THE UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, *Plaintiff*, v. ALEX M. AZAR, II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants*.	Civil Case No. 1:19-cv-01672 COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. This is an action pursuant to the Administrative Procedure Act challenging a U.S. Department of Health and Human Services final rule entitled *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (May 21, 2019) (the "Rule"). The Rule eviscerates the careful consideration that Congress, courts, and Plaintiff Mayor and City Council of Baltimore (the "City") have given to preserving the right to nondiscriminatory health care and informed consent while accommodating conscience concerns of health care providers. The Rule, in contrast, appears to grant any individual, entity, or provider in health care—from front office staff to ambulance drivers—the unqualified right to deny patients care, including reproductive and emergency care, not just on the basis of conscience protections, but also on the basis of "ethical, or other reasons." *Id.* at 23264.

2. Under the Rule, care may be denied without meaningful provision of prior notice of any religious, moral, or ethical objection, without substantiation, and without any consideration of the countervailing rights of patients. The Rule goes far beyond the statutes it purports to

implement; it directly violates statutes that prohibit creating unreasonable barriers to access, impeding timely access to health care, and interfering with communications regarding treatment options; it is unjustified and unworkable; and it violates Constitutional law.

3. To even attempt compliance the City would need to pay for and train alternate staff for a wide variety of positions in its own programs, as well as compliance monitors for its subgrantees and partners. This "solution" is financially and operationally impossible. Thus, compliance with the Rule will force the City to provide substandard, stigmatizing, and unethical care to its residents—for example a transgender individual who is refused transport to the emergency room or an IV drug user who is turned away from a reproductive health clinic when seeking contraception and STD/HIV testing and treatment.

4. The Rule has grave consequences for the City in its capacity as guardian of Baltimore's public health. Baltimore's population includes many historically marginalized groups that have long been victims of health care discrimination and other injustices. In addition to inflicting harm upon its direct victims, this discrimination imposes enormous public costs. The Baltimore City Health Department (BCHD)—which was founded in 1793 and is the oldest continuously operating health department in the United States—has spent decades working to eradicate such discrimination and persuade vulnerable populations to seek necessary health care without fear, in furtherance of the public health. If the Rule were to take effect, it would sanction, and require the City to endorse, the very stigma the City has been combatting, leading to increased discrimination against vulnerable groups, reduced access to and quality of care, increased medical and insurance costs, and adverse patient outcomes. The harm that the Rule threatens to inflict—particularly on vulnerable populations—will irreparably damage Baltimore public health.

5. In addition, the City self-funds health insurance for its approximately 12,000 employees and 37,000 retirees (and their families) who live and travel in every state of the United States. As the City's insureds experience stigmatizing denials of care, they will be driven from cost-effective preventive health care, and into costlier critical and emergency care for advanced conditions.

6. Failure to comply with the Rule's vague, sweeping, unworkable, and unlawful strictures would have draconian consequences for the City. The Rule allows HHS to withdraw, deny, terminate, and even purportedly claw-back Medicare and Medicaid reimbursements and all other federal funds if HHS determines there has been a failure to comply with the Rule or related statutes. These penalties could be applied for even a single violation or a violation by a different entity, such as a subgrantee private clinic. For the City, this means the potential loss of millions in federal funding, including 80% of the Health Department budget and 75% of the emergency transport budget, and the defunding of critical programs such as HIV and STD prevention and treatment, reproductive health and family planning, tuberculosis screening, treatment, and control, addiction treatment, immunizations, and emergency room diversion and care.

7. The Rule places the City in an impossible bind: comply with the Rule and compromise the City's public health mission and ethical obligation to provide care to patients in need, or risk losing federal funding for failure to comply, thereby requiring drastic reduction in City services. Either option will come at great cost to the City—including the cost of administrative hurdles or loss of funding, the increased cost of greater numbers of acute emergencies and more residents relying on BCHD, increased insurance costs, and a compromised public health mission—and result in irreparable harm to residents of Baltimore and surrounding areas.

8. As described in more detail below, the Rule exceeds statutory authority, directly conflicts with existing federal statutes and the Constitution, is vague and unworkable, and was enacted without justification and without adequate consideration of countervailing interests and potential harm.

9. Thus, the City, in its capacity as a health care provider, health insurer, and guardian of Baltimore's public health, brings this action to vacate the Rule and enjoin its implementation on a national level because it is contrary to law, exceeds Defendants' statutory jurisdiction, authority, and limitations, is in violation of the United States Constitution, and is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law in violation of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A)-(C).

JURISDICTION AND VENUE

10. This Court has jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 2201(a), as this case arises under the APA, 5 U.S.C. §§ 701-706, and challenges final agency action for which there is no other adequate remedy in a court. 5 U.S.C. §§ 704, 706.

11. The Court has the authority to issue declaratory and injunctive relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and APA, 5 U.S.C. §§ 705, 706.

12. Venue is proper in the District of Maryland under 28 U.S.C. § 1391(b) and (e)(1) because the City resides in this District, a substantial part of the events or omissions giving rise to this action occurred in this District, and each defendant is an officer of the United States sued in his or her official capacity or an agency of the United States.

13. Defendants are subject to suit in any federal jurisdiction in challenges to federal regulations, and no real property is involved in this action. 42 U.S.C. §1391(e)(1)

14. The challenged Rule is final and subject to judicial review under 5 U.S.C. §§ 702, 704, and 706.

PARTIES

15. Plaintiff **Mayor and City Council of Baltimore** is a municipal corporation organized under Articles XI, XI-A, XI-B, XI-C, and XI-D of the Maryland Constitution and located within the District of Maryland.

16. The Baltimore City Health Department is a City agency, *see* Baltimore City Charter, Article VII, §§ 54-56. Formed in 1793, the Department is the oldest continuously operating health department in the United States. The Department has been working to improve the health and well-being of Baltimore residents for more than 220 years. For many of Baltimore's more than 600,000 residents, the Department is the health care provider of last resort.

17. Baltimore City's Fire and Emergency Medical Services Department provides emergency medical transports in Baltimore in response to 911 calls. In 2018, Fire/EMS received 153,232 calls for emergency transport.

18. The City manages health benefits for its employees and its retired City and Police Department of Baltimore City employees, who live and travel in every state. The City's health insurance program is predominantly self-funded, with covered members also paying modest premiums. As a result, any increased costs in health care for insureds imposes increased costs to the City.

19. Defendant **Alex M. Azar** is Secretary of U.S. Department of Health and Human Services (HHS) and is sued in his official capacity. Secretary Azar has responsibility for implementing and fulfilling HHS's duties under the Constitution and other federal law, including the Patient Protection and Affordable Care Act (ACA) and the APA.

20. Defendant **HHS** is an agency of the United States government and bears responsibility, in whole or in part, for the acts complained of in this Complaint. The Office for Civil Rights (OCR) is an entity within HHS. On January 18, 2018, the Acting Secretary of HHS

established a new Conscience and Religious Freedom Division within OCR with responsibility for enforcing religious-refusal laws. Subsequently, OCR increased the budget of the Conscience and Religious Freedom Division by $1.546 million. According to OCR, the increase allows for the expansion of this new division to perform policy, enforcement, and outreach activities.

FACTUAL BACKGROUND

A. City of Baltimore

1. Power to Safeguard the Public Health

21. The Baltimore City Charter vests the City with the general power "to provide for the preservation of the health of all persons within the City," Baltimore City Charter, art. II, § 11. The Charter also establishes BCHD and assigns to it the "general care of, and responsibility for, the study and prevention of disease, epidemics, and nuisances affecting public health." *Id.* art. IV, §56.

22. The City Charter also grants the City full "police power." *Id.* art. II, § 27. As the Supreme Court has recognized, the "police power" is the broad authority to protect and advance public health, safety, and well-being of a jurisdiction's residents. *See, e.g.*, *Gonzales v. Raich*, 545 U.S. 1, 42 (2005) (O'Connor, dissenting) ("The States' core police powers have always included authority . . . to protect the health, safety, and welfare of their citizens.") (citing *Brecht v. Abrahamson*, 507 U.S. 619, 635 (1993); *Whalen v. Roe*, 429 U.S. 589, 603 n.30 (1977)). Through this police power the City, and specifically the Baltimore City Health Department, is tasked with protecting the health and welfare of its residents. *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982) (observing that states have "quasi-sovereign interest[s] in the health and well-being—both physical and economic—of its residents in general."); *see also* Baltimore City Charter Article II, § 47 (empowering the City to "pass any ordinance. . . as it may deem proper in maintaining the . . . health and welfare of Baltimore City. . . ").

