IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

STEPHANIE DIPIERRO, Plaintiff, v. HUGH J. HURWITZ, in his official capacity as Acting Director of the Federal Bureau of Prisons, and DR. DEBORAH G. SCHULT, in her official capacity as Assistant Director of the Health Services Division of the Federal Bureau of Prisons, Defendants.	C.A. No. 1:19-cv-10495

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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Frederickson Decl., Ex. __	Exhibit to the Declaration of Robert Frederickson III
S. DiPierro Decl. ¶ __	Declaration of Stephanie DiPierro
C. DiPierro Decl. ¶ __	Declaration of Ciriaco DiPierro
Berwald Decl. ¶ __	Declaration of Rose Ann Berwald, M.D.
MacDonald Decl. ¶ __	Declaration of Ross MacDonald, M.D.
Melvin Decl. ¶ __	Declaration of Carol Melvin
Potee Decl. ¶ __ or Potee Decl., Ex. __	Declaration of Ruth A. Potee, M.D., or exhibits thereto
Rosenthal Decl. ¶ __ or Rosenthal Decl., Ex. __	Declaration of Richard N. Rosenthal, M.D., or exhibits thereto
Walley Decl. ¶ __	Declaration of Alexander Yale Walley, M.D., MSc
Arroyo Decl. ¶ __	Declaration of Ernesto Arroyo
FDA	U.S. Food and Drug Administration
BOP	Federal Bureau of Prisons
MAT	Medication-assisted treatment or medication for addiction treatment
ONDCP	President's Office of National Drug Control Policy
SAMHSA	Substance Abuse and Mental Health Services Administration
WHO	World Health Organization
OUD	Opioid use disorder

INTRODUCTION

Plaintiff Stephanie DiPierro has a deadly medical condition for which she receives FDA-approved and doctor-prescribed medication that keeps her alive. On April 8, 2019, she is scheduled to report to a federal Bureau of Prisons (BOP) facility to begin a 366-day sentence. But, unless this Court intervenes, BOP officials will halt Ms. DiPierro's life-saving medication. That is because her condition is opioid use disorder, her medication is methadone, and BOP's policy categorically denies all non-pregnant inmates access to methadone as a treatment for opioid use disorder. This policy, as applied to Ms. DiPierro, likely violates the Eighth Amendment, as well as multiple federal statutes. This Court should grant a preliminary injunction requiring the BOP to provide Ms. DiPierro her medically-necessary treatment.

America is in the midst of a public health crisis caused by opioid addiction. To confront this crisis, multiple federal agencies have embraced the medical consensus that the standard of care to treat opioid use disorder is medication for addiction treatment, or MAT, which incorporates FDA-approved medications like methadone or buprenorphine. The medical consensus does not change in the correctional environment. U.S. Attorney's Offices have even initiated investigations against state and local correctional institutions that withhold MAT from inmates. Yet the BOP remains an outlier. Although it prescribes methadone to treat inmates for pain and to treat pregnant inmates for opioid use disorder, BOP expressly prohibits methadone as treatment for opioid use disorder for all non-pregnant inmates.

The BOP's policy imminently threatens Ms. DiPierro's ongoing recovery and her physical and mental health. With the help of her doctor-prescribed methadone treatment, Ms. DiPierro has escaped years of active addiction and entered long-term recovery. A rare success in the public health crisis, Ms. DiPierro has reestablished connections with her family and works as a personal care assistant to help a friend suffering from cerebral palsy. Ms. DiPierro made a

mistake in not reporting her employment to the agencies from which she receives benefits—for which she accepted responsibility and pled guilty—but that mistake should not claim her life.

Absent an injunction, the BOP's policy will cause Ms. DiPierro to suffer painful withdrawal and will place her at a high risk of relapse, overdose, and death. Accordingly, Ms. DiPierro seeks emergency injunctive relief to require the BOP to provide her with continued access to her medically necessary, physician-prescribed medication to treat her opioid use disorder when she is imprisoned on April 8, and throughout her incarceration. The relief Ms. DiPierro seeks is not without precedent. This Court recently granted a preliminary injunction requiring a Massachusetts county facility to provide an inmate with continued access to methadone, despite a similar policy banning such treatment, because denying methadone likely violated both the Eighth Amendment and the Americans with Disabilities Act (ADA). *See Pesce v. Coppinger*, Civil Action No. 18-11972-DJC, 2018 WL 6171881 (D. Mass. Nov. 26, 2018).

This Court should reach a similar conclusion here, as the BOP's policy likely violates the Eighth Amendment, the Rehabilitation Act, and the Administrative Procedures Act (APA). Because the other equitable factors also favor relief, this Court should issue an order requiring Defendants to provide Ms. DiPierro with continued access to methadone when she is in custody.

FACTS

A. Opioid Use Disorder Is a Serious Medical Issue and a Public Health Crisis.

Opioid use disorder ("OUD") is a chronic brain disease. Rosenthal Decl. ¶ 11; Potee Decl. ¶ 6. OUD symptoms include cravings, withdrawal symptoms, and a loss of control. *Id*. Without treatment, people with OUD often cannot control their use of opioids. Rosenthal Decl. ¶ 12; Potee Decl. ¶¶ 8-10. Like many other chronic diseases, genetic factors account for much of a person's vulnerability to addiction. Rosenthal Decl. ¶ 16; Potee Decl. ¶ 7. Other risk factors include early exposure and childhood trauma. Rosenthal Decl. ¶ 17; Potee Decl. ¶ 7.

