%20study.pdf. The evaluation found an increase in the use of psychotropic medications six months after individuals had been transferred out of institutions into the community and reasoned the increase could be due to compensation for the less restrictive environment that could at least temporarily invoke an increase in challenging behaviors. *Id.* at 13.
- 84 210 ILL. CODE. R. 47/2-106 (LexisNexis 2018); MASS. ANN. LAWS ch. 123B, § 8 (LexisNexis 2018) (transporting individuals with intellectual disabilities between facilities); 115 MASS. CODE REGS. 5.11(5) (LexisNexis 2018) (requiring documentation of drug's behavioral effects checked by staff trained in medication administration). Massachusetts has an emergency exception that excuses the requirement for a physical examination by the authorized prescribing physician if this physician has a phone conversation with another physician, physician assistant, or nursing professional who is present with the individual experiencing the emergency requiring a chemical restraint and has performed a physical examination of the individual. *Id.*
- 85 *See generally* 115 MASS. CODE REGS. 5.11(5); *see infra* notes 130-134 and accompanying text (describing lack of oversight and fragmentation of enforcement between physician practices, state agencies and courts).
- 86 *See e.g.*, Christopher N. Osher & Jennifer Brown, *Drug Firms Have Used Dangerous Tactics to Drive Sales to Treat Kids*, DENVER POST (last updated Apr. 27, 2016, 3:37 PM), <https://www.denverpost.com/2014/04/13/drug-firms-have-used-dangerous-tactics-to-drive-sales-to-treat-kids/> (stating Johnson & Johnson aggressively marketed Risperdal to pediatricians and child psychiatrists); PHARMA LETTER, *Autistic Disorder Therapeutics Market Set to Grow to \$5.5 Billion by 2018* (Oct. 19, 2011), <https://www.thepharmaletter.com/article/autistic-disorder-therapeutics-market-set-to-grow-to-5-5-billion-by-2018> (describing market dominated by Abilify and Risperdal, two drugs approved for irritability associated with autism).
- 87 *See* Jessica Wright, *Pharma Company May Have Downplayed Side Effects of Autism Drug*, SPECTRUM (Aug. 20, 2015), <https://spectrumnews.org/news/news-pharma-company-may-have-downplayed-side-effects-of-autism-drug/> (stating Janssen concealed table showing increased prolactin levels and gynecomastia correlation among children taking risperidone). Janssen Pharmaceuticals is the distributor of Risperdal, JOLLC is the manufacturer of Risperdal tablets, and Janssen Belgium is the manufacturer of Risperdal oral solution. LABEL FOR RISPERDAL, *supra* note 22, at 49.
- 88 *See* Wright, *supra* note 87. Gynecomastia is an increase in the size of breast tissue. *Id.*; *see also* Kreves v. Ortho-McNeil-Janssen Pharm., No. 3671, 2013 WL 3480286, at *59-60 (Ct. Com. Pl. of Pa. June 19, 2013) (affirming lower court's summary judgment for Janssen); Max Mitchell, *Janssen, Plaintiffs Sparing Over Risperdal Verdict*, 252 LEGAL INTELLIGENCER 1 (Dec. 24, 2015) (stating plaintiff's attempt for non-economic damages of bullying as result of gynecomastia). Prolactin, produced by the pituitary gland in the brain, is a hormone that normally stimulates breast growth and milk production in females, but has no known normal functions among males. Anas K. Gremida, *Prolactin*, MEDSCAPE (Dec. 11, 2015), <https://emedicine.medscape.com/article/2089400-overview>.
- 89 JOINT COMM'N, *Informed Consent: More than Getting a Signature*, QUICK SAFETY, Feb. 2016, at 1, https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf (suggesting providers implement various decision aids to communicate risks and benefits to patients). Physicians should make sure

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to alert patients and their caregivers to all possible side effects that can manifest as changes in behaviors, especially in individuals with developmental disabilities. Chrissoula Stavrakaki et al., *Psychopharmacological Treatments in Persons with Developmental Disabilities (DD)*, in *DUAL DIAGNOSIS: AN INTRODUCTION TO THE MENTAL HEALTH NEEDS OF PERSONS WITH DEVELOPMENTAL DISABILITIES* 239, 245 (Dorothy Griffiths et al. eds., 2002). Side effects that manifest as “behavioral” are involuntary movements and in cases of life-threatening neuroleptic malignant syndrome, the patient may exhibit signs of confusion and agitation. *Id.* at 275.

90 *See* *Pledger v. Janssen Pharms. Inc.*, No. 01997, 2017 Phila. Ct. Com. Pl. LEXIS 246, at *49 (Pa. C.P., Aug. 10, 2017).

91 *See id.* A main legal claim in the case argued Janssen's withholding of the significant chance of gynecomastia among children taking risperidone meant the prescribing doctor lacked adequate information. *Id.* at *48. This information would have been vital to warn the mother about the harmful side effects of the drug she was going to administer to her child. *Id.*

92 *See id.* The duty to warn is related to informed consent because the doctor makes an informed decision based on the pharmaceutical company's warnings to the doctor. *Id.* A prescribing doctor cannot obtain informed consent from the patient without being fully warned of the risks of the medication himself or herself. *Pledger*, No. 01997, 2017 Phila. Ct. Com. Pl. LEXIS 246.

93 *See Mississippi Supreme Court Vacates \$1.95M Risperdal Verdict, Remands for Retrial*, 22 MEALEY'S EMERGING DRUGS & DEVICES 1 (2017) (finding negligently marketing Risperdal by failing to adequately warn of tardive dyskinesia); *Risperidone*, in *DRUGS IN LITIGATION: DAMAGE AWARDS INVOLVING PRESCRIPTION AND NONPRESCRIPTION DRUGS* 1 (Matthew Bender, rev. ed. 2017) (citing four lawsuits for failure to warn of Risperdal's tendency to cause tardive dyskinesia).

94 *See* Peter Breggin, *\$1.5 Million Award in Autistic Child Tardive Dyskinesia Legal Case*, HUFFINGTON POST, https://www.huffingtonpost.com/dr-peter-breggin/15-million-award-in-child_b_4861391.html (last updated May 3, 2014) (including tardive akathisia, internal feeling of restlessness that can cause agitation); *see also supra* note 17 and accompanying text.