2. Baltimore City Health Department

23. BCHD was formed in 1793, when the governor appointed the City's first health officers in response to a yellow fever outbreak in the Fells Point neighborhood. Today, the agency includes a workforce of approximately 800 employees and has a budget of approximately $126 million.

24. BCHD is responsible for protecting public health in a wide range of areas, including acute communicable diseases, chronic disease prevention, HIV/STD prevention and treatment, addiction treatment, reproductive health and family planning, maternal and child health (including pregnancy prevention), school health, adolescent services, senior services, and youth violence prevention. BCHD's mission is to protect health, eliminate disparities, and ensure the well-being of every Baltimore resident through education, advocacy, and direct service delivery, which it does in collaboration with other city agencies, health care providers, community organizations, and funders.

25. The City faces significant public health challenges compared to the rest of the state and to the country as a whole. Baltimore has an age-adjusted mortality rate 40% higher than the rest of the state and ranks last on key health outcomes compared to other jurisdictions in Maryland. An estimated 12,500 residents are living with HIV, and Baltimore's HIV diagnosis rate is twice that of the state. An estimated 11% of residents aged 12 or older abuse or are dependent on illicit drugs or alcohol; in 2016, Baltimore had the highest age-adjusted overdose mortality rate among large metropolitan counties in the U.S. *See* Baltimore City Health Department, *State of Health in Baltimore*, May 2018, https://health.baltimorecity.gov/policies-and-initiatives/state-health-baltimore.

26. Many Baltimore residents face systemic social, political, economic, and environmental disparities that have an enormous impact on public health. The City's most

vulnerable residents are disproportionately likely to experience negative health outcomes. One in three Baltimore children live below the federal poverty line, and the average life expectancy for children born in Baltimore's poorest neighborhoods is up to 19 years lower than those in wealthy areas. Members of historically marginalized groups, especially African-Americans and Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) individuals, are also more likely to have poor health outcomes. For example, while African-Americans constitute 63% of the City's population, they account for more than 82 percent of those living with HIV. HIV also disproportionately affects sexual minorities. According to a 2017 federal health survey of 23 U.S. cities, Baltimore City had the highest prevalence of HIV among men who have sex with men. *See* Centers for Disease Control and Prevention, *HIV Infection Risk, Prevention, and Testing Behaviors Among Men Who Have Sex With Men—National HIV Behavioral Surveillance, 23 U.S. Cities, 2017*, HIV Surveillance Special Report 22 (Feb. 2019), https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.

27. Baltimore residents with the greatest health needs are often the most difficult to reach through public health intervention. Many Baltimore residents have experienced trauma resulting from discrimination, poverty, homelessness, exposure to physical violence, child abuse and neglect, or involvement in the criminal-justice system, among other adverse experiences. These experiences have made many residents mistrustful of and reluctant to engage with medical providers and public officials. Many people from marginalized communities who have sought out health care services have been met with judgment and blame by providers, making them less likely to continue to seek care in the future.

28. When some members of the community do not trust the government to provide them with safe, judgment-free services, the overall public health suffers. Many public health experts, including HHS, recognize that addressing serious public health issues requires dedicated

outreach to marginalized populations to ensure that they receive and stay connected to care. *See, e.g.*, HHS Trauma Informed Care Toolkit, https://www.acf.hhs.gov/trauma-toolkit#chapter-6.

29. BCHD uses trauma informed care in administering care, an approach endorsed by HHS. *See* HHS Trauma Informed Care Toolkit ("The practice of trauma informed service is less about 'what' you're doing, and more about 'how' you're doing it."); Baltimore City Health Department Press Release, *Baltimore City Awarded $5 Million SAMHSA Grant to Implement Community-based Trauma Informed Care in West Baltimore* (Sept. 15, 2016), https://health.baltimorecity.gov/news/press-releases.

30. For years, BCHD has dedicated significant efforts and resources to implement a trauma-informed approach, which means eliminating stigma associated with particular diseases, conditions, or groups of people, building trust with individuals in targeted communities, providing judgment-free care, and removing as many structural and administrative barriers to care as possible. This approach shapes every aspect of patient interaction across multiple services. Many BCHD programs bring treatment to patients where they are, such as mobile vans offering HIV-prevention services, or home visiting programs for pregnant women and new mothers. If services require travel to a clinic, BCHD designs clinic environments to be welcoming, with clear signage and easy patient navigation. BCHD clinics strive to minimize all sense of institutionalization and to never be penal. Instructions and paperwork use simple terms, with pictures where possible, and are available in multiple languages. Administrative and intake staff are required to treat patients kindly and with patience and ensure that patients understand that they are entitled to privacy and confidentiality with respect to the care they receive.

31. Through these actions, BCHD has painstakingly built trust in communities that historically have been marginalized and disenfranchised. For example, in the case of a preteen girl

at a Baltimore public school, it took almost a year of outreach and trust-building by BCHD employees at the school before the girl felt comfortable enough to go to a clinic for an STD test, where she ultimately tested positive for chlamydia and received treatment.

32. Any policy change that impedes trust-building public-health efforts in marginalized communities can set programs back years, if not decades. Disruptions in care for high-risk groups threaten the broader population with devastating harms, including increased prevalence of communicable diseases like tuberculosis, HIV, and sexually transmitted diseases, as well as teen pregnancies, infant deaths, and opioid overdoses.

BCHD Hiring Processes

33. The City's hiring processes for health care workers make it uniquely vulnerable to harm from the Rule's mandate to accommodate objectors above all else. Most City job openings are listed on a central City Human Resources Department website and describe the open positions in general terms. The BCHD clinic full time City employee positions are governed by the City's Civil Service law. Baltimore City Charter Art. VII § 99. This requires submitting an application, or taking a Civil Service exam, to qualify to be on the list for a specific classification of position. These are generic exams or applications, in which one demonstrates education, licensure, relevant experience and knowledge. If an applicant does not qualify to be on the applicable list, they are ineligible to be hired. BCHD may not hire candidates for a Civil Service position who are not appropriately listed.

34. Some BCHD clinics hire contract employees through Johns Hopkins University. Johns Hopkins posts announcements for BCHD job openings separately from other openings, specifically noting that successful applicants will be contracted with BCHD. Applicants learn of the specific job duties of the position and the services they would be asked to provide only during

the interview for the position. Thus, applicants who would object to providing certain services or treating some subpopulations might not know that the job required them to perform those services for those people until at least partway through the hiring process.

35. Unlike at many private non-profit clinics whose mission statements make explicit that they are devoted to serving historically underserved or stigmatized populations, or to providing health procedures that a provider might find objectionable, applicants to BCHD and the other City entities that participate in the administration of health care may not share in or even know of the City's public health mission, and may bring any number of religious, moral, or personal views about individual choices, minority groups, or health care procedures.

36. A rule requiring the City to hire persons to perform services they have no intention of performing would be unworkable given the size of clinic staff and the lack of staff redundancy. Even if the City had the funding to hire additional staff—it does not—creating redundancies would violate the City's mandate to use public funds efficiently.

37. the particular challenges of Baltimore's population, BCHD's hiring processes and available resources, and its longstanding public health mission make it especially vulnerable to harm if the Rule is permitted to take effect, including at the clinics and entities discussed below.

Specific BCHD Programs

38. The City directly operates several clinical services facilities, including: two physical locations and two mobile clinics offering STD, HIV, hepatitis C, pre-exposure prophylaxis (PrEP) (medication to prevent HIV infection), buprenorphine (medication to treat opioid dependency), dental services, and tuberculosis treatment services; three family-planning and reproductive-health clinics; one immunization clinic; nine Women, Infants and Children

clinics; and seven school-based health clinics. In addition, the City provides subgrants to other clinics that provide similar services throughout Baltimore.

39. BCHD community clinics and school-based health centers collectively handle over 20,000 visits per year. The City also subgrants funding to numerous private health clinics. The family planning and reproductive health clinics provide care to one-third of Baltimore women.

Bureau of Clinical Services & HIV/STD Prevention Services

40. The Bureau of Clinical Services & HIV/STD Prevention Services (Clinical Services) operates within the Division of Population Health & Disease Prevention in BCHD.

41. Clinical Services operates STD, HIV, hepatitis C, PrEP, buprenorphine, dental, and tuberculosis clinics in two physical locations open during standard business hours. It also offers additional mobile-clinic services using two vans. Currently BCHD lacks resources to offer weekend and evening hours for these clinics – something the City is seeking to provide.