More than half a million people in America have died from opioids in the last 20 years. Rosenthal Decl. ¶¶ 18-21. Every day, more than 115 Americans die after overdosing on opioids. *Id.* ¶ 21. The situation in Massachusetts is particularly dire. There were 2,069 confirmed and estimated opioid-related overdose deaths in Massachusetts in 2017, an average of almost six per day. *Id.* ¶ 22.

As the President's Commission on Combating Drug Addiction and the Opioid Crisis recognized, OUD is especially dangerous for people who are or have been incarcerated. Frederickson Decl., Ex. 2 at 72; Potee Decl. ¶¶ 23-26. In 2015, nearly 50 percent of all deaths among those released from incarceration were opioid related. Potee Decl. ¶ 23. A recent study by the Massachusetts Department of Public Health found that "[t]he opioid overdose death rate is 120 times higher for those recently released from incarceration compared to the rest of the adult population." *Id.* ¶ 26.

B. MAT Is the Standard of Care for Treating Opioid Use Disorder.

The standard of care for treating OUD is known as medication for addiction treatment or medication-assisted treatment (MAT), which combines medication and counseling. Potee Decl. ¶¶ 11-13; Rosenthal Decl. ¶¶ 26-27. The three FDA-approved medications for treating this disease are methadone, buprenorphine (Suboxone), and naltrexone (Vivitrol). Rosenthal Decl. ¶¶ 27, 29. Methadone and buprenorphine activate opioid receptors to relieve withdrawal symptoms and control cravings, and can be prescribed to people with opioids in their systems. *Id.* ¶¶ 29-30. Naltrexone, in contrast, blocks opioid receptors, preventing opioids from producing euphoric effects. *Id.* ¶ 29. Because this antagonistic effect can accelerate withdrawal symptoms, naltrexone cannot responsibly be prescribed to someone with heroin, methadone, or buprenorphine in their systems. *Id.* Not every medication works equally well for each patient,

and if one form of MAT is working for a patient, it is against the standard of care to involuntarily terminate it. Walley Decl. ¶ 5; Berwald Decl. ¶ 5; Potee Decl. ¶ 15.

MAT's effectiveness is well documented, and has been shown to decrease opioid use, opioid-related overdose deaths, criminal activity, and infectious disease transmission. Rosenthal Decl. ¶ 27. Other regimens, such as abstinence, have not proven successful, and studies have shown that maintenance medication treatments have a more robust effect than behavioral interventions. *Id*. ¶ 28. As a result, "[a] growing coalition of state and federal government agencies and physicians groups has advocated for increased access to MAT to combat the growing crisis of opioid addiction." *Id*. ¶ 33.

For example, the World Health Organization (WHO) deems buprenorphine and methadone "essential medicines" for treating OUD. *Id*. ¶ 30. The FDA has declared "[i]mproving access to prevention, treatment and recovery services, including the full range of MAT, is a focus of FDA's ongoing work to reduce the scope of the opioid crisis." *Id*. ¶ 27. The President's Commission recommends that OUD "treatment should include . . . access to MAT." Frederickson Decl., Ex. 2 at 68. The President's Office of National Drug Control Policy (ONDCP) recently promised the "Administration will work across the Federal government to remove barriers to substance use disorder treatments, including those that limit access to any forms of FDA-approved MAT[.]" Frederickson Decl., Ex. 15 at 10. And the Substance Abuse and Mental Health Services Administration (SAMHSA) offers billions of dollars in federal grants to increase MAT programs and support. Rosenthal Decl. ¶ 33.

C. Methadone Is Medically Necessary for Ms. DiPierro.

Ms. DiPierro suffers from OUD, anxiety and bipolar disease. S. DiPierro Decl. ¶ 2; Berwald Decl. ¶ 9. She began using heroin in the mid-1990s at age 14, after her mother died. Her use soon escalated into years of active addiction. S. DiPierro Decl. ¶¶ 7-10. For most of the

late 1990s and early 2000s, Ms. DiPierro could not keep a job or endure a day without using opioids. *Id.* ¶ 10. Her relationships deteriorated, and her father worried that he was going to receive a call saying that she overdosed or died. *Id.* ¶ 11; C. DiPierro Decl. ¶ 8.

Ms. DiPierro spent years trying unsuccessfully to overcome her opioid use, and underwent detoxification several times. S. DiPierro Decl. ¶ 12; C. DiPierro Decl. ¶ 9. But, as is well understood by medical practitioners, detoxification is not treatment. Rosenthal Decl. ¶ 28. Not surprisingly, it did not prevent Ms. DiPierro from experiencing overwhelming cravings that led her to relapse. S. DiPierro Decl. ¶ 12; C. DiPierro Decl. ¶ 9.

Ms. DiPierro finally achieved active recovery in the late 2000s, when she was prescribed a correct dose of methadone as part of a treatment program in Boston that also includes counseling and other therapies. S. DiPierro Decl. ¶¶ 13-15. The methadone is administered orally in a liquid form similar to cough syrup, which she takes daily. Berwald Decl. ¶ 8; S. DiPierro Decl. ¶ 15. Under treatment with methadone, Ms. DiPierro has now been in active recovery for many years. S. DiPierro Decl. ¶¶ 15-18; C. DiPierro Decl. ¶ 11; Arroyo Decl. ¶¶ 3, 5. According to her treating physician, Dr. Berwald, this is particularly remarkable given her lengthy history of active addiction and her co-morbid bipolar disorder. Berwald Decl. ¶¶ 9-10. Dr. Berwald's medical opinion is that continued methadone treatment is medically necessary to treat Ms. DiPierro's OUD. *Id.* ¶ 8; *see also* Arroyo Decl. ¶ 5.