95 *See* Transcript of Record at Vol. 1, 40-41, *Angel v. Segal*, No. 09-L-003496, 2014 WL 1090025 (Ill. Cir. Ct. Feb. 6, 2014) (No. 09-L-003496), https://breggin.com/wp-content/uploads/2014/02/BregginTestimonyTranscript_AngelTDcase_2014.pdf (testimony of Dr. Breggin).

96 *See* Johnny I. Matson & Sara Mahan, *Antipsychotic Drug Side Effects for Persons with Intellectual Disability*, 31 RES. DEV. DISABILITIES 1570, 1571 (2010) (studying development of antipsychotic side effects by analyzing a variety of research studies); *see also* Rory Sheehan et al., *Movement Side Effects of Antipsychotic Drugs in Adults With and Without Intellectual Disability: UK Population-Based Cohort Study*, 7 BRIT. MED. J. OPEN 1, 4 (2017), <https://bmjopen.bmj.com/content/bmjopen/7/8/e017406.full.pdf> (finding individuals with intellectual disabilities are more vulnerable to movement disorder side effects from antipsychotics). Movement disorders have a tendency to be underreported among individuals with intellectual disabilities because physicians mistakenly attribute the patient's abnormal movements to be a core symptom of the disability. *Id.* at 5.

97 *See* Matson & Mahan, *supra* note 96, at 1571. The researchers note a potentially false reassurance that atypical/second-generation antipsychotics are significantly safer when, instead, studies found that atypical antipsychotics cause serious extrapyramidal symptoms. *Id.* at 1571-72.




98 *See* Guy Shefer et al., *Diagnostic Overshadowing and Other Challenges Involved in the Diagnostic Process of Patients with Mental Illness Who Present in Emergency Departments with Physical Symptoms - A Qualitative Study*, PLOS ONE (Nov. 14, 2014), <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0111682>. (describing diagnostic overshadowing as a form of discrimination). One theory for this lack of physician awareness is that the majority of studies touting the effectiveness and tolerance of atypical antipsychotics have only evaluated short-term side effects and tardive dyskinesia may take years until it manifests in some patients. *See* Matson & Mahan, *supra* note 96, at 1572; *see also* Findling et al., *supra* note 5 and accompanying text (describing extrapyramidal symptoms).

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- 99 See GAO-14-362, *supra* note 47, at 14-16 (monitoring adverse effects allows physicians to adjust medications and dosages as needed to improve treatment success). The report also found that psychotropic medications were being given at doses higher than those approved by the FDA, which would constitute off-label prescribing. *Id.* at 3; see *supra* note 69 and accompanying text. Only five out of twenty-three cases showed documentation of informed consent, with the lack of shared decision making impacting the caregiver's ability to recognize certain side effects, such as agitation and insomnia. See GAO-14-362, *supra* note 47, at 15-16.
- 100 See MASS. GEN. LAWS ch. 111, § 72BB(c) (2018) (requiring facility to obtain informed consent from resident, resident's healthcare proxy, or guardian). “[A] physician owes to his patient the duty to disclose in a reasonable manner all significant medical information that the physician possesses or reasonably should possess that is material to an intelligent decision by the patient”  [Harnish v. Children's Hospital Med. Ctr.](#), 439 N.E.2d 240, 243 (Mass. 1982).
- 101 See generally Revised Circular Letter 17-2-699 from Eric Sheehan, Dir., Bureau of Health Care Safety and Quality & James Lavery, Dir. Bureau of Health Professions Licensure to Long-Term Care Facility Adm'rs 1 (Feb. 1, 2017), <http://www.mass.gov/files/documents/2017/02/zr/dhcq-699.pdf> (informing of revised informed written consent for use of psychotropic medications in long-term care facilities).
- 102 *Id.* at 3; see generally  [Rogers v. Comm'r of Dep't of Mental Health](#), 458 N.E.2d 308 (Mass. 1983). In *Rogers*, a class action of seven plaintiffs challenged the state mental health hospital's seclusion and medication of the plaintiffs, as patients, against their will.  *Id.* at 311. The Court emphasized that adult patients of mental health facilities do not lose their competence to make treatment decisions unless a judge, through a formal hearing, determines that the adult is incompetent.  *Id.* at 312-13. If the judge finds that the adult is incompetent, only then may the judge apply the substituted judgment decision.  *Id.* at 314. The substituted judgment decision is one that would be made by the incompetent person if he or she were competent, taking that person's character and circumstances into account as much as possible.  *Id.* at 316. The Court concluded that court approval is mandatory before a physician or healthcare facility can forcibly administer antipsychotic medication to an incompetent patient.  *Id.* at 316. But see Louise Harman, *Falling off the Vine: Legal Fictions and the Doctrine of Substituted Judgment*, 100 YALE L. J. 1, 65 (1990) (claiming substituted judgment allows state to invade person's bodily integrity without having to justify decision).
- 103 See  [Rogers](#), 458 N.E.2d at 316 (explaining Massachusetts courts consider treatment with antipsychotic drugs a type of extraordinary treatment); MASS. TRIAL COURT PROB. & FAM. CT. DEPT, GUIDE TO ROGERS GUARDIANSHIP 1, 2 (2015) [hereinafter GUIDE ROGERS GUARDIANSHIP], <https://www.mass.gov/files/documents/2016/08/wx/rogers-guardianship-booklet.pdf> (describing Rogers guardianships).
- 104 See GUIDE ROGERS GUARDIANSHIP, *supra* note 103, at 2; see also Maureen Howley, Note, *A Federal Solution to Foster Care's Psychotropic Drug Crisis*, 69 N.Y.U. ANN. SURV. AM. L. 837, 864-66 (2014) (describing *Rogers* petition process in cases of foster care children).
- 105 GUIDE TO ROGERS GUARDIANSHIP, *supra* note 103, at 2-3 (explaining substituted judgment process, which includes *Rogers* orders).
- 106 *Id.* As adopted from *Rogers*, the court must consider any of the individual's previously expressed preferences regarding treatment, the impact that the decision will have on the individual's family, the prognosis with and without treatment, the person's religious beliefs, and the likelihood of the medication resulting in adverse side effects. *Id.* at 3; see also  [Rogers](#), 458 N.E.2d at 316.
- 107 GUIDE TO ROGERS GUARDIANSHIP, *supra* note 103, at 3-4.
- 108 See *id.* at 4-5, 9. This process involves reviewing the individual's medical records, filing an initial clinical team report and filing a clinician's affidavit. *Id.* If the clinician determines that the individual is incapable of giving informed consent,

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then the individual's right to refuse antipsychotic medication is ultimately disregarded and instead the informed consent process shifts to the judge. *Id.* at 2.