42. The clinics are funded in significant part by federal financial assistance administered through HHS either directly or passed through the State of Maryland. This includes funds under the Public Health Services Act, the Ryan White HIV/AIDS Program, and grants from the Centers for Disease Control and Prevention. Clinical Services currently administers two subgrants of HHS funds: one Ryan White Part A subgrant, and one for TB elimination. Clinical Services does not presently have a staff member assigned to ensure compliance with the terms and conditions of these subgrants. Clinical Services currently administers over 30 subgrants of federal funds from HHS. These subgrants support outreach, HIV and STD surveillance and prevention, behavioral health, and other programs.

43. Together, the clinics provide outpatient services at low or no cost to residents of Baltimore and the surrounding areas. In 2017, there were 14,000 clinic visits. In 2018, there were over 16,000 visits.

44. The clinics employ around 10–12 nurse practitioners, one physician's assistant, four nurses, six clerical staff, two social workers, five case managers, two peer navigators, two medical directors, two deputy medical directors, two managers, two full-time doctors, two part-time doctors, and two additional case managers who drive the mobile-clinic vans.

45. The nurse practitioners, nurses, doctors, and the two case managers who drive the mobile-clinic vans are contracted employees through Johns Hopkins University. In addition, the vans used for the mobile clinics are owned by Johns Hopkins. To any patient these employees appear to be City employees.

Title X and the Bureau of Maternal and Child Health

46. The City has been a Title X participant since the program's inception in 1970. In 2017, Title X clinics in Baltimore, including the City's subgrantees and Planned Parenthood, served over 16,000 patients, providing over 22,000 clinical visits.

47. Title X centers in Maryland are some of the only family planning providers that accept Medicaid in a state where, as of 2017, 22% of residents are enrolled in Medicaid or the Children's Health Insurance Program, 6% are uninsured, and 8% have incomes below the federal poverty line.

48. These clinics provide support to a staggering one in three Baltimore women. This includes Baltimore's teens, immigrants and refugee communities, substance users, and incarcerated women, as well as the uninsured or underinsured.

49. The City currently receives $1,430,000 in funding per year through Title X of the Public Health Services Act. Administered through HHS's Office of Population Affairs, *see* Public Health Service Act, 42 U.S.C. §§ 300 to 300a-6.

50. Title X funds clinics operated by BCHD's Bureau of Maternal and Child Health (MCH). MCH applies a trauma-informed approach in the provision of adolescent and family

reproductive-health services; care for pregnant women; and care for mothers, infants, and children in Baltimore. The programs are designed to improve health before pregnancy including family planning and reproductive health; to ensure quality care during pregnancy; and to support families in raising healthy children. The programs seek to reduce the teen birth rate; reduce the rates of fetal, infant, and maternal mortality, and reduce the number of child and adolescent deaths.

51. Among the services offered at the MCH clinics are: clinical examinations; prescription, distribution, and administration of contraceptives, including intrauterine devices and subdermal implants; emergency contraceptives; pregnancy testing and referrals; options counseling for pregnant individuals, including referrals for abortion; breast exams; pap tests; STD screening and treatment; HIV testing, counseling, and referrals; substance-use and mental-health screenings and referrals; individual, group, and family counseling; and health education and outreach.

52. MCH funds and operates three clinics that offer family-planning and reproductive-health services: the Druid Family Planning Clinic in West Baltimore, the Eastern Family Planning Clinic in East Baltimore, and the Healthy Teens and Young Adults Clinic. The mission of these clinics is to reduce unintended pregnancies and to improve pregnancy outcomes by providing family-planning and reproductive-health services to women and men ages 25–50. The Druid Clinic also hosts the Healthy Teens and Young Adults Clinic, which offers these same services to young women and men ages 10–24.

53. The clinics operate weekdays during normal business hours, with some extended hours offered at the Druid and Eastern Clinics each week. In addition to appointments, both clinics offer blocks of walk-in hours each week. These three clinics employ approximately 25 people, including one physician, two nurse practitioners, one nurse, and 20 administrative and other staff.

Scheduling of Spanish-speaking staff is coordinated to offer patients the option to receive care in Spanish. Clinic staff members are all full-time employees of BCHD.

54. Out of the Druid and Eastern Health Centers, BCHD operates an Immunization Program to help prevent vaccine-preventable disease, to conduct disease surveillance, and to provide and monitor immunization-related health education and community outreach. The clinics operate during selected hours throughout the week. The Immunization Program is funded by the U.S. Centers for Disease Control and Prevention via the Maryland Department of Health.

55. More than 5,000 people receive care at these clinics each year. For many patients, clinic visits are the primary or sole source of reproductive or related health care.

56. MCH also operates 9 Women Infants and Children (WIC) clinics throughout Baltimore. WIC clinic services include food vouchers, nutrition education, health screening, breastfeeding assistance, and referrals to other health and social agencies. These services are provided free of charge to income-eligible Maryland residents who are pregnant, a new mother, or an infant or child under 5 years of age. The WIC clinics serve over 17,000 families per year.

57. The WIC clinics have 23 employees: one director (a registered nurse), one administrator, 13 nutrition technicians, 2 nutrition aides, 5 intake and other office support staff, and one lactation technician.

58. In addition to operating its own family-planning and reproductive-health clinics, BCHD provides subgrants to four other clinics throughout Baltimore that provide similar services. BCHD also operates clinics at seven schools in Baltimore. The clinics operate during school hours and have dedicated full-time staff. These clinics offer the same family-planning and reproductive-health services as the other three clinics, including the provision of contraceptives, STD screening, options counseling for pregnant patients, including referrals for prenatal care, adoption or abortion;

and other counseling services. The school clinics offer their services for free to students who are unable to pay. The school clinics receive Title X funding through M&C. These clinics are operated by BCHD's Bureau of School Health.

59. BCHD's Maternal and Infant Care Program (M&I) provides support services to pregnant women and women with young children in Baltimore through a program of home-visiting and group-based interventions. M&I operates the Nurse Family Partnership Program, an evidence-based intervention that employs nurses to provide home care to low-income, first-time-pregnant women. Baltimore's NFP program caters particularly to teens and pregnant women up to 24 years old. Patients often possess chronic medical conditions that may complicate their pregnancies, along with mental-health or substance-use disorders. The program serves approximately 100 women at any given time. The program is supported by federal funds from HHS's Maternal, Infant, and Early Childhood Home Visiting Program.

60. The care provided through home visiting is intensive and the services wide-ranging. The frequency of visits varies according to the patients' stage of pregnancy, the developmental milestones of their infants, or other needs, in accordance with the guidelines of both the NFP and Healthy Families America models. Visits may occur weekly, biweekly, or monthly. All programs are provided at no cost to those receiving the services.

61. The Teen Pregnancy Prevention Program seeks to reduce teen births by increasing access to family-planning clinical services, health education, and information. Each year, more than 10,000 students receive sexual-health education funded by the Teen Pregnancy Prevention Program. BCHD receives $1.74 million each year for five years from HHS for this Program.

62. The Baltimore Infants and Toddlers Program (I&T) provides support services to families of developmentally delayed infants and children up to two years old or infants and

children who have been diagnosed with a condition that is likely to affect development. These are mandated services under Part C of the Individuals with Disabilities Education Act. *See* 20 U.S.C. §§ 1432-1435.

63. Approximately 2,000 infants and toddlers receive early-intervention services annually from I&T. BCHD is the lead agency designated by the Mayor's Office to provide services to infants and toddlers with special needs. BCHD coordinates the care for these families and contracts with the Baltimore City Public School System and private entities to offer the required clinical and developmental services. Where not otherwise covered through Medicaid or other insurance, the Program is provided at no cost to the families receiving the services, made possible by HHS funding.

3. Fire and Emergency Medical Services

64. Baltimore City Fire and Emergency Medical Services (Fire/EMS) operates a fleet of medic units to respond to emergency (911) calls and to transport people to appropriate medical care. Baltimore City has one of the busiest EMS departments per capita in the U.S. Calls for emergency medical services are unusually high in Baltimore and have been increasing over the past several years. Between FY2015 and FY2016, Fire/EMS transports in Baltimore increased by nearly 5,918 patients, and the City saw an additional 2,972 patient transports between FY2016 and FY2017. In FY2017, Fire/EMS received an all-time high of 154,621 calls for emergency transport and transported 100,894 people to area hospitals. In FY2018, Fire/EMS received 153,232 calls for transport, only a slight decline from the prior year. For FY2018 transports, Fire/EMS received a total of $19,243,494 in billing, $14,790,374, of which approximately 76% came from Medicaid or Medicare billing.