Since entering active recovery, Ms. DiPierro has rebuilt relationships with her family and provides daily personal care assistance to a friend with cerebral palsy. S. DiPierro Decl. ¶¶ 17-18, 22; Melvin Decl. ¶ 3. Ms. DiPierro wishes to remain in recovery for herself and her father, who has already lost a son to an opioid overdose death. S. DiPierro Decl. ¶ 34; C. DiPierro Decl. ¶ 15. As explained below, Defendants' policies jeopardize Ms. DiPierro's health and recovery.

D. Absent Judicial Intervention, the BOP Will Contravene the Standard of Care and Terminate Ms. DiPierro's Methadone Treatment.

Ms. DiPierro is proud of the help she provides as a personal care assistant, but she failed to report her employment to the agencies from which she received benefits. S. DiPierro Decl. ¶¶ 22-23. Accepting responsibility for that mistake, she pled guilty to several federal offenses relating to benefits fraud and was sentenced to serve 366 days at an as-yet-undesignated BOP facility. *Id*. ¶ 24. She is scheduled to self-surrender on April 8, 2019. *Id.* ¶ 24.

Although the BOP permits the use of methadone for pain management, as a matter of policy and practice the BOP does not provide methadone or buprenorphine to non-pregnant inmates who suffer from OUD, even those who have been successfully prescribed these medications before their incarceration and are in active recovery. Frederickson Decl., Ex. 3 at 37, Ex. 4 at 15. The BOP's Pharmacy Services Program Statement and National Formulary, which apply to and bind all BOP institutions, mandate that "inmates will not be maintained on methadone with the exception of pregnant inmates," and that buprenorphine will "NOT" be approved for "maintenance therapy." *Id.* There are no exceptions to this policy.

Under the BOP's detoxification procedure, Ms. DiPierro will be involuntarily tapered off of her methadone treatment either within three days or at a rate of 10% per day. Frederickson Decl., Ex. 5 at 16. Both of these protocols will trigger excruciating withdrawal symptoms, such as vomiting, diarrhea, body shakes, and an inability to sleep for weeks or even months at a time, which can lead to life-threatening complications. Potee Decl. ¶¶ 21-22; Rosenthal Decl. ¶ 34; Berwald Decl. ¶ 13; Arroyo Decl. ¶¶ 7-8. Ms. DiPierro will also be at risk of relapsing into opioid use—either during or immediately following her incarceration—increasing the chance that she will overdose and die. Rosenthal Decl. ¶ 35; Potee Decl. ¶¶ 23-26; Berwald Decl. ¶¶ 14-16. Involuntary halting methadone treatment is particularly risky for Ms. DiPierro, as doing so

could trigger her bipolar disorder symptoms, which include severe depression, and raise a significant risk of self-harm and suicide. Potee Decl. ¶¶ 16, 19-22; Rosenthal Decl. ¶ 35; MacDonald Decl. ¶ 23.

On February 28, 2019, Ms. DiPierro's counsel sent a letter to both Defendants informing them of her serious medical need and requesting assurance that Ms. DiPierro will be provided with her physician-prescribed dose of methadone while in their custody. Frederickson Decl., Ex. 6 at 1. On March 6, 2019, counsel for the BOP called Ms. DiPierro's counsel and stated that Ms. DiPierro would be given an individualized assessment of her general medical needs and would be given treatment of some kind. It therefore appears that BOP will not provide Ms. DiPierro with the necessary methadone treatment as counsel for the BOP would not confirm the same, and did not suggest that Defendants could or would deviate from their mandatory blanket prohibition of methadone maintenance treatment for non-pregnant inmates.

E. Providing Medication for Addiction Treatment to Inmates with Opioid Use Disorder Has Had Demonstrable Success.

The BOP's refusal to provide MAT to inmates stands in stark contrast to the positive results other correctional institutions have experienced by offering MAT, and the federal government's own admonishments to state and local correctional institutions which have not yet adopted this treatment regimen. Various state prisons either already administer methadone and buprenorphine to their inmates or are preparing to do so. MacDonald Decl. ¶ 10; Potee Decl. ¶¶ 27-35. These programs have profoundly helped inmates and their communities. For example, Rhode Island experienced large and clinically meaningful reductions in post-incarceration deaths from overdose among inmates released from incarceration after implementing a statewide MAT program. Potee Decl. ¶ 34. In addition, the President's ONDCP recently declared that one of the Administration's priorities is "increasing the availability of MAT for incarcerated individuals."

Frederickson Decl., Ex 15 at 9. The Department of Justice has also invoked the ADA to eliminate barriers to OUD recovery, and the U.S. Attorney is investigating several Massachusetts jails and prisons based on their failure to provide MAT to incarcerated people. In so doing, the U.S. Attorney emphasized "that all individuals in treatment for OUD, regardless of whether they are inmates or detainees, are already protected by the ADA, and [] the DOC has existing obligations to accommodate this disability." Frederickson Decl., Ex. 7.

ARGUMENT

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008). These factors also govern a motion for a temporary restraining order. *See Largess v. Supreme Judicial Court for State of Mass.*, 317 F. Supp. 2d 77, 80 (D. Mass. 2004). Applying this test, this Court in *Pesce* recently granted a preliminary injunction under the Eighth Amendment and the ADA to an individual suffering from OUD who challenged, as applied to him, a county house of correction's blanket policy denying methadone maintenance treatment. 2018 WL 6171881, at *1. All factors favor granting similar relief against the BOP's methadone policy as applied to Ms. DiPierro.