- 109 *See* *Guardianship of Brandon*, 677 N.E.2d 114, 119 (Mass. 1997) (determining whether individual would no longer consent to antipsychotic treatment previously authorized by court). In a case where a young man had seizures, tuberous sclerosis, autism and a behavior disorder in which he was extremely self-injurious, the judge authorized electric shock treatment with a graduated electronic decelerator (“GED”). *Id.* at 118. In response to Brandon's counsel's appeal from the probate court judge's order authorizing an increased level of GED, called GED-4, the Supreme Judicial Court transferred the case on its own accord and affirmed the Probate judge's decision. *Id.* The Court held that there was no substantial change of circumstances since the original substituted judgment order that Brandon would no longer consent to the GED-4 if he were competent. *Id.* at 122. In determining whether Brandon would have no longer consented in response to the change in circumstances, that change being the increased intensity of the GED, the Court evaluated through expert witness testimony and medical documentation whether GED-4 still comported with accepted professional medical practice. *Id.* at 120-21. The Court additionally found that Brandon's significant progress in communication and dressing himself, as well as his decreased aggression, outweighed the minor increase in adverse effects of the GED-4 treatment compared with the original GED treatment. *Id.* at 121.
- 110  MASS. ANN. LAWS ch. 190B, § 5-306A (LexisNexis 2018) (codifying substituted judgment proceeding). As part of the Massachusetts version of Article V of the Uniform Probate Code, § 5-306A took effect on July 1, 2009. Jennifer A. Maggiacomo, *Introduction to the Massachusetts Uniform Probate Code: Guardianship & Conservatorship*, MASSLEGALSERVICES (Apr. 30, 2009), <https://www.masslegalservices.org/content/mcle-introduction-massachusetts-uniform-probate-code-2009>. The Department of Developmental Services (“DDS”) regulations require a court order to specify treatment with antipsychotic medications unless the person has provided informed consent or there is a medical emergency. 115 MASS. CODE REGS. 5.15(4) (LexisNexis 2018).
- 111 *See generally* 105 MASS. CODE REGS. 150.011(E)(5)(d) (Long-term Care Facilities); 110 MASS. CODE REGS. 11.14 (LexisNexis 2018) (Department of Children and Families); 115 MASS. CODE REGS. 5.15(4) (LexisNexis 2018) (Department of Developmental Services); 603 MASS. CODE REGS. 18.05(9)(f)(9) (LexisNexis 2018) (Secondary School Education); 606 MASS. CODE REGS. 3.05(2)(d) (Residential Programs Serving Children and Teen Parents); SHARYN EKLUND, GUARDIANSHIP ABUSE OF THE ELDERLY: A VIOLATION OF CONSTITUTIONAL RIGHTS PRECIPITATING AN EXTREME PUNITIVE CIVIL PENALTY 1, [http://www.probatecourtreform.com/files/guardianabuse\(3\).pdf](http://www.probatecourtreform.com/files/guardianabuse(3).pdf) (last visited Mar. 24, 2019) (explaining flaws in Massachusetts probate court system allowing continued victimization of elderly under guardianship).
- 112 MASS. ANN. LAWS ch. 190B, § 5-207 (LexisNexis 2018); *see* ARTICLE V: PROTECTION OF PERSONS UNDER DISABILITY AND THEIR PROPERTY: PREFATORY NOTE, V-1 (July 2012), <http://www.mass.gov/courts/docs/courts-and-judges/courts/probate-and-family-court/art5.pdf> (explaining Massachusetts' addition of “limited guardianship” concept to Uniform Probate Code Article V). “Limited guardianship” permits the court to limit a guardian's authority by giving back one or more areas of control to the individual under guardianship, such as medical decisions or finances. *Id.* at V-19.
- 113 *See*  MASS. ANN. LAWS ch. 190B, § 5-306A(a) (LexisNexis 2018) (mandating court to utilize physician or psychiatric nurse testimony regarding substituted treatment decision); *supra* note 104 and accompanying text. An incapacitated person “... has a clinically diagnosed condition that results in an inability to receive and evaluate information or make or communicate decisions to such an extent that the individual lacks the ability to meet essential requirements for physical health, safety, or self-care, even with appropriate technological assistance.”  MASS. ANN. LAWS ch. 190B, § 5-101(9) (LexisNexis, 2018). Guardians of individuals with intellectual disabilities have to submit a clinical team report completed by a psychologist, social worker, and physician, in which each reporter must comment as to the individual's capacity to give informed consent for antipsychotic medication. MASS. PROB. & FAM. CT., MPC 402 CLINICAL TEAM REPORT 1, 3 (2011), <https://www.mass.gov/files/documents/2016/08/nc/mpc402-clinical-team-report-fill.pdf>.
- 114 *See supra* notes 98-99, 104-107 and accompanying text.