65. Fire/EMS also partners with the University of Maryland to administer a two-year pilot program for Mobile Integrated Healthcare in West Baltimore. Mobile Integrated Healthcare

is a community-based health care solution for areas with a high volume of preventable or unnecessary ambulance trips and limited access to regular health care. The program provides rapid-response care to "low-acuity" patients (those who need treatment but not an emergency room setting) and assists in maintaining individuals' health at their homes. This model has improved healthcare access for underserved populations and reduced the strain on overburdened emergency systems. The program is funded by a $668,200 grant from the University of Maryland.

4. The City as self-insurer of current and former employees nationwide

66. The City is a "self-insured" entity, meaning that the costs of the health care benefits it provides to current and former employees and their families are paid directly by the City. Currently there are approximately 12,000 City and Baltimore Policy Department employees, and 37,000 retirees (and families) receiving health care benefits from the City.

B. A Robust Statutory Scheme Gives Fair Consideration to Conscience Rights and Rights to Non-Discriminatory Health Care and Informed Consent.

67. Congress has enacted a series of laws to reasonably accommodate conscience interests without interfering with the right to health care. States and cities, including the City of Baltimore, have followed suit, resulting in a detailed legal framework recognizing limited rights to conscience-based objections in health care—many of which are further limited to the contexts of either abortion and sterilization or assisted suicide, euthanasia, and mercy killing—while preserving patients' rights to informed consent and nondiscriminatory care.

1. Congress enacted self-enforcing laws protecting conscience interests alongside laws protecting patient rights.

68. By the Rule, HHS purports to "implement[] full and robust enforcement of approximately 25 provisions passed by Congress protecting longstanding conscience rights in

healthcare."[1] In contrast to the sweeping scope of the Rule, these statutes principally concern two categories of medical care: (i) abortion and sterilization, and (ii) assisted suicide, euthanasia, and mercy killing. *See* 84 Fed. Reg. at 23,264-67 (to be codified at 45 C.F.R. §§ 88.3(a), (b), (c), (e), (f), (i), (p)). Specifically:

a. The Church Amendments, codified at 42 U.S.C. § 300a-7, prohibit government entities that receive certain federal funds from discriminating against physicians or health care personnel because they performed or assisted in the performance of any **sterilization** procedure or **abortion** or refused to do so because of religious beliefs or moral convictions. 42 U.S.C. § 300a-7(c)(1). The Church Amendments also prohibit the use of federal funds to require any individual to perform or assist in the performance of any **sterilization** procedure or **abortion**, if contrary to that individual's religious beliefs or moral convictions. *Id*. § 300a-7(b)(1).

b. The Coats-Snowe Amendment, codified at 42 U.S.C. § 238n, prohibits state and local governments that receive federal funds from discriminating against "health care entities," based on the refusal to provide, undergo or make arrangements for training in **abortion** procedures. "Health care entities" are defined to include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." *Id.* §§ 238n(a), (c)(2).

c. The Weldon Amendment[2] provides that none of the funds appropriated in the Act may be made available to any state or local government if it discriminates against

[1] https://www.hhs.gov/about/news/2019/05/02/hhs-announces-final-conscience-rule-protecting-health-care-entities-and-individuals.html.

[2] The Weldon Amendment is an appropriations rider that has been included in each HHS appropriations statute enacted since 2004. *See, e.g.*, Department of Defense and Labor, Health and

any institutional or individual health care entity "on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for **abortions**." Pub. L. No. 115-245, § 507(d)(1), 132 Stat. at 3118. Health care entity is defined as, "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* § 507(d)(2), 132 Stat. at 3118.

d. Section 1303 of the ACA permits states to exclude **abortion** coverage from qualified health plans; provides that health plans are not required to cover **abortion** services as part of their essential health benefits; and prohibits health plans from discriminating against providers because of their unwillingness to provide or refer for **abortions**. 42 U.S.C. §§ 18023(a)(1), (b)(1)(A), (b)(4).

e. Section 1553 of the ACA proscribes state and local governments that receive federal funding under the ACA from discriminating against a health care entity on the basis that the entity "does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by **assisted suicide, euthanasia, or mercy killing**." 42 U.S.C. § 18113(a).

f. The Assisted Suicide Funding Restriction Act of 1997 provides that the advanced directives requirements applicable to state-administered Medicaid programs, codified at 42 U.S.C. § 1396a(w), do not require a provider, organization, or its

Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 507(d), 132 Stat. 2981, 3118 (Sept. 28, 2018).

employees "to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by **assisted suicide, euthanasia, or mercy killing** . . . ." 42 U.S.C. § 14406.

69. The narrow, context-specific laws described above are self-enforcing and do not require implementing regulations. *See* 76 Fed. Reg. 9968, 9975 (Feb. 23, 2011) (the Church, Weldon, and Coats-Snowe Amendments do not require "promulgation of regulations for their interpretation").

70. The Rule also purports to implement additional statutes relating to religious refusals to provide care outside the context of abortions, sterilizations, assisted suicide, and euthanasia. 84 Fed. Reg. at 23,266-69 (to be codified at 45 C.F.R. § 88.3(h), (j)-(o), (q)). However, each of these statutes deals with a discrete program or issue, such as vaccination, any many relate only to conditions imposed on "religious nonmedical health care providers." None provides statutory support for the sweeping mandates of the Rule:

a. The Medicaid Act states that Medicaid managed care organizations are not required "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds," so long as this policy is communicated to prospective enrollees. 42 U.S.C. § 1396u-2(b)(3)(B).

b. The ACA's individual mandate, 26 U.S.C. § 5000A, includes an exemption for individuals whose religious beliefs prohibit accepting the benefits of private or public insurance. 26 U.S.C. § 5000A(d)(2)(A)(i); see 26 U.S.C. § 1402(g)(1).

c. 42 U.S.C. § 1320a-1(h) is directed at "Christian Science Sanatoriums," and provides that "religious **nonmedical** health care providers" are exempt from certain regulations relating to capital expenditures.

d. 42 U.S.C. § 1320c-11 similarly exempts "religious **nonmedical** health care providers" from certain contracting standards.

e. 42 U.S.C. § 1395i-5 addresses conditions for coverage of religious **nonmedical** health care institutional services under the Social Security Act.

f. 42 U.S.C. §§ 1395x(e) and 1395x(y)(1) provide that, for purposes of the Social Security Act, the terms "hospital" and "nursing care facility" also include religious nonmedical health care institutions, "but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1395i–5 of this title."

g. 42 U.S.C. 1396a(a) addresses State plans for medical assistance, and again limits the application of certain limited requirements to religious nonmedical health care institutions.

h. 42 U.S.C. § 1397j–1 provides that "nothing shall be construed to interfere with or abridge an elder's right to practice his or her religion through reliance on prayer alone for healing" under certain circumstances.

71. Entirely absent from the Rule is any acknowledgement of or deference to Congress' framework recognizing as paramount patients' right to prompt access to nondiscriminatory

medical care and ensuring those rights are no comprised by accommodation of the aforementioned refusal rights.

72. Section 1554 of the ACA provides that "[n]otwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that:

> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
>
> (2) impedes timely access to health care services;
>
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
>
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
>
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
>
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs."

42 U.S.C. § 18114.

73. Section 1557 of the ACA, 42 U.S.C. § 18116, prohibits discrimination in health care by providing: "[A]n individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance."

74. The Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd, governs how hospitals examine and offer treatment (including medically necessary abortion services) to a patient in an unstable medical condition. A hospital that "determines that [an] individual has an emergency medical condition" must "provide either (A) within the staff and

facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or (B) for transfer of the individual to another medical facility in accordance with subsection (c) of this section." *Id .* § 1395dd(b)(1). EMTALA defines the term "emergency medical condition" to include "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy . . . ." *Id.* § 1395dd(e)(1)(A).

75. In recognition of the sanctity of an individual's right to necessary health care, no matter who the individual is or the choices the individual makes, the ACA provides that right-of-conscience exemptions in the abortion context must not "be construed to relieve any health care provider from providing emergency services as required by State or Federal law," including EMTALA. 42 U.S.C. § 18023

76. Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e, *et seq.*, reflects the careful consideration of health care employees' religious objections to participating in certain procedures without interfering with the practical requirements of delivering health care to patients. Although Title VII prohibits discrimination against employees based on their religious beliefs, employers' ability to ensure ethical and appropriate care for their patients is recognized as a "business necessity" under Title VII. 42 U.S.C. 2000e-2(k)(1)(A)(i). It allows for the provision of accommodations *unless* such accommodation would cause "undue hardship." 42 U.S.C. § 2000e(j).