I. MS. DIPIERRO IS LIKELY TO SUCCEED ON THE MERITS.

To obtain preliminary injunction relief, Ms. DiPierro need only show that she is likely to succeed on one of these claims. *See Eve of Milady v. Impression Bridal, Inc.*, 957 F. Supp. 484, 487 (S.D.N.Y. 1997). First, Ms. DiPierro is likely to prove that Defendants, pursuant to BOP policy, will be deliberately indifferent to her serious medical need in violation of her rights under the Eighth Amendment. Second, Ms. DiPierro is also likely to show that Defendants, pursuant to BOP policy, will violate Section 504 of the Rehabilitation Act. And finally, for similar reasons,

Ms. DiPierro is likely to succeed on her APA claim, because the BOP policy as applied to her is an unlawful final agency action.

A. Ms. DiPierro Is Likely to Show That Defendants' Denial of Methadone Treatment Constitutes Deliberate Indifference to a Serious Medical Need Violating the Eighth Amendment.

Ms. DiPierro is likely to succeed on her Eighth Amendment claim that halting access to her prescribed methadone treatment constitutes cruel and unusual punishment. Because "society takes from prisoners the means to provide for their own needs," they "are dependent on the State for food, clothing, and necessary medical care." *Brown v. Plata*, 563 U.S. 493, 510 (2011). "Just as a prisoner may starve if not fed, he or she may suffer or die if not provided adequate medical care." *Id*. at 510-11. "A prison that deprives prisoners of basic sustenance, including adequate medical care, is incompatible with the concept of human dignity and has no place in civilized society." *Id.* at 511. Prison officials thus have an affirmative obligation to provide prisoners with medical care. *See Estelle v. Gamble*, 429 U.S. 97, 104 (1976). An Eighth Amendment claim has objective and subjective elements. *Kosilek v. Spencer*, 774 F.3d 63, 81 (1st Cir. 2014) (en banc). Objectively "it must be proven that there is a serious medical need and that adequate care has not been provided." *Soneeya v. Spencer*, 851 F. Supp. 2d 228, 241 (D. Mass. 2012). Subjectively, it must be proven that Defendants are deliberately indifferent to the serious medical need. *Id.* at 241-42. Ms. DiPierro is likely to satisfy both elements.

1. Ms. DiPierro Is Reasonably Likely to Satisfy the Objective Prong of Her Eighth Amendment Claim.

Ms. DiPierro is "reasonably likely to satisfy the objective inquiry" of the Eighth Amendment analysis. *Pesce,* 2018 WL 6171881, at *7.[1]

First, OUD is a serious medical need. A medical need is "serious" if it "is one that has

[1] Ms. DiPierro's medical need is serious even though she is not yet in federal custody. "A significant risk of future harm that prison administrators fail to mitigate may suffice under the objective prong." *Kosilek*, 774 F.3d at 85. The application of BOP's methadone policy imposes a grave risk to Ms. DiPierro's recovery, health,and life.

been diagnosed by a physician as mandating treatment, or one that is so obvious that even a lay person would easily recognize the necessity for a doctor's attention." *Miranda-Rivera v. Toledo-Davila*, 813 F.3d 64, 74 (1st Cir. 2016). Ms. DiPierro's physician has prescribed methadone to treat her OUD, a chronic brain disease that kills more than one hundred Americans every single day. Berwald Decl. ¶ 8; Frederickson Decl., Ex. 1.

Second, Ms. DiPierro's methadone is medically necessary to adequately treat her OUD. Of her many attempts to achieve recovery, only methadone treatment has worked. S. DiPierro Decl. ¶¶ 9, 12, 15; C. DiPierro Decl. ¶¶ 9-10. Her prescribing physician has determined that methadone "is medically necessary to treat [her] opioid use disorder," and that "it would violate medical standards of care to involuntarily remove [her] from this treatment." Berwald Decl. ¶ 8. That MAT is the standard of care to treat OUD is widely embraced by entities including the Department of Health and Human Services, the National Institute on Drug Abuse, the FDA, SAMHSA, and WHO. *See* Frederickson Decl., Ex. 8, Ex. 9, Ex. 10. Once a patient is successfully recovering using methadone, abruptly and involuntarily halting that medication for reasons other than medical necessity contradicts sound medical practice and prudent professional standards of care. Potee Decl. ¶ 15; Rosenthal Decl. ¶ 36; *see also* Berwald Decl. ¶¶ 5-8.

Directly contradicting Ms. DiPierro's own doctor and the weight of medical authority, the BOP's methadone policy will categorically deny Ms. DiPierro access to adequate care. Frederickson Decl., Ex. 3 at 37, Ex. 11 at 102. Under the Eighth Amendment "[a]dequate care is based on an individualized assessment of an inmate's medical needs in light of relevant medical considerations." *Soneeya*, 851 F. Supp. 2d at 242. But the BOP's blanket policy preempts this constitutionally required assessment, mandating that "[i]nmates will not be maintained on methadone with the exception of pregnant inmates." Frederickson Decl., Ex. 3 at 37. BOP

officials have not claimed any authority to deviate from this ban, for which there is no written exception, and Plaintiff is unaware of any instance in which a non-pregnant inmate received methadone maintenance treatment at a BOP facility.[2] There can be no individualized assessment under these circumstances, because any evaluation will necessarily ignore the option of methadone treatment regardless of Ms. DiPierro's needs. *Cf. Kosilek*, 774 F.3d at 91 (noting that "any such [blanket] policy would conflict with the requirement that medical care be individualized based on a particular prisoner's serious medical needs").[3]