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- 115 *See generally* McGuire et al., *supra* note 67 (commenting on misuse of antipsychotics as chemical restraints); Pledger v. Janssen Pharm. Inc., No. 01997, 2017 Phila. Ct. Com. Pl. LEXIS 246, at *49 (Pa. C.P., Aug. 10, 2017) (involving drug company withholding information, which prevented patient from providing informed consent).
- 116 *See*  *Olmstead v. L.C.*, 527 U.S. 581, 587 (1999) (deciding individuals' rights to live in community and be free from unjustified segregation); QUALITY OF CARE IN NURSING HOMES, *supra* note 28, at 312 (requiring facilities to maintain and improve resident's ability to function independently. "[T]reatment with antipsychotic drugs not only affected the patient's bodily integrity but the patient's mind, the 'quintessential zone of human privacy.'" Flaherty, *supra* note 52, at 12; Brasic & Morgan, *supra* note 17 (describing increased vulnerability of individuals with developmental disabilities to develop antipsychotic-induced involuntary movements).
- 117 *See* Resident Assessment in Long-Term Care Facilities, *supra* note 33, at 61616 (reviewing behavior status for possibility of reducing or eliminating antipsychotic medications); Brooks, *supra* note 62 (emphasizing lack of comprehensive assessment prior to prescribing antipsychotics leads to inappropriately utilized medications).
- 118 *See* MEDICAID, *supra* note 79, at 3-4 (requiring antipsychotic prescribers to submit signed informed consent sheets to prior authorization call centers). After Arkansas implemented this pre-authorization protocol among Medicaid-enrolled children, physicians substantially decreased dispensing of antipsychotic prescriptions. *Id.* at 2. In an attempt to decrease the use of psychotropic medications, including antipsychotics, Indiana's new psychotropic protocol requires a "thorough health history, psychosocial assessment, mental status exam and physical exam" as part of obtaining informed consent. *Id.* at 16. Massachusetts has no laws or regulations to guide physicians on informed consent for individuals with developmental or intellectual disabilities, unlike the codified process outlined for patients of long-term care facilities. *See* MASS. GEN. LAWS. ch. 111, § 72BB (2018) (requiring documented informed consent for administration of antipsychotics to residents of long-term care facilities); *see also supra* note 101 and accompanying text.
- 119 *Compare*  115 MASS. CODE. REGS. 2.01(c) (2018) (excluding antipsychotics administered under *Rogers* guardianship from classification as chemical restraint) *with* MEDICAID, *supra* note 79 (finding many states decreased inappropriate antipsychotic use after implementation of state Medicaid protocols) & QUALITY OF CARE IN NURSING HOMES, *supra* note 28, at 222 (establishing antipsychotic utilization as part of uniform quality of care measurements for nursing home residents). Massachusetts' DDS regulations deposit responsibility of antipsychotic oversight on the courts by allowing these powerful medications to be used for "treatment purposes in accordance with the requirements and procedures for extraordinary treatment that have been established by the Massachusetts Supreme Judicial Court in *Rogers*."  115 MASS. CODE. REGS 2.01(c) (2018).
- 120 *See* Eklund, *supra* note 111, at 16 (identifying Massachusetts substituted judgment doctrine as "legal fiction"). The implementations of the probate review process "indicate a tendency toward unconsidered, rubber-stamp approval of severe medical treatments." *Id.*; Harman, *supra* note 102, at 65. "Substituted judgment requires the court to piece together testimony from relatives and acquaintances to construct a persona who then represents and decides for the incompetent. The entire endeavor appears more an exercise in fictional characterization than an enhancement of rights." *Id.* at 64 (quoting Walter M. Weber, *Substituted Judgment Doctrine: A Critical Analysis*, 1 ISSUES L. & MED. 131, 145-46 (1985)).
- 121 *See* Committee on Ways & Means, *supra* note 44, at 11 (statement of Julie Zito) (emphasizing need to evaluate whether psychotropic drugs are improving outcomes for foster care children). Individuals with developmental and intellectual disabilities, similar to foster care children, are particularly vulnerable to receiving ineffective and unnecessary medications because of their lack of control in making decisions and the tendency of organizations to shuffle them between healthcare providers. *Id.* By providing stricter monitoring of psychotropic prescribing practices, Massachusetts would be in the position to prohibit the misuse of these medications to control and discipline individuals and refine the use of these medications to treat specifically defined medical and psychiatric disorders. *Id.* at 30. If treatment is ineffective and carries heavy risks, then the antipsychotic medications are not being used for medical treatment and are instead being used to control behavior, which qualifies as a chemical restraint. *Id.*

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See [MASS. GEN. LAWS ch. 111, § 70E](#) (2018) (requiring informed consent provided to patients of facilities); GAO-14-362, *supra* note 47, at 16; *supra* note 47 and accompanying text (finding incomplete or no documentation of informed consent in eighteen out of twenty-three cases); *Committee on Ways & Means, supra* note 44, at 24 (statement of Tricia Lea, PhD.) (commenting on helpfulness of auditing foster care case files to monitor psychotropic use). Dr. Lea emphasized the importance of physicians documenting informed consent and monitoring the effects of the medications at regular intervals. *Id.* at 25. Dr. Laurel Leslie, a physician at Tufts, stated the problem of foster care parents' lack of legal authority to receive information on their foster children's health outcomes. *Id.* at 30. As with many individuals with developmental and intellectual disabilities who are often shuttled between schools and group homes, foster care children lack continuity of care, which contributes to uninformed diagnoses and therefore, ineffective medication regimens. *Id.* Although professional medical associations, such as the American Academy of Child Psychiatry ("AACAP") established practice parameters for physicians to perform complete psychiatric and medical evaluations and educate patients as part of the informed consent process, each state's adherence to these parameters will remain unclear without regular audits. Levinson, *supra* note 50, at 22-26; *see also* Lunsky et al., *supra* note 1 (postulating physicians' minimal training involving patients with learning disabilities as one reason for inappropriate prescribing). In order to deter physicians from prescribing antipsychotic medications in a casual manner, state protocols should incorporate a type of sanctioning provision for physicians who are irresponsibly prescribing antipsychotic medications. *Infra* note 167 (granting medical board authority to sanction physicians for inappropriately prescribing psychotropic medications to minors).

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See [In re Guardianship of Roe, 421 N.E.2d 40, 52 \(Mass. 1981\)](#) ((applying five factors in making substituted judgment decision); [Rogers v. Comm'r of Dep't of Mental Health, 458 N.E.2d 308, 310 \(Mass. 1983\)](#) (asserting that at least six factors required for substituted judgment decision); *see e.g.,* [Guardianship of Jackson, 814 N.E.2d 393, 398 \(Mass. 2004\)](#) (agreeing with trial court's determination that individual with schizophrenia required continuance of substituted judgment); [Guardianship of Weedon, 565 N.E.2d 432, 433 \(Mass. 1991\)](#) (concluding significant public interest in clarifying substituted judgment treatment plan requirements); [Guardianship of Linda, 519 N.E.2d 1296, 1299 \(Mass. 1988\)](#) (rejecting inconvenience argument); [In re Moe, 432 N.E.2d 712, 723 \(Mass. 1982\)](#) (acknowledging difficulty of applying substituted judgment decision for individual with severe intellectual disability since birth). In *Linda*, Judge Hennessey reasoned that protecting the ward's privacy rights outweighed the potential inconvenience of obtaining prior judicial approval prior to administering antipsychotic medications, in nonemergency circumstances. [519 N.E.2d at 1299](#).