77. Alongside the statement that "amounts provided to [Title X] projects . . . shall not be expended for abortions," Congress has included language that emphasizes that "all pregnancy

counseling shall be nondirective." *See, e.g.*, Continuing Appropriations Act, 2019, Pub. L. 115–245, 132 Stat. 2981, 3070–71 (2018); *see also* 65 Fed. Reg. 41,272-73. Under the 2000 regulations, Title X grantees are required to "provide neutral, factual information and nondirective counseling on each of the options, and referral" upon request, including information about "pregnancy termination." 42 C.F.R. § 59.5(a)(5) (July 3, 2000); 65 Fed. Reg. at 41,279.

2. Maryland and Baltimore City Law Reflects and Promotes Congress' Consideration of Refusal Rights When Ensuring the Right to Health Care and Protecting the Public Health.

78. Maryland and the City of Baltimore have enacted laws that reflect the need to accommodate conscience objections of health care providers without harming patients and the public health. These laws provide careful consideration of conscience while maintaining patients' right against discrimination, right to emergency care, right to informed consent, and right to have lawful prescriptions filled.

79. Maryland law prohibits employers from discriminating against any individual with respect to that individual's religion, except when providing a notice or advertisement indicating a bona fide occupational qualification for employment. *See* Md. Code Ann., State Gov't § 20-606.

80. Maryland law provides that a person may not be required "to perform or participate in, or refer to any source for, any medical procedure that results in artificial insemination, sterilization, or termination of pregnancy," except insofar as "the failure to refer a patient to a source for any medical procedure that results in sterilization or termination of pregnancy" would be the cause of death or serious physical injury or serious long-lasting injury to the patient or otherwise contrary to the standards of medical care. Md. Code. Ann., Health Gen. § 20-214.

81. Maryland law prohibits a physician and other health care providers from abandoning a patient. *See, e.g.*, Md. Code Ann., Health Occ. § 14-404(a)(6).

82. Maryland law requires that patients give informed consent before any nonemergency care is provided, which calls for patients to be informed of "the benefits and risks of the care, alternatives to the care, and the benefits and risks of alternatives to the care." 2019 Md. Laws ch. 285 (to be codified at Md. Code Ann., Health-Gen. § 19-342); *see also Sard v. Hardy*, 281 Md. 432 (1977). Informed consent is separately statutorily required for HIV testing, Md. Code Ann. Health-Gen. § 18-336, and for treatment using an investigational drug, biological product, or device, *id.* § 21-2B-01.

83. Under Maryland law, a pharmacist may refuse to fulfill a prescription based only on "professional judgment, experience, knowledge, or available reference materials." Md. Code. Ann., Health Occ. § 12-501. The Rule will interfere with this law insofar as it allows individual pharmacists or pharmacies to refuse to provide or dispense lawful prescriptions. *See* 84 Fed. Reg. at 23,196, 23,264 (to be codified at 45 C.F.R. § 88.2).

84. The City of Baltimore's Community Relations law prohibits discrimination in many contexts, including health care, where discrimination is defined as "any difference in the treatment of an individual or person because of race, color, religion, national origin, ancestry, sex, marital status, physical or mental disability, sexual orientation, gender identity or expression." Baltimore City Code Article 4, § 1-1(f)(1).

85. With respect to health care specifically, the law provides: It is an unlawful practice for any health and welfare or any owner, supervisor, staff person, director, manager, or officer of a health and welfare agency to:

> (1) discriminate against any person by refusing, denying, or withholding from him any of the services, programs, benefits, facilities, or privileges of any health and welfare program or service;

(2) discriminate against any person in the setting of rates or charges for any of the services, programs, benefits, facilities, or privileges of any such agency; or

(3) communicate, publish, advertise, or represent:

(i) that any of the services, programs, benefits, facilities, or privileges of any health and welfare agency are withheld from or denied to any person on a discriminatory basis; or

(ii) that the patronage of any person is unwelcome, objectionable, or unacceptable because of race, color, religion, national origin, ancestry, sex, marital status, physical or mental disability, sexual orientation, or gender identity or expression.

Id. § 3-4.

C. <u>HHS Improperly Promulgated the Unlawful Rule.</u>

86. Although the Rule purports to implement congressional mandates, in fact, it was promulgated in furtherance of executive, not congressional intent. On May 4, 2017, President Trump signed an Executive Order entitled "Promoting Free Speech and Religious Liberty." Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 8, 2017). The Executive Order directed the Attorney General to issue "Religious Liberty Guidance . . . interpreting religious liberty protections in Federal law." *Id.*

87. Pursuant to Executive Order 13,798, on January 26, 2018, the Acting Secretary published a Notice of Proposed Rulemaking "to enhance the awareness and enforcement of Federal health care conscience and associated anti-discrimination laws, to further conscience and religious freedom, and to protect the rights of individuals and entities to abstain from certain activities related to health care services without discrimination or retaliation." *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3880, 3881 (proposed

Jan. 26, 2018) (the "Proposed Rule"). The Proposed Rule anticipated refusal to provide health care services or research activities on *any ground*—"religious, moral, ethical, or other." *Id.* at 3923.

1. HHS lacked justification for the new Rule.

88. Prior to 2018, the existing rule implementing OCR's authority to resolve complaints of violation of conscience rights was enacted in 2011. The 2011 rule replaced a 2008 rule that was rescinded in 2009 on the ground that the 2008 Rule "raised a number of questions that warrant[ed] further careful consideration." 74 Fed. Reg. 10207 (Mar. 10, 2009). The 2011 rule provided for the enforcement of the Church, Weldon, and Coats-Snowe Amendments, and changed the 2008 rule by removing provisions containing definitions of terms, requirements, prohibitions, and a certification requirement. *See* 76 Fed. Reg. 9968 (Feb. 23, 2011). The 2011 rule designated OCR to "receive complaints based on the Federal health care provider conscience protection statutes," and to "coordinate the handling of complaints with [HHS] funding components from which the entity, to which a complaint has been filed, receives funding." *Id.* at 9975, 9977. Importantly, the 2011 rule clarified that "[f]ederal provider **conscience statutes…were never intended to allow providers to refuse to provide medical care to an individual because the individual engaged in behavior the health care provider found objectionable**." *Id.* at 9973-74 (emphasis added).

89. OCR's purported justification for the 2018 Proposed Rule's unprecedented expansion of Congress' statutory framework for protection of conscience rights is that, "[s]ince the designation of OCR as the agency with authority to enforce Federal health care conscience laws in 2008, OCR has received a total of forty-four complaints" of violation of conscience rights. 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018) (Notice of Proposed Rulemaking). Thirty-four of those complaints were received since the 2016 election. *Id.* From 2008 to 2016—including in the 5 years after the 2011 Rule went into effect—OCR received only **1.25 complaints per year**. *Id.* The

Notice of Proposed Rulemaking describes the procedures undertaken for resolving these complaints and no mention is made of how the existing procedures for receiving and resolving complaints were deficient.

90. The Notice of Proposed Rulemaking makes no mention of the fact that more than 30,000 complaints alleging violation of *patient* rights were received by HHS from fall of 2016 to fall of 2017. In other words, HHS presented no evidence in its record supporting the Proposed Rule that demonstrates the need to enhance OCR's existing, adequate enforcement authority over religious refusal laws, or to justify elevating provider religious refusals over the rights of patients.

2. The 2018 proposed rulemaking was deficient.

91. The Rule states that HHS received over 72,000 comments on the Proposed Rule—over 242,000 comments when additional comments attached to public submissions were considered. 84 Fed. Reg. at 23,180 & n. 41. Comments opposed to the Proposed Rule came from a broad array of individuals, major medical associations, hospitals, state and local governments, reproductive rights organizations, children's rights organizations, disease advocates, and civil-liberties organizations.

92. Nineteen states, including Maryland and the District of Columbia opposed the Proposed Rule and identified the potential harms to public health that it would cause as well as its conflicts with federal, state, and local law.

93. The nation's most prominent professional health care organizations also challenged the reasonableness and legality of the Proposed Rule. For example, the American Medical Association (AMA) commented that the Proposed Rule "would undermine patients' access to medical care and information, impose barriers to physicians' and health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical

obligations to treat patients." The AMA noted that "several provisions and definitions in the Proposed Rule go beyond this stated purpose and are ambiguous, overly broad, and could lead to differing interpretations, causing unnecessary confusion among health care institutions and professionals, thereby potentially impeding patients' access to needed health care services and information." The AMA further commented that "[t]he Proposed Rule attempts to expand existing refusal of care/right of conscience laws—which already are used to deny patients the care they need—in numerous ways that are directly contrary to the stated purpose of the existing laws."

94. The Association of American Medical Colleges (AAMC) asked that the proposed rule be withdrawn because there is no demonstrable need for the Proposed Rule due to existing laws and protections. AAMC asserted that the paucity of complaints does not justify an expansion of enforcement authority, that the proposed rule is overly expansive in its reach and incongruous with medical professionalism, and that it will do harm to lower-income Americans, racial and ethnic minorities, the LGBTQ community, and patients in rural areas.