This, therefore, is not a case where "two alternative courses of treatment exist, and both alleviate negative effects within the boundaries of modern medicine." *Cf. Kosilek*, 774 F.3d at 90. Here, the BOP's policy does not permit *any* treatment during incarceration. But even if it did, there is no reasonable alternative to methadone here given that (1) Ms. DiPierro has had tremendous success with methadone, (2) her physician has determined methadone is medically necessary to treat her OUD and that it would violate the standard of care to terminate this treatment, and (3) she is at high risk for dangerous withdrawal and relapse if methadone is abruptly withdrawn. Berwald Decl. ¶¶ 8-13. The BOP's methadone policy therefore denies Ms. DiPierro constitutionally adequate care for her serious medical need.

2. Ms. DiPierro Is Likely to Satisfy the Subjective Prong to Her Eighth Amendment Claim.

As applied to Ms. DiPierro, the BOP's methadone policy constitutes deliberate indifference. "In the First Circuit, allegations that prison officials denied or delayed

[2] Indeed, the BOP's National Formulary includes methadone for pain management only. Frederickson Decl., Ex. 11 at 102-03. Non-formulary requests can be approved only where specific criteria outlined in the Formulary itself are met. Frederickson Decl., Ex. 4 at 4. The Formulary does not include any criteria to justify non-formulary requests for methadone maintenance treatment of non-pregnant women. *Id.* at 11-32.

[3] This contrasts sharply with the BOP's policy regarding treatment of inmates with gender identity disorder, which mandates "[a]ll appropriate treatment options prescribed for inmates with GID in currently accepted standards of care will be taken into consideration during evaluation[.]" Frederickson Decl., Ex. 12 at 41. Here, "***all***" appropriate treatment options are not on the table.

recommended treatment by medical professionals may be sufficient to satisfy the deliberate indifference standard." *Pesce*, 2018 WL 6171881, at * 7 (citation omitted). Here, the BOP's policy is designed to disregard Ms. DiPierro's medical needs in favor of a one-size-fits-all prohibition of methadone maintenance treatment for all non-pregnant inmates. Ms. DiPierro is thus "likely to succeed on the merits of h[er] Eighth Amendment claim" because the BOP's "policy ignores treatment prescriptions given to Plaintiff by [her] doctors." *Id.* at *8. Indeed, the Defendants have been notified of Ms. DiPierro's serious medical need and her methadone prescription, yet they have not agreed that she will be able to continue her treatment.

Although prison officials might not be deliberately indifferent if they "make judgments balancing security and health concerns that are within the realm of reason and made in good faith," *see Kosilek*, 774 F.3d at 92 (citation omitted), that is not the situation here. The BOP *already offers methadone* to inmates for pain management and permits methadone maintenance therapy for pregnant inmates. Frederickson Decl., Ex. 3 at 37, Ex. 11 at 102-03. BOP's policies do not, and could not, identify security reasons for banning liquid methadone, much less weigh them against Ms. DiPierro's urgent need for continued treatment. *Id.*, Ex. 3 at 37-39, Ex. 11 at 102-03. Indeed, state jails and prisons have implemented MAT policies that allow inmates to continue methadone treatment for OUD. *See* Potee Decl. ¶¶ 27-35; MacDonald Decl. ¶¶ 9-10. And several institutions, including the National Commission on Correctional Health Care and the National Sheriffs' Association, have called for the provision of all three forms of MAT in jails and prisons. Frederickson Decl., Ex. 13 at 9, Ex. 14 at 4-6. Thus, security concerns cannot justify denying Ms. DiPierro her methadone treatment. *Pesce*, 2018 WL 6171881, at *6.

B. Ms. DiPierro Is Likely to Show That Defendants' Denial of Methadone Treatment Violates the Rehabilitation Act.

Ms. DiPierro is also likely to succeed on her claim that denying her access to methadone

constitutes unlawful discrimination under the Rehabilitation Act.[4] Section 504 of the Rehabilitation Act prohibits federal entities like the BOP from discriminating against a qualified individual with a disability on the basis of that disability. *See* 29 U.S.C. § 794. To succeed, Ms. DiPierro must show: "(1) that [s]he is a qualified individual with a disability; (2) that [s]he was either excluded from participation in or denied the benefits of some public entity's services, programs, or activities or was otherwise . . . discriminated against; and (3) that such exclusion, denial of benefits, or discrimination was by reason of [her] disability." *Buchanan v. Maine*, 469 F.3d 158, 170-71 (1st Cir. 2006); *see Gorman v. Bartch*, 152 F.3d 907, 912 (8th Cir. 1998). Each element is satisfied here.

1. Ms. DiPierro Is a Qualified Individual with a Disability.

Individuals with OUD, including Ms. DiPierro, are qualified individuals with disabilities under the Rehabilitation Act. *See Pesce*, 2018 WL 6171881, at *6 (finding same under the ADA). A "disability" includes "a physical or mental impairment that substantially limits one or more major life activities." 42 U.S.C. § 12102; 29 U.S.C. § 705(20)(B). Such impairments include "drug addiction, and alcoholism." 28 C.F.R. § 35.108(b)(2).[5] Ms. DiPierro's disability is severe and chronic. Berwald Decl. ¶ 9; Rosenthal Decl. ¶¶ 8-17. Left untreated, her OUD "substantially limits" her major life activities, such as caring for herself, learning, concentrating, thinking, communicating, and working. S. DiPierro Decl. ¶¶ 2, 14-18; Rosenthal Decl. ¶¶ 11-15. Ms. DiPierro therefore qualifies for protection under the Rehabilitation Act.