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See [115 MASS. CODE REGS. 5.03 \(LexisNexis 2018\)](#) (stating services for people with intellectual disabilities should promote self-determination and dignity). By relying on judges to make substituted medical judgments for incapacitated individuals, Massachusetts inaccurately deems judges qualified to make conclusions that are typically reserved for doctors, who attend four years of medical school and years of clinical training before they can become licensed to make the very same type of decision. *Id.* The only non-judicial process in Massachusetts to assure physicians are adequately obtaining informed consent from adults with developmental and intellectual disabilities is an annual review of the individual's individual service plan. [115 MASS. CODE REGS. 5.08 \(LexisNexis 2018\)](#). There are no specific guidelines for physicians to assure that they are communicating effectively with their patients during the informed consent process for patients who have capacity to consent. *Id.* Barriers to the patient's understanding include ineffective communication between the provider and the patient, lack of a health-based literacy procedure, and the provider's assumption that the patient's signature means they understood and processed all of the material relating to the medication. *See Informed Consent: More than Getting a Signature, supra* note 89, at 1-2; *see also* Winick, *supra* note 36, at 51-52 (noting high proportion of foreign medical graduates in psychiatric hospitals contributing to communication barriers).


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See [JOINT COMM'N, supra](#) note 89, at 1-2. A significant part of obtaining informed consent is clear and complete transmission of the medication's benefits and side effects, which is more difficult to accomplish for patients with certain developmental and intellectual disabilities who often have difficulties with speech and language. *Id.*; *see also* Tyrer et al., *supra* note 61, at 62-63 (finding antipsychotic medications are equal to placebo at treating aggression among individuals with intellectual disabilities). If Tyrer's study accurately reflects the efficacy of atypical antipsychotic medications, there is a startling possibility that many individuals with developmental and intellectual disabilities are given harmful medication for no reason other than incompetence and even deliberate indifference on the part of physicians. *Id.* Judges

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who utilize one physicians' affidavit to make substituted judgment decisions are likely to overlook the inefficient communication of medical information to the individual receiving the antipsychotic medication. *Id.*

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See  [Rogers](#), 458 N.E.2d at 313-14 (explaining individual is presumed competent unless otherwise deemed incompetent resulting from a court hearing); [Guardianship of Pamela](#), 519 N.E.2d 1335, 1337 (Mass. 1988) (emphasizing competency analysis must pertain to individual's *current* competency to make informed consent decisions). The court emphasized “current” ability because of the recognition that the person's condition that causes incompetence at one point in time may change and thus, that person can regain competency at another point in time. *Id.*

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See, e.g., Levinson, *supra* note 50 (finding inadequate treatment protocol for psychotropic use among Medicaid-enrolled children); GAO-14-362, *supra* note 47 (finding lack of compliance in obtaining informed consent for psychotropic medication among managed care participants); GAO-15-211, *supra* note 26 (critiquing misused antipsychotic medications for symptoms of agitation rather than prescribing for specific medical condition). Medicaid-enrolled children, foster care children, nursing home patients, and individuals with developmental and intellectual disabilities are unified by their vulnerabilities to being mistreated, some due to financial dependence and others due to dependence upon others to care for them. See Levinson, *supra* note 50; GAO-15-211, *supra* note 26.

128

See Teeluckdharry et al., *supra* note 4, at 8 (concluding difficulty obtaining informed consent significantly contributed to prescribers' failure to meet guidelines).



129

See Reardon, *supra* note 60 (exposing studies finding antipsychotics no better than placebos in treating aggressive behaviors); Tyrer et al., *supra* note 61, at 62-63 (concluding antipsychotic medications not mainstream treatment for aggressive behaviors associated with intellectual disabilities). Yet, since antipsychotic medications are very common, it is questionable how much these medications are actually functioning for their therapeutic value to the individual versus their convenience to staff and false reassurance of improvement to prescribers. Lunksy et al., *supra* note 1 (finding high prevalence of antipsychotic medications prescriptions lacking consistent medical justifications). Physicians and other healthcare professionals must discuss the strong possibility that antipsychotics prescribed for aggression are often not working to treat the clinically indicated medical condition and are instead used solely to control behavior or for the illusion that they are controlling behavior. *Id.*

130

See [115 MASS. CODE REGS. 5.15\(4\)](#) (LexisNexis 2018). The regulations allow antipsychotic medications for controlling behavior if the medication is “in accordance with the recommendations of an individual service plan” and “where there is a court order specifying the treatment.” *Id.*

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Id. The court order refers to the process in [Rogers](#), which requires the judge to consider at least six factors to determine the substituted judgment decision regarding antipsychotic treatment.  [458 N.E.2d at 318](#). Although this protocol does not limit antipsychotic treatment decisions to the probate and family court, this becomes the only option for incapacitated individuals without a diagnosed mental illness. *Id.* at 423;  [MASS. GEN. LAWS ch. 123, § 8B](#) (2018) (referring to district court only for individuals subject to commitment for treatment of their mental illness). To combat the overuse of antipsychotic medications in other populations, such as children, some states have found success with a peer review process. Ian Schmid, et al., *Medicaid Prior Authorization Policies for Pediatric Use of Antipsychotic Medications*, 313 JAMA 966, 966-68 (2015). In this study, peer review policies required “contracted clinicians (peer reviewers) to adjudicate antipsychotic prescriptions for children.” *Id.* at 966.