95. The American Academy of Pediatrics, which represents 66,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists, urged HHS to ensure that children have appropriate access to needed health care in the areas of vaccines, mental health services, newborn hearing screening, reproductive health, medical neglect, treatment for sexual assault, including screening for sexually transmitted diseases and pregnancy prevention, and supportive care for LGBTQ youth.

96. The American College of Emergency Physicians, on behalf of its 37,000 members, expressed concerns that the Proposed Rule failed to reflect the moral and legal duty of emergency physicians to treat everyone "who comes through our doors," stating that [b]oth by law and by oath, emergency physicians care for all patients seeking emergency medical treatment," and concluding that "[d]enial of emergency care or delay in providing emergency services on the basis

of race, religion, sexual orientation, gender identity, ethnic background, social status, type of illness, or ability to pay, is unethical."

97. The American Hospital Association objected that the Proposed Rule would impose regulatory burdens on hospitals that should instead be focused on providing patient care. It also explained that the overbroad and expanded definitions risk creating unintended consequences for patient care and run counter to hospital policies not to discriminate in the delivery of emergency, urgent, and necessary care on the basis of a patient's race, color, national origin, citizenship, alienage, religion, creed, sex, sexual orientation, gender identity, age, or disability.

98. The American Nurses Association and the American Academy of Nursing stated that while they "strongly support the right and prerogative of nurses—and all healthcare workers—to heed their moral and ethical values," they had concerns that the Proposed Rule would "lead to inordinate discrimination against certain patient populations—namely individuals seeking reproductive health care services and [LGBTQ] individuals." This proliferation of discrimination could "result in reduced access to crucial and medically necessary health care services and the further exacerbation of health disparities between these groups and the overall population."

99. Physicians for Reproductive Health warned that the Proposed Rule unlawfully exceeds HHS's authority by impermissibly expanding federal conscience laws, creates barriers to healthcare and exacerbates already existing inequities, and will cause severe consequences for providers while undermining the provider-patient relationship.

100. The American Physical Therapy Association urged that the Proposed Rule not be finalized because discrimination under the guise of religion or morality runs counter to their Code of Ethics and the principle of patient-centered care, both of which are foundational to the physical therapy profession. In their view, the Proposed Rule also would severely compromise patient access to medically necessary health care services.

101. The Association of Women's Health, Obstetric and Neonatal Nurses opposed the Proposed Rule as unnecessary to protect the rights of providers and noted that the existing rule issued in 2011 adequately protects the conscience of providers while also protecting patients; the Proposed Rule also undermines the Title X program.

102. The National Association of Councils on Developmental Disabilities opposed the Proposed Rule, pointing out that it would "introduce broad and poorly defined language," is "vague and confusing," and "creates the potential for exposing patients to medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, and undermines the ability of health facilities to provide care in an orderly and efficient manner." The comment continues: "Most important, the regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and [LGBTQ] individuals. These communities already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, possibly ending in in poorer health outcomes. By issuing the proposed rule along with the newly created 'Conscience and Religious Freedom Division,' the Department seeks to use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need."

103. HHS failed to include or account for the substantial monetary and nonmonetary costs of the health consequences and patient burdens resulting from increased likelihood of stigmatizing denials of medical services and care to vulnerable populations, as set forth in the comments above.

D. <u>The Rule Exceeds Statutory Authority, Conflicts with Law, and Is Arbitrary and Capricious.</u>

104. President Trump announced the Rule at a White House event on May 2, 2019. The President proclaimed that the Rule provided "**new protections** of conscience rights for physicians, pharmacists, nurses, teachers, students, and faith-based charities." The Rule was published in the Federal Register on May 21, 2019. 84 Fed. Reg. 23,170 (May 21, 2019).

105. The final Rule is substantially identical to the Proposed Rule. Despite receiving comments from critical stakeholders that the Proposed Rule was vague, excessively broad, unworkable, and conflicted with both medical ethics and federal, state, and local laws, HHS summarily concluded that such claims were unfounded and that HHS could be trusted to reconcile conflicts on a "case-by-case" basis, without providing any guidance or workable application of apparent conflicts between the Rule and statutes protecting patient rights. The following is just one example of HHS's failure to meaningfully respond to the substance of the comments submitted:

> *Comment:* The Department received many comments expressing confusion or concern as to how the proposed rule would interact with or be in conflict with other Federal laws, such as the Emergency Medical Treatment and Active Labor Act (EMTALA) and Federal anti-discrimination statutes (such as section 1557 of the ACA).
>
> *Response*: . . . With respect to EMTALA, the Department generally agrees with its explanation in the preamble to the 2008 Rule that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and anti-discrimination laws. The Department intends to give all laws their fullest possible effect.

84 Fed. Reg. at 23,183. *See also id.* at 23,188 ("declin[ing] to take . . . a categorial approach" regarding when an ambulance crew would be covered by the Rule and offering no reconciliation with EMTALA).

106. Like the Proposed Rule, the Rule purports to "protect the rights of individuals, entities, and health care entities to refuse to perform, assist in the performance of, or undergo certain health care services or research activities to which they may object for religious, moral,

ethical, **or other reasons**." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.1) (emphasis added).

107. As described below, HHS has attempted to accomplish this purpose by (1) expanding beyond recognition the statutes it purports to enforce; (2) assigning to itself an extraordinarily broad and coercive enforcement power that would allow it to terminate billions of dollars in federal health care funds if HHS finds a failure to comply; and (3) ignoring or expressly claiming to abrogate contrary federal law, including patient protections in Title X, the Affordable Care Act, the Emergency Medical Treatment and Labor Act, and Title VII of the Civil Rights Act of 1964.

1. The Rule expands beyond recognition the statutes it purports to enforce.

108. While claiming to implement approximately 25 existing statutes, the Rule in fact expands these statutes beyond recognition, and directly conflicts with legislation protecting the rights of patients in contravention of the careful consideration Congress gave to conscience objections while protecting patient rights and avoiding harm to the public health.

109. One of the ways in which the Rule exceeds statutory authority is in its expansive definitions of terms—definitions that go well beyond the definitions in the statutes.

110. For example, the Rule defines "assist in the performance" to mean "to take an action that has a specific, reasonable, and articulable connection to furthering a procedure," which "may include counseling, referral, . . . or otherwise making arrangements for the procedure . . . depending on whether aid is provided by such actions." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

111. In addition to the broad sweep of the phrase "articulable connection," the term "making arrangements" suggests that administrative tasks such as scheduling an appointment,

transporting an individual in need of emergency care to a facility, or preparing a room, could qualify. The Rule confirms the definition's broad sweep, stating that "assist in the performance" covers "EMTs and paramedics" and could apply to "ambulance crews"—though it "declines to take . . . a categorical approach," regarding these employees, thus affirming the vagueness of the Rule. 84 Fed. Reg. at 23,188. Recipients of federal funds will be required to guess at which employees must be permitted to opt out of tasks relating to provision of, for example, service to a woman with an ectopic pregnancy in need of an emergency abortion.

112. Likewise, the Rule's expansive definition of "discriminate or discrimination" provides that employers will need a "persuasive justification" to ask an employee if they are willing to perform an essential job function to which they might morally object; cannot create an accommodation that excludes a staff member from their "field[] of practice," even if the objected-to act is an essential job function within that field of practice; and allows an objecting employee to reject any proposed accommodation, no matter how reasonable or proportionate. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). In other words, the definition appears to require the City to hire employees to work in its clinics offering reproductive health care including abortion referrals, HIV/STD treatment, and general care to stigmatized communities without knowing, or asking, whether the employee will be willing to provide the care that is typical of and critical to the health care entity's mission. Upon learning that an employee of the Bureau of Clinical Services & HIV/STD Prevention Services is, for example, unwilling to treat transgender individuals, the City would not be able to transfer that employee to a different clinic.

113. Under the Rule, these refusal scenarios will not be limited to direct medical care. The Rule defines "health care entity" to extend far beyond "health care personnel" to include pharmacists, pharmacies, medical laboratories, and research facilities; and, for purposes of the

Weldon Amendment, health insurance issuers, health insurance plans, and plan sponsors or third-party administrators. 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

114. This definition is broader than the clear definitions of "health care entity" contained in the Coats-Snowe Amendment, which is limited to physicians or health care professionals, *see* 42 U.S.C. § 238n(c)(2) ("an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions"); and the Weldon Amendment, *see* Pub. L. No. 115-245, § 507(d)(2), 132 Stat. at 3118, which does not mention pharmacies, pharmacists, third-party administrators, or research facilities.