[4] Cases interpreting the Rehabilitation Act and the ADA are interchangeable. *See Theriault v. Flynn*, 162 F.3d 46, 48 n.3 (1st Cir. 1998) ("Title II of the ADA was expressly modeled after Section 504 of the Rehabilitation Act, and is to be interpreted consistently with that provision"); *Hainze v. Richards*, 207 F.3d 795, 799 (5th Cir. 2000) ("[j]urisprudence interpreting either [Title II or the Section 504 of the Rehabilitation Act] is applicable to both).

[5] Pursuant to 29 U.S.C. § 705(20)(B), the definition of "disability" under the ADA, 42 U.S.C. § 12102, applies to Section 504 of the Rehabilitation Act. The DOJ interpretation of the provisions of 42 U.S.C. § 12102 in 28 C.F.R. § 35.108(b)(2) therefore also applies to the term "disability" in the Rehabilitation Act.

2. Ms. DiPierro Will Be Denied the Benefit of Health Care Services and Discriminated Against Because of Her Disability.

Ms. DiPierro also satisfies the second and third elements for demonstrating a Rehabilitation Act violation: medical care is a service within the meaning of the Rehabilitation Act, and the Defendants' methadone policy will deny that service to Ms. DiPierro by reason of her disability. *See Pesce*, 2018 WL 6171881, at *6. In *Pesce*, the Court held that a county policy resembling the BOP's was "either 'arbitrary or capricious-as to imply that it was pretext for some discriminatory motive' or 'discriminatory on its face.'" *Pesce*, 2018 WL 6171881, at *7. Likewise, the U.S. Attorney has instigated ADA investigations against state and county facilities for imposing such a blanket policy to deny inmates access to methadone and buprenorphine during incarceration. Frederickson Decl., Ex. 7. Here, in at least two ways, Ms. DiPierro is likely to show that the BOP's blanket policy of refusing to administer methadone treatment to her denies services based on her disability, and thus violates the Rehabilitation Act.

First, halting Ms. DiPierro's methadone treatment discriminates based on her disability because Defendants' policy, as applied to Ms. DiPierro, discriminates "amongst classes of the disabled." *Iwata v. Intel Corp.*, 349 F. Supp. 2d 135, 148-49 (D. Mass. 2004) (citing *Olmstead v. L.C.*, 527 U.S. 581 (1999)); *see, e.g.*, *McNally v. Prison Health Servs.*, 46 F. Supp. 2d 49, 58-59 (D. Me. 1999). If Ms. DiPierro suffered from diabetes, heart disease, or any number of other chronic health conditions requiring regular medication, Defendants would meet her medical needs. Frederickson Decl., Ex. 12 at 6 (chronic conditions including diabetes and heart disease considered "medically necessary"). But because Ms. DiPierro suffers from OUD, she will be denied the methadone her physician has prescribed. Indeed, BOP policy provides methadone when the inmate's condition is chronic pain or when the inmate is pregnant, but it prohibits the same exact medication when the non-pregnant inmate's diagnosis is OUD. Frederickson Decl.,

Ex. 3 at 37-39, Ex. 11 at 102-03. This disparity underscores that the reason the BOP will not provide Ms. DiPierro methadone has nothing to do with a legitimate security or health concern and everything to do with her diagnosis. That is quintessential disability discrimination that the Rehabilitation Act forbids.

Second, halting Ms. DiPierro's methadone treatment discriminates based on her disability because it is a refusal to provide a reasonable accommodation. "Discrimination" under the Rehabilitation Act and the ADA includes failing to make reasonable accommodations for a qualified individual with a disability. *See Henrietta D. v. Bloomberg*, 331 F.3d 261, 273 (2d Cir. 2003); 29 U.S.C. § 794; 42 U.S.C. § 12112(b)(5)(A). Here, Ms. DiPierro seeks a reasonable accommodation of her OUD—her prescribed methadone treatment—that will not fundamentally alter the BOP's health services, which already provide methadone for pain management and to pregnant inmates. *See* Frederickson Decl., Ex. 3 at 37, Ex. 11 at 102-03; *Pesce*, 2018 WL 6171881, at *6. Defendants' policy requiring Ms. DiPierro to discontinue treatment, undergo painful and dangerous withdrawal, and risk relapse, overdose, and death, is not a reasonable accommodation. Rosenthal Decl. ¶¶ 34-37; Berwald Decl. ¶¶ 12-14. Far from relying on "reasoned medical judgment," Defendants "have not given any consideration to [Ms. DiPierro's] specific medical needs nor indicated any likelihood to do so when [s]he is incarcerated given their present policy against methadone treatment." *Pesce*, 2018 WL 6171881, at *6.

C. Ms. DiPierro Is Likely to Show that the BOP Has Violated the APA by Taking Final Agency Actions that, In Turn, Violate the Rehabilitation Act.