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See [603 MASS. CODE REGS. 18.05\(9\)\(f\)\(9\)](#) (LexisNexis 2018) (describing situations in which special education staff may administer antipsychotic medication to students); Kapitein & Weiland, *supra* note 75 (exemplifying how “normal” children's behaviors become inappropriately medicated); Post-Trial Brief for Petitioner, *supra* note 76, at 194 (finding developmental disability center administered psychotropic drugs for behavior changes that were environmentally caused). Behaviors that are triggered by environmental changes, including new staff or disruptive residents, should be addressed by making modifications to the environment *before* resorting to psychotropic medications. *Id.* Without a state protocol requiring specific staff training on how to differentiate “problem behaviors” from potential side effects of antipsychotic medications, staff are likely to continue administering antipsychotic medications to individuals with



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developmental and intellectual disabilities for the wrong reasons and inadvertently harm the people they are entrusted to help. *Id.*

- 133 *See*GA. QUALITY MGMT SYS, *supra* note 83, at 14-15 (finding lower rates of psychotropic medications among individuals living with families compared to group homes). The Georgia Division of Developmental Disabilities made several suggestions to decrease the inappropriate use of psychotropic medications for individuals with developmental and intellectual disabilities, including a medication utilization board and establishing statewide medication reduction protocols. *Id.* at 16.
- 134 *See*MASS. ANN. LAWS ch. 190B, § 5-306(A) (Lexis Nexis 2018) (allowing court to assign guardian to monitor individual's treatment and receive compensation directly from ward's estate); ARTICLE V, *supra* note 112, at V-31-32 (describing limited guardianship). A limited guardianship means that the guardian can only have authority over specific problems related to the person's incapacity. *Id.* In practice, courts rarely take this initiative and the only other way for a limited guardianship to occur is for the incapacitated person or an interested party to request that the guardian's powers be limited. *Id.*; *see also* Teaster et al., *supra* note 57, at 219 (finding between zero and ten percent utilized limited guardianships among public guardianship court models); Eklund, *supra* note 111, at 16 (concluding Massachusetts courts rarely find “substantial change in circumstances” when reviewing substituted judgment decisions); [Guardianship of Brandon](#), 677 N.E.2d 114, 119-22 (Mass. 1997) (explaining factors considered for substantial change in circumstances review).
- 135 *See* Brooks, *supra* note 62 (discussing overuse of antipsychotic medications); GAO-14-362, *supra* note 47, at 9 (finding varying quality in documentation supporting psychotropic prescriptions). The GAO's experts suggested that prescribers of psychotropic medications must monitor patients for negative medical effects in order to properly evaluate each patient's outcome. *Id.* at 14. With the premise that most physicians have good faith intentions in prescribing antipsychotic medications, there is a lack of clear and enforceable guidance to ensure physicians understand the nuances of prescribing these powerful medications. NPS MEDICINEWISE, *supra* note 74 (providing antipsychotic monitoring tool in Australia). The Australian monitoring tool includes metabolic blood tests, an annual electrocardiogram, and monitoring for extrapyramidal side effects at least every 6 months. *Id.*
- 136 *See*PRACTICE GUIDELINES, *supra* note 70, at 8 (reporting inaccurate diagnoses often used to justify psychotropic medication prescriptions). Furthermore, prescribers should pay extra attention to communicating with individuals with developmental and intellectual disabilities because patients “may be unable to give a clear verbal account of their psychopathology.” *Id.* at 10. Ironically, the side effects of antipsychotic medications, such as involuntary movements, often become attributed to further evidence of the individual's “challenging behavior” and physicians may use this association to justify the continued prescribing of the damaging medication. Jarrett Barnhill & Anne Desnoyers Hurley, *Movement Disorders: Things that Do Go Bump in the Night, Part II*, MENTAL HEALTH ASPECTS DEV. DISABILITIES 1 (Jan. 2009) (suggesting detailed screening process when evaluating individuals with involuntary movements); Findling et al., *supra* note 5, at 10 (emphasizing importance of obtaining patient's family and medical history prior to prescribing atypical antipsychotic); Post-Trial Brief for Petitioner, *supra* note 76, at 178 (describing special education center's mistaking extrapyramidal side effects for core symptoms of resident's developmental disability).
- 137 *See*PRACTICE GUIDELINES, *supra* note 70, at 9. Since there is such a wide variety of behaviors that can be characterized as “challenging,” the UK report emphasizes the importance of investigating underlying causes of challenging behaviors rather than using the term as a clinical indication for prescribing antipsychotic medication to individuals with intellectual disabilities. *Id.*
- 138 *See* Post-Trial Brief for Petitioner, *supra* note 76, at 182. The failure to evaluate non-psychiatric causes of challenging behavior while treating individuals with psychiatric medications implicates disability discrimination statutes, such as the Americans with Disabilities Act. *Id.*; *see also* McGuire et al., *supra* note 67, at S141 (explaining problem behaviors in children with autism may indicate gastrointestinal or mouth pain).
- 139 *See supra* note 79 and accompanying text. When searching for antipsychotic medication material under the NASDDDS's “Resources,” there is only one six-year old report on psychiatric medications, not even specific to the unique problems associated with antipsychotic medications. *See Medication*, NASDDDS, <http://www.nasddd.org/resource-library/>

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behavioral-challenges/mental-health-treatment/medication/ (last visited Mar. 24, 2019); NCI DATA BRIEF, *supra* note 76, at 8 (finding forty-nine percent of sample taking antipsychotics for challenging behavior).