115. The Rule's definition of "health care entity" appears to expand the applicable statutes beyond recognition to permit objections by human-resources analysts, customer-service representatives, data-entry clerks, and numerous others who believe that analyzing benefits, answering a benefits-related question, or entering a particular pre-authorization for an objected-to procedure, for example, is inconsistent with their personal beliefs.

116. The Rule defines "referral or refer for" broadly to mean "the provision of information in oral, written, or electronic form . . . where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure." 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2). Even the posting of notices is considered a "referral." 84 Fed. Reg. at 23264. The provision of referrals for abortions and sterilizations is a key service provided in the City's reproductive health care clinics, yet this definition appears to permit employees to refuse even to provide information on all options, when requested.

117. In contrast to the Weldon, Church, and Coats-Snowe Amendments, which refer to specific circumstances in which health care providers or certain enumerated health care entities may not be required to participate in abortions, sterilizations, or certain health service programs and research activities, the Rule's vague and overbroad definitions appear to authorize refusals of any health care service by almost any individual with a tangential role, including those not at all involved in the provision of health care. *See, e.g.*, 84 Fed. Reg. at 23186 (stating that Rule applies to preparing a procedure room or scheduling an appointment). The Rule also appears to authorize health care personnel to refuse care based not only upon the nature of the procedure required, but also based on the sexual orientation, gender identity, marital status, and other characteristics of an individual patient.

2. The Rule conflicts with federal, state, and Constitutional law.

118. The Rule not only expands beyond recognition the conscience statutes it purports to enforce—it conflicts directly with other federal law governing provision of health care.

119. Section 1554 of the Affordable Care Act prohibits HHS from promulgating any regulation that "(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114.

120. The Rule is contrary to each of the limitations on HHS's rulemaking authority that Congress imposed through Section 1554 of the ACA. Indeed, the Rule expressly states that "finalizing the rule is appropriate without regard to whether data exists on the competing

contentions about its effect on access to services" and "represents Congress's considered judgment that these rights are worth protecting **even if they impact overall or individual access** to a particular service, such as abortion." 84 Fed. Reg. at 23182 (emphasis added).

121. HHS's assertion in the Rule that Section 1554 applies only to regulations that themselves implement the ACA, 84 Fed. Reg. at 23,224, is contrary to both the text and judicial application of that statute, as courts in this district and beyond have already recognized. 42 U.S.C. § 18114; *see Baltimore v. Azar*, No. 19-cv-1103-RDB, 2019 WL 2298808, at *9 (D. Md. May 30, 2019) ("Baltimore City has shown that the Final Rule [implementing Title X] likely violates the ACA § 1554 by creating unreasonable barriers for patients to obtain appropriate medical care…."); *accord Oregon v. Azar*, No. 19-cv-317, 2019 WL 1897475, at *12 (D. Or. Apr. 29, 2019); *California v. Azar*, No. 19-cv-1184, 2019 WL 1877392, at *21-22 (N.D. Cal. Apr. 26, 2019).

122. The Medicaid and Medicare statutes that the Rule purports to interpret, *see* 84 Fed. Reg. at 23,263, 23,266-67 (to be codified at 45 C.F.R. § 88.3(h)), provide that statutes shall not "be construed to affect disclosure requirements under State law." 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); *see also* 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice). But the Rule, by its definition of referral would interfere with the enforcement of State and local disclosure requirements designed to protect informed consent. *See supra* ¶80 (discussing Maryland disclosure law).

123. The Rule gives a cursory nod to EMTALA, noting only that "where EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible." 84 Fed. Reg. at 23,188. The Rule, however, contains no directive as to how or even whether emergency care is to be provided when that mandate conflicts with the categorical refusal-of-care rights that the Rule confers on employees.

Id. at 23,263. Moreover, it purports to extend rights to ambulance drivers among other emergency providers, *id.*, without any express exception for life-threatening conditions or other emergencies. By its terms, the Rule directly conflicts with EMTALA.

124. Title VII of the Civil Rights Act of 1964 requires employers to accommodate employees' religious beliefs, 42 U.S.C. § 2000e-2(a), but not to the extent that such an accommodation would cause "undue hardship." 42 U.S.C. § 2000e(j). The Rule, in direct conflict, expressly eschews Title VII's balancing act, stating that it does not incorporate any assessment of undue hardship or other burden on employers. 84 Fed. Reg. at 23,190-91.

125. Like Congress, Maryland and the City of Baltimore have enacted laws designed to accommodate employees' religious or moral beliefs without harming employers' obligations to patients, their business, and other employees. The Rule ignores and conflicts directly with these laws permitting accommodations for religious refusals in hiring, creating emergency exceptions to religious refusals to provide care; mandating informed consent and prohibiting discrimination in the provision of health care (*see supra* Section B.2).

126. In accommodating an employee's religious objections over patient health, the Rule places an undue burden on third parties— patients seeking health care and health care providers seeking to fulfill their ethical mandates to provide such care—in violation of the Establishment Clause of the United States Constitution. *Burwell v. Hobby Lobby Stores, Inc.*, 134 S.Ct. 2751, 2781 n.37 (2014) (requiring consideration of the burden placed on third parties by a religious accommodation).

127. The Rule violates the Spending Clause of the Constitution because it coerces state and local governments to adhere to the Final Rule or lose millions of dollars in federal funds. *See*

Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 581 (2012) (Congress cannot use threat to withdraw funding as a "gun to the head")).

128. The Rule also violates the Spending Clause because it (1) does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds (*see Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)); (2) constitutes unlawful post-acceptance conditions on federal funds (*see id.*); and (3) is not rationally related to the federal interest in the program that receives the federal funds (*see South Dakota v. Dole*, 483 U.S. 203, 207 (1987)).

129. The Rule interferes with these federal, state, and constitutional laws by requiring the absolute accommodation of all employees with religious objections, without considering the needs of employers or patients. By protecting an objector's rights without enforceable countervailing protection for the rights of patients and employers, the Rule will substantially harm the City's interest in enforcing its employment accommodation laws and in improving patient health outcomes. As set forth below, the resulting harms to the City will be grave.

3. The Rule imposes vague and arbitrary administrative hurdles and draconian sanctions for failure to comply.

130. In addition to conflicting with law, the Rule's definitions place the City in impossible binds, in its capacities as an employer and direct provider of health care, as a regulator and funder of others who provide health care, and as an insurer. As HHS appears to interpret (or decline to clarify) the Rule, an EMT driver, a doctor, nurse or intake employee at a clinic may assert the right not to be asked prior to hiring whether they will execute the core functions of their jobs without objection.

131. The Rule places unprecedented limitations on the ability of the City's agencies to inquire about whether members of their staff object to "performing, referring for, participating in, or assisting in the performance of" particular services or activities.

a. The Rule prohibits inquiry into prospective staff members' religious or moral objections prior to their hiring, whether or not such objections would materially impact the prospective employee's ability to fulfill their job obligations. *See* 84 Fed. Reg. at 23,263 (to be codified at 85 C.F.R. § 88.2).

b. Post-hiring, the City's health institutions may inquire about staff members' objections no more frequently than "once per calendar year," absent a "persuasive justification" which is not specified or defined in the Rule. *Id.*

c. The Rule places no duty—and appears to prohibit the City from imposing a duty—on staff members to disclose known religious or moral objections to participating in a service or activity. *See id.*

d. If a clinic learns of a religious, moral, or other objection by a staff member—even one that forecloses performance of a substantial part of the member's duties—any accommodation offered to that individual must be "voluntarily accept[ed]" by the staff member and must be "effective—a term undefined in the Rule—in order for the City to avoid "engag[ing] in discriminatory action." *Id.*

e. Finally, any effort a clinic makes to continue providing any objected-to service, program, or treatment using alternate staff cannot "require any additional action" by the objecting individual, or "exclude protected [persons] from fields of practice." *Id*.

132. This regulatory framework is particularly problematic for the City, whose health care facilities and clinics may not signal to applicants their mission of non-discriminatory provision of care to all individuals no matter who they are or what treatment they seek.

133. While some of the Rule's definitions are unclear in scope, the City will have little choice but to accept expansive interpretations. Failure to interpret and apply these sweeping definitions correctly carries severe and irreversible consequences for the City, its subgrantees, and, by extension, its population.

134. The Rule authorizes HHS to withhold, deny, suspend, or terminate "Federal financial assistance or other Federal funds" if it determines there is a "failure to comply." 84 Fed. Reg. at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)(3)). Funds can be terminated even during the pendency of good-faith compliance efforts. 84 Fed. Reg. at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)(3).