Because the above Rehabilitation Act violations arise from final agency actions, Ms. DiPierro is also likely to succeed on the merits of her APA claim.[6] A federal agency, such as the

[6] Reviewing a claim under the Rehabilitation Act for injunctive relief, this Court recently reaffirmed "Section 504 . . . applies to federal prisoners who are in the Bureau of Prisons' care." *Kendall v. Murray*, 340 F. Supp. 3d 61, 69-70 (D. Mass. 2018); *see also J.L. v. Social Security Admin*, 971 F.2d 260, 269 (9th Cir. 1992) (private right of action for injunctive relief against federal executive agencies under Rehabilitation Act); *American Council of the Blind v.*

BOP, violates the APA when it takes a final action that is not in accordance with the law, including "a federal statute other than the agency's enabling statute." *Cousins v. Sec'y of the U.S. Dep't of Transp.*, 880 F.2d 603, 609 (1st Cir. 1989) (en banc); *see* 5 U.S.C. §§ 701, 704, 706(2)(A). An agency action is final if it "mark[s] the consummation of the agency's decisionmaking process" and if "rights or obligations have been determined or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). In other words, the agency must have "completed its decisionmaking process," and the result of that process must "directly affect the parties." *Sig Sauer v. Brandon*, 826 F.3d 598, 600 n.1 (1st Cir. 2016). Here, the BOP's violations of the Rehabilitation Act arise from two final agency actions.

First, the portions of the BOP's Program Statement on Pharmacy Services and its National Formulary that categorically ban methadone maintenance treatment for OUD in all non-pregnant inmates constitute a final agency action. *See Glaus v. Anderson*, 408 F.3d 382, 387 (7th Cir. 2005) (suggesting inmate could bring "an Administrative Procedures Act challenge to the BOP guidelines on treatment for hepatitis C"); *Somerville v. Federal Bureau of Prisons*, 579 F. Supp. 2d 821, 824-25 (E.D. Ky. 2008) (holding BOP's Program Statement on Categorization of Offenses was final agency action subject to APA review). There is nothing "tentative" or "interlocutory" about these documents. *Bennett*, 520 U.S. at 177-78. The Formulary specifies "ALL BOP institutions, including Medical Centers, are expected to abide by the formulary as outlined in the BOP Pharmacy Services Program Statement." Frederickson Decl., Ex. 4 at 4 (emphasis in original). The Program Statement mandates "each institution will use the Bureau's

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Paulson, 463 F. Supp. 2d 51 (D.D.C. 2006) (same). Ms. DiPierro pleads her APA claim in the alternative without waiving the argument that her claim properly lies within the Rehabilitation Act. Plaintiff's Rehabilitation Act arguments are identical for the purposes of APA review. *Cousins*, 880 F.2d at 605, 609-10 (substantive law is the same in a Rehabilitation Act claim and an APA claim based on a Rehabilitation Act violation); *Wisher v. Coverdell*, 782 F. Supp. 703, 709-10 (D. Mass. 1992) (agency "must comply with the Rehabilitation Act whether its actions are being reviewed pursuant to a private right of action under § 504 or under the APA").

National Drug Formulary" and "a local formulary can only be more restrictive than the National Formulary." Frederickson Decl., Ex. 3 at 5, 6; *see also Chiang v. Kempthorne*, 504 F. Supp. 2d 343, 350 (D.D.C. 2007) (agency guidelines "easily satisfy the first prong of the final action test" where they direct staff to "implement this guidance effective immediately").

These documents also "directly affect the parties" as they bind the BOP without exception to deny access to methadone maintenance treatment to all non-pregnant inmates, including Ms. DiPierro. *See Chiang*, 504 F. Supp. 2d at 350 (mandatory language of a guideline can be sufficiently binding to render it a final agency action for the purposes of APA review). The Formulary warns the "prescribing of medications against the restrictions, without an approved non-formulary request, is considered an unauthorized use of government funds." Frederickson Decl., Ex. 4 at 3. It goes on to direct that BOP physicians can only prescribe non-formulary uses when all of the criteria are met, consultant physicians must do the same, and clinical directors "will disapprove, at the local level, any request which does not meet the non-formulary use criteria." *Id.* at 4-5.[7] Finally, it mandates that all clinical directors, health services administrators, associate wardens and wardens are "expected to support and ensure compliance with the BOP National Formulary." *Id*. The BOP has no choice under this policy but to categorically deny methadone maintenance treatment to all non-pregnant inmates. For the reasons described *supra*, this final agency action violates the Rehabilitation Act.

Second, the BOP's decision to deny Ms. DiPierro access to her methadone maintenance treatment is another final agency action. BOP decisions on individual inmate medical care are subject to judicial review under the APA. *See Kane v. Winn*, 319 F. Supp. 2d 162, 211-12 (D. Mass. 2004) ("None of the statutes governing the BOP appears to exempt its decisions regarding

[7] There are no non-formulary criteria to justify methadone maintenance treatment for non-pregnant inmates.

medical care from judicial review."); *Wisher*, 782 F. Supp. at 711-12 (conducting APA review of agency's decision to medically disqualify plaintiff based on her hepatitis B diagnosis). Here, the BOP's policy leaves it no choice but to deny Ms. DiPierro her methadone treatment, and recent statements by BOP's counsel to Ms. DiPierro's counsel—in which the BOP would not commit to considering methadone—indicate that this denial has already occurred. This final action also violates the Rehabilitation Act.