- 140 *See* QUALITY OF CARE IN NURSING HOMES, *supra* note 28, at 154-55 (suggesting more intensive reviews of correction plans would facilitate better compliance with documentation). Documentation of antipsychotic medication plans is essential for government agencies to enforce nursing home compliance with laws and regulations intended to protect the rights of nursing home residents because increased antipsychotic use is associated with lower quality of care. *Id.* at 155. Similarly, documentation audits should help enforce provider compliance with enforcing the rights of individuals with developmental and intellectual disabilities. *Id.* The Developmental Disabilities Assistance and Bill of Rights Act of 2000 does not require any documentation review for prescribing antipsychotic medications. 42 U.S.C. § 15001 et seq. (2011).
- 141 *See* GAO-14-362, *supra* note 47, at 17 (finding only partial documentation between treatment providers for children under Medicaid). The Health and Human Services Office of Inspector General report reveals an inconsistency of documentation compliance among settings, such as between group homes and foster homes, in which continuity of medical care is a significant issue. *Id.*
- 142 *See* McGuire et al., *supra* note 67, at S143-44 (listing labs, electrocardiogram, and screening movement disorders as some ways to monitor for adverse effects).
- 143 115 MASS. CODE REGS. 7.02, 5.11(5), 5.15 (LexisNexis 2018) (allowing chemical restraints under emergency circumstances or if documented in individual support plan); 115 MASS. CODE REGS. 5.14(4) (stating individual support plan is not responsible for dealing with psychotropic medication issues). Massachusetts's regulations conflict with each other regarding who or what is responsible for monitoring the use of psychotropic medications among individuals with developmental and intellectual disabilities. *Id.*
- 144 *See* Matson & Mahan, *supra* note 96, at 1571 (explaining abnormal movements mistaken for symptoms of individual's disability rather than adverse effect of antipsychotic); *see also* Sheehan et al., *supra* note 4, at 5 (describing physician practices of misdiagnosing tardive dyskinesia as a core symptom of intellectual disability).
- 145 *See* Matone et al., *supra* note 59, at 1855 (noting increased use of atypical antipsychotics may be result of pressure to treat symptoms quickly). When encountering children with “challenging behavior” that lacks a clear etiology, many physicians prescribe the antipsychotic medication to place a Band-Aid on the symptoms. *Id.* Then, those physicians look to justify the prescription by prematurely diagnosing the patient with a psychiatric disorder. *Id.*
- 146 GA. COMP. R. & REGS. 82-3-1-.13(5)(b) (2012) (prohibiting use of chemical restraints in crisis stabilization units serving individuals with developmental disabilities). The District of Columbia requires a medical review procedure before prescribing psychotropic medications to individuals with intellectual disabilities. D.C. CODE § 7-1305.06c; WASH. ST. DEP'T SOC. & HEALTH SERVS., *supra* note 81.
- 147 *See* Committee on Ways & Means (statement of Tricia Lea), *supra* note 44, at 22-24 (explaining Tennessee's committee to review medical practices and conduct internal audits regarding psychotropic medications); GA. QUALITY MNMT SYS., *supra* note 83, at 14-16 (suggesting psychotropic medication utilization boards).
- 148  42 C.F.R. § 483.45 (2018) (mandating monthly drug review for long-term care residents, including complete review of resident's medical chart); D.C. CODE § 7-1305.06c (2018) (appointing Department on Disability Services to develop procedures and identify responsible entities in psychotropic prescribing). One straightforward indicator of a “red flag” would be for PRN orders (medications administered to patient as needed) of antipsychotic medications that are given to patients for longer than a designated time period. *See*  42 C.F.R. § 483.45(e). Massachusetts could add some flexibility to this limitation by allowing prescribers to extend PRN orders beyond the fourteen-day requirement adopted by the Code of Federal Regulations. *Id.* The medication review system should flag patterns in which multiple PRN orders have been extended beyond fourteen days, regardless of recorded medical justifications. *Id.*; Committee on Ways & Means, *supra* note 44, at 10 (statement of Julie M. Zito) (suggesting individualized patient record review for youth

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contemporaneously receiving three or more psychotropic medications); D.C. CODE § 7-1305.06c (2018) (mandating written report recommending potential use of alternatives to psychotropic medications and informed consent).

149 See *infra* notes 140-155 and accompanying text; see also *Resident Assessment Instrument*, *supra* note 35 at 9 (providing guidance to help nursing home staff integrate critical information into resident's individual care plan).

150 See 42 C.F.R. § 483.45(c) (2018) (requiring monthly drug review by pharmacist and identifying indicators of unnecessary psychotropic drugs); D.C. CODE § 7-1305.06c (2018) (requiring DDS to establish psychotropic medication review team); D.C. CODE § 7-1305.06b (establishing independent panel of psychiatrist, other licensed professional, and advocate for person with intellectual disability).

151 42 C.F.R. § 483.45(c) (2018) (adding pharmacist to the team); *Committee on Ways & Means*, *supra* note 44, at 12 (suggesting team of clinical pharmacists); *D.C. Team Review*, *supra* note 81 (including nurse or program specialist, behavior specialist or family member, and physician); WASH. ST. DEPT SOC. & HEALTH SERVS., *supra* note 81, at 4 (including independent physician, clinical pharmacist, and prescribing physician in mandated reviewers).

152 See MASS. GEN. LAWS ANN. ch. 190B, § 5-306A (2018) (requiring court authorization whenever incapacitated individual receives new antipsychotic prescription or competent individual refuses antipsychotic). Technically, the judge is mandated to consider testimony from a physician or nurse specialist in making the decision of whether to allow the order treating the individual with antipsychotic medications. *Id.* The Massachusetts statute does not specify whether the physician or nurse specialist writing the affidavit is required to be employed independently from the original prescribing physician. *Id.* Without further clarity, the judge may be relying on biased documentation when the testimony comes from the same physician who originally opined that antipsychotics were necessary. See *id.*

153 See Eklund, *supra* note 111, at 8-9. Given the high number of individuals with developmental and intellectual disabilities who are both unable to consent and prescribed antipsychotic medications, the substituted judgment procedure places an enormous burden on the probate and family courts, which are already full of vacancies and staff shortages. *Id.* In guardianship proceedings that typically precede or coincide with substituted judgment decisions, a medical certificate or a clinical team report is required as part of the petition for court appointment of a guardian of an incapacitated person, or in the absence thereof, a report detailing the nature of any circumstance which makes it impossible to obtain such documents. MASS. GEN. LAWS ch. 190B, § 5-303(b)(11).

154 MASS. GEN. LAWS ch. 190B, § 5-306A(c) (mandating that treatment authorization order is reviewed at least annually).

155 *Id.*; MASS. PROB. & FAM. CT. *supra* note 113 (determining appointment of guardianship for individual with intellectual disability); MASS. PROB. & FAM. CT., MEDICAL CERTIFICATE GUARDIANSHIP OR CONSERVATORSHIP (2010), <https://www.mass.gov/files/documents/2016/08/xn/mpc400-medical-certificate-guardianship-or-conservatorship-fillable-2010.pdf> (determining appointment of guardianship for individual in some or all areas of capacity and decision-making). The Medical Certificate asks the following: "With reasonable medical certainty, within the next 90 days, is the individual's mental and/or physical conditions likely to change substantially?" *Id.* at 2 (emphasis in original).


156 See D.C. CODE § 7-1305.06b(e) (2012) (requiring review every nine months); 42 C.F.R. § 483.45(c) (20172) (mandating monthly review); WASH. ST. DEPT SOC. & HEALTH SERVS., *supra* note 81, at 4 (compelling review and documentation of presence/absence of tardive dyskinesia at least every ninety days).