D. Ms. DiPierro's Claims Do Not Require Exhaustion.

Finally, no exhaustion requirement defeats Ms. DiPierro's likelihood of success on the merits of her claims. The Department of Justice's administrative remedy for the Rehabilitation Act is not mandatory and can be waived by judicial discretion. *See, e.g.*, *Cooke v. Bureau of Prisons*, 926 F. Supp. 2d 720, 732-33 (E.D.N.C. 2013). It is appropriate to do so where, as here, the "plaintiff may suffer irreparable harm if unable to secure immediate judicial consideration of [her] claim," and where the administrative agency has "predetermined" the challenged issue. *Portela-Gonzalez v. Sec'y of the Navy*, 109 F.3d 74, 77 (1st Cir. 1997); *see also American Council of the Blind v. Snow*, 311 F. Supp. 2d 86, 90 (D.D.C. 2004) (exhaustion unnecessary where it is futile). And because Ms. DiPierro is not yet incarcerated, she need not exhaust any administrative remedies under the BOP's Remedy Program, which applies only to "inmates *in* institutions operated by the Bureau of Prisons, to inmates designated to contract Community Corrections Centers (CCCs) under Bureau of Prisons responsibility, and to former inmates for issues that arose during their confinement." 28 C.F.R. 542.10 (emphasis added).[8]

[8] The APA does not impose an independent exhaustion requirement. *Darby v. Cisneros*, 509 U.S. 137, 154 (1993).

II. MS. DIPIERRO FACES IMMEDIATE IRREPARABLE INJURY.

Ms. DiPierro will suffer irreparable harm unless she receives her methadone treatment while she is incarcerated. "'Irreparable injury' in the preliminary injunction context means an injury that cannot adequately be compensated for either by a later-issued permanent injunction, after a full adjudication on the merits, or by a later-issued damages remedy." *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 76 (1st Cir. 2005). Absent injunctive relief, Defendants' policy will force Ms. DiPierro into acute withdrawal with painful physical and psychological symptoms. Rosenthal Decl. ¶¶ 34-37; Potee Decl. ¶¶ 18-22. Because of her bipolar diagnosis, Ms. DiPierro will be at an especial risk of suicide and self-harm. Berwald Decl. ¶ 15. Forced withdrawal will also increase Ms. DiPierro's risk of relapsing, overdosing, and dying. Rosenthal Decl. ¶ 36. "Death is three times as likely for people out of treatment versus when in treatment," partly because the patient is no longer in remission and the patient's tolerance to narcotics is gone. *Id.*; Potee Decl. ¶ 22. Putting Ms. DiPierro at risk of these dire consequences is irreparable harm. *See Pesce*, 2018 WL 6171881, at *8 (finding irreparable harm where there was a "high risk of overdose and death upon [] release if not treated during [] incarceration.").

III. THE BALANCE OF HARMS FAVORS GRANTING MS. DIPIERRO'S MOTION.

The irreparable, and potentially permanent, harm suffered by Ms. DiPierro absent relief greatly outweighs any potential harm to Defendants. As discussed above, the BOP already provides methadone for inmate pain management and for maintenance therapy of pregnant inmates. Frederickson Decl., Ex. 3 at 37-39, Ex. 11 at 102-03. It is difficult to conceive of how providing the same exact medication to Ms. DiPierro would pose any burden on Defendants. Granting injunctive relief would therefore impose no measurable harm on Defendants aside from the cost of providing methadone, which is extremely cost-effective. *Id.*; *see also* Potee Decl. ¶¶ 27-31. By contrast, the harm Ms. DiPierro would face absent her prescribed-methadone

treatment includes a high risk of overdose and death. The balance of harms therefore clearly favors granting Ms. DiPierro's motion.

IV. THE PUBLIC INTEREST STRONGLY FAVORS THE GRANT OF EMERGENCY INJUNCTIVE RELIEF.

The public interest also favors Ms. DiPierro's requested injunctive relief. Defendants' policy of denying MAT, even to people with existing prescriptions, provides one more barrier to effective treatment for those suffering from OUD, enhancing rather than ameliorating the ongoing opioid crisis. Indeed, Defendants' policies worsen that crisis by disrupting effective treatment and making relapse and potential overdose more likely. "[T]he public interest is better served by ensuring [Ms. DiPierro] receives the medically necessary treatment that will ensure [s]he remains in active recovery." *See Pesce*, 2018 WL 6171881, at *8.

CONCLUSION

For the foregoing reasons, this Court should issue a Temporary Restraining Order and Preliminary Injunction requiring Defendants to provide methadone to Ms. DiPierro throughout her incarceration in a BOP facility.

Respectfully submitted,

STEPHANIE DIPIERRO,

By her attorneys,

/s/ Robert Frederickson III
Robert Frederickson III (BBO 670111)
Marielle Sanchez (BBO 703897)
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, Massachusetts 02210
Tel.: 617.570.1000
Fax: 617.523.1231
RFrederickson@goodwinlaw.com
MSanchez@goodwinlaw.com

Ira J. Levy (*Pro hac vice*)
Alexandra D. Valenti (*Pro hac vice*)
Tiffany Mahmood (*Pro hac vice*)
Christine Armellino (*Pro hac vice*)
GOODWIN PROCTER LLP
The New York Times Building
620 Eight Avenue
New York, NY 10018
Tel.: 212.813.8800
Fax: 212.355.3333
ILevy@goodwinlaw.com
AValenti@goodwinlaw.com
TMahmood@goodwinlaw.com
CArmellino@goodwinlaw.com

Matthew R. Segal (BBO 654489)
Jessie J. Rossman (BBO 670685)
American Civil Liberties Union
Foundation of Massachusetts, Inc.
211 Congress Street
Boston, MA 02110
Tel.: 617.482.3170
msegal@aclum.org
jrossman@aclum.org

Attorneys for Plaintiff Stephanie DiPierro

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