157 WASH. ST. DEPT SOC. & HEALTH SERVS., *supra* note 81, at 2-3. Washington's Division of Developmental Disabilities requires the individual's medical plan to include a strategy to reduce and discontinue psychoactive medications unless otherwise contraindicated. *Id.* CMS's Resident Assessment Instrument Guidance instructs the antipsychotic medication assessor to "review the medical record to determine if a gradual dose reduction has been attempted." *Resident Assessment Instrument*, *supra* note 35, at N-12. In contrast to the aforementioned clear directive


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to attempt a dose reduction of antipsychotics, the Massachusetts substantial change in circumstances test is too arbitrary to enable judges to analyze the complex decision of whether to attempt a dose reduction. *Id.*; *see also supra* note 150 and accompanying text.

158

See  *In re Guardianship of Roe*, 421 N.E.2d 40, 52 (Mass. 1981) (describing test used by Massachusetts judges in determining substituted judgment decision for incapacitated individuals); *supra* note 53 and accompanying text; *Committee on Ways & Means, supra* note 44, at 50 (statement of Dr. Christopher Bellonci) (suggesting medication decisions be based on complete medical history, psychiatric assessment, and medication history).

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See Committee on Ways & Means, supra note 44, at 50. Dr. Bellonci's drafted psychotropic medication review protocols also include making sure the medication is appropriate to the target symptoms of the individual's diagnosis on record, periodically attempting to taper medications, and continually reassessing the risk-benefit ratio of the medication for the individual patient.  *Id.* at 49-50; *see also* Barnhill & Hurley, *supra* note 136, at 1 (discussing physicians' failure to recognize genetic, neurological, and metabolic causes of movement disorders); McGuire et al., *supra* note 67, at S140-41 (describing need for assessing medical, psychiatric, and developmental history, including antecedents to target behaviors); *California Guidelines, supra* note 82, at 10 (requiring differential diagnosis performed prior to prescribing psychotropic medications to foster care children). Although the California guidelines apply to children in foster care, they would apply similarly to individuals with developmental and intellectual disabilities who have been declared incapacitated because there is a substituted medical responsibility in both groups of individuals. *Id.* at 1. The state is responsible for the medical care of foster care children, whereas guardians are responsible for medical care of incapacitated individuals; both the state and guardians are required to obtain judicial approval for extraordinary treatment decisions. *Id.* at 6.

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See GUIDE TO ROGERS GUARDIANSHIP, *supra* note 103, at 5 (lacking any requirement of medical training).

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See id. Probate and family courts entrust the Rogers monitor to ensure that the incapacitated individual's antipsychotic medication is administered in accordance with the court-ordered plan and to meet with the individual's guardian (if a separate person from the monitor) regularly to review medical records and discuss the plan of care. *Id.* In fact, guardians ad litem, those who take the role of a Rogers monitor for foster care children receiving antipsychotic medications, have voiced discomfort in questioning the authority of the psychiatrist prescribing the antipsychotic medication. Howley, *supra* note 104, at 866. Article Five of the Massachusetts' version of the Uniform Probate Code merely states the court will appoint a "suitable monitor" if the incapacitated individual's guardian is unable to serve as the monitor of antipsychotic administration. ARTICLE V, *supra* note 112, at V-32-33. *See e.g. Resident Assessment in Long-Term Care Facilities, supra* note 33, at 61614 (suggesting checklist of triggers to cue prescribers on when to lower dosage or stop antipsychotic medication); Findling et al., *supra* note 5, at 10 (stressing importance of in-depth assessment prior to prescribing antipsychotic medications).

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See D.C. CODE § 7-1305.06b (requiring psychiatrist, other licensed professional, and disability advocate on medical review team); WASH. ST. DEPT SOC. & HEALTH SERVS., *supra* note 81, at 4 (requiring review and documentation of medication's adverse effects by physician and pharmacist every 90 days).

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MASS. PROB. & FAM. CT., CLINICIAN'S AFFIDAVIT AND REPORT FOR EXTENSION AND/OR AMENDMENT OF SUBSTITUTED JUDGMENT TREATMENT PLAN (June 17, 2011), <https://www.mass.gov/lists/probate-family-court-forms-for-guardianship-and-conservatorship>; *see* NPS MEDICINEWISE, *supra* note 74, at 1 (suggesting more frequent reviews depending on patient's unique medical needs).

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NPS MEDICINEWISE, *supra* note 74, at 1. *Id.* The Australian monitoring tool provides a detailed checklist for the prescriber, including a box to assess for tremors, rigidity, and involuntary movements every six months as well as sedation and anticholinergic events every visit. *Id.* Anticholinergic effects are a decrease in parasympathetic nervous system activity, which can involve a wide range of symptoms, including blurred vision, decreased sweating, dry mouth, and difficulty urinating. Barbara Bolen, *The Side Effects of Anticholinergic Medications*, VERYWELLHEALTH (Feb. 22, 2018), <https://www.verywell.com/anticholinergic-effects-1944856>.

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- 165 *See California Guidelines, supra* note 82, at 11 (suggesting prescriber obtain “[a]ll prior mental health, physical health, and developmental records”).
- 166 *Id.* The California guidelines suggest that prescribers order laboratory tests as part of both their initial, comprehensive assessments in ruling out medical causes of the patient's problematic behaviors and their plans to monitor for side effects that increase in frequency depending on the patient's other conditions. *Id.* at 9-10. For example, patients with a pattern of nighttime awakenings may require a separate workup for sleep disorders, seizures, and mood disorders prior to starting them on antipsychotic medications. *See* McGuire et al., *supra* note 67, at S142.
- 167 *See* CAL. BUS. & PROF. CODE *supra* note 82 (granting medical board authority to discipline physicians for repeated acts of excessively prescribing psychotropic medications). Similar to the California statute, Massachusetts would not need to automatically sanction any physician who is found to have inappropriately prescribed antipsychotic medication, but would rather permit the Board of Registration in Medicine to conduct investigations. *Id.* If the investigations result in substantiated findings, then the medical board would have the authority and responsibility of determining and applying sanctions upon the physician. *Id.*; *see also* MASS. GEN. LAWS ANN. ch. 112, § 5 (permitting Board to revoke, suspend, or cancel physician's registration upon proof obtained from administrative hearing).
- 168 *See generally* D.C. CODE § 7-1305.06b; WASH. ST. DEPT SOC. & HEALTH SERVS., *supra* note 81, at 4.

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