135. The Rule contains no description of the funds a recipient stands to lose if HHS determines that the recipient has not complied with the Rule. *See id.* at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)). This sweeping enforcement scheme encompassing all federal funding disregards that Congress in the relevant statutes conditioned funding from *specific* sources to *specific* requirements and prohibitions. *Compare, e.g.,* 42 U.S.C. § 300a-7(c)(1) (Church Amendment restrictions that apply to specific statutory funding sources), *with id*. § 300a-7(c)(2) (Church Amendment restrictions that apply only to "grant[s] or contract[s] for biomedical or behavioral research).

136. Yet a violation of the Rule "threaten[s]" funding streams implicated by **any** of the statutes it purports to implement. 84 Fed. Reg. at 23223. Thus, the Rule places at risk not only the City's receipt of all federal funds from HHS, but also federal funds from the Department of Labor

and Department of Education, implicated by the Weldon Amendment, including, potentially, funds entirely unrelated to healthcare. *See* Departments of Labor, HHS, Education, and Related Agencies Appropriations Act, Pub. L. No. 115-245, §§ 3, 507(d), 132 Stat. at 2981, 3118, 3122; 84 Fed. Reg. at 23,172, 23,265-66, 23,272 (to be codified at 45 C.F.R. §§ 88.3(c), 88.7(i)(3)(i), (iii)). HHS cited no statutory support for its purported authority to create a regulatory enforcement mechanism to terminate funds originating from the Department of Labor and the Department of Education.

137. In addition to placing millions of dollars of federal funding at risk, the **process** to effect compliance if there is a determination of "failure to comply" is described by cursory reference to three disparate administrative procedures, each identified by way of **non-exclusive** example. *See* 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 88.7(i)(3)) ("[C]ompliance . . . may be effected . . . pursuant to statutes and regulations which govern the administration of contracts (*e.g.,* Federal Acquisition Regulation), grants (*e.g*., 45 CFR Part 75) and CMS funding arrangements (*e.g*., the Social Security Act)."). This vague description provides insufficient notice to the City and its subgrantees of their rights and responsibilities in an administrative process that could cost the City millions of dollars in health care and other resources.

138. The Rule authorizes initiation of investigation based not only on a "complaint" or "compliance review" but also on "any … information" found by OCR, not only of an "actual failure to comply" but also of any "indicat[ion]" of a "threatened" or "potential" failure to comply not only with any federal conscience statute, but also with the Rule itself. 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 88.7(d)).

139. HHS also claims the right in any investigation to require the City to waive any rights to doctor or patient privacy or confidentiality. *Id.* at 23,270-71 (to be codified at 45 C.F.R. § 88.6(c)).

140. Defendants justify the Rule in part on "presidential priority of protecting conscience and religious freedom." 84 Fed. Reg. at 23227, *citing* Executive Order 13798, 82 FR 21675 (May 4, 2017). But the validity of the Rule depends on its relationship to legislative, not executive, action: if the underlying federal statutes do not support the Rule, executive action cannot justify the departure from the statutes. *See Baltimore v. Azar*, 2019 WL 2298808 at *1 ("[T]he executive branch of government is not entitled to circumvent by administrative order existing laws passed by the United States Congress.").

4. The Rule fails to consider countervailing considerations of access to health care.

141. As further evidence of the Rule's inadequate deference to federal, state, and constitutional law protecting patients' right to care and the City's right to administer that care, the Rule's Regulatory Impact Analysis purporting to quantify the costs and benefits of the Rule contains a cursory and insufficient treatment of the impact of the Rule on access to care. *See* 84 Fed. Reg. at 23,226.

142. The cost-benefit analysis in the Rule expressly declines to quantify the impact of the Rule on access to care, the effect the Rule will have on refusals to refer for services, or the effect on the patients who delay or forgo health care as a result of the Rule and, more broadly, on the public health. *Id.* at 23,250-54. In place of a reasoned assessment, HHS concluded without evidence that the Rule would likely enhance access to care, and that the Rule should be implemented "without regard to whether data exists on the competing contentions about its effect on access to services." *Id.* at 23,182. Courts have recognized that such cursory and speculative analyses with no basis in the record are insufficient to comply with the APA's requirement of reasoned rulemaking. *See California v. Azar,* 2019 WL 1877392, at *1 (rule is arbitrary and capricious where "the record evidence indicates that HHS promulgated the Final Rule, which

represents a sharp break from prior policy, without engaging in any reasoned decision-making [and] cited speculative, unsubstantiated fears . . . and touted anticipated benefits of the Final Rule that have no basis in the record, while cursorily dismissing overwhelming evidence of the significant adverse impact the Rule will have.”).

143. The Rule fails to offer any justification for its departure from the 2011 rule and existing federal policy accommodating conscience interests while ensuring the right to quality health care. *See id.*; *F.C.C. v. Fox Television Stations, Inc*., 556 U.S. 502, 516 (2009) (holding that “a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy”).

E. <u>The Rule Will Irreparably Harm the City of Baltimore.</u>

144. The Rule will irreparably harm the City as health care provider, employer, subgrantor, insurer, and guardian of the public health. If the City complies with the Rule—a near impossible task—it will be crippled in its ability to provide quality care and Baltimore’s public health will suffer. The costs of non-compliance are even higher and could result in loss of most of BCHD’s funding as well as funding from the U.S. Department of Labor and the U.S. Department of Education.

1. The Rule’s requirements will be impossible for the City to administer as an employer and subgrantor.

145. The Rule, if implemented, will impose an impossible administrative burden on City agencies by making it impossible for the City to obtain advance notice of and make accommodations for providers with conscience objections. *See supra* ¶ 131.

146. Employees of BCHD clinics and home visit programs perform work that is highly targeted and involves the same types of services every day. Therefore, a provider or staff member objecting to assisting in the provision of a service or to helping a particular patient demographic

would necessarily refuse to perform a significant portion of his or her job duties. Without being able to fill that position with someone willing to perform critical job duties, BCHD's only alternative would be to double-staff the clinics—and even that might not resolve the issue if the added staff members also were objectors. Adding such redundancy is financially impossible, as the City's clinical and other programs are already understaffed and—even without an interruption to funding—lack the financial resources to fill duplicate positions.

147. An added hurdle to staffing is the specialized training requirements in some of BCHD's clinics. To prescribe buprenorphine, for example, medical professionals are legally required to undergo specialized training. And once certified, providers may treat only up to a maximum number of patients depending on the level of certification. Similarly, TB treatment is highly specialized and new nurses must train for up to six months before they can provide the full spectrum of care for TB patients. Providers at the reproductive health clinics must also complete specialized training in order to prescribe and administer long-acting reversal contraceptives. Thus, even if funding could be secured, accommodating staff refusals in these clinics would thus create a gap in services before new staff could be put in place. In the interim, patients would suffer, overdoses might increase, or TB cases could increase in Baltimore, potentially leading to a TB outbreak.

148. Fire/EMS would face similar administrative barriers. EMTs are dispatched for emergency care based on the 911 callers' report of what the injured person needs and the proximity of a Fire/EMS resource. Time is of the essence. If, upon arrival at the scene, any Fire/EMS employee were entitled to refuse to provide care to the person they encounter needing care, there would be no alternative care immediately available and people will die as a result. Fire/EMS has neither the funding or the logistical capacity to staff every ambulance and every fire truck with

multiple EMTs to cover the possibility that the person in crisis could be gay, transgender, experiencing an ectopic pregnancy, an IV drug user, a sex worker, or some other person objectionable to a particular EMT employee for whatever reason the employee might assert.

149. The subgrantee-compliance certification that the Rule appears to require would also create unmanageable administrative burdens. Currently BCHD ensures that its subgrantees comply with federal law as required by the terms of the subgranted federal funding. However, BCHD lacks staff resources to additionally review and monitor the internal personnel policies and procedures of its subgrantees to ensure they are organizing their health care to prioritize employee objections over patient care. Not only would the requirement to monitor subgrantee human resources practices increase BCHD's workload, current BCHD grant compliance staff are not human resources professionals or employment law specialists and these functions are beyond their capacity.

150. In addition, BCHD's strategy for expanding outreach to underserved populations is increasingly to subgrant federal funds to small, community-based organizations. These smaller organizations tend to be new and have few paid staff members, but they know, and are trusted by their client populations. The nature of these organizations complements BCHD's patient-centered philosophy by allowing those who implement its programs to from the patients' own communities. But because of their inexperience and lack of resources, these small organizations sometimes lack processes that would allow the BCHD to ensure that their internal personnel policies comply with the Rule.

151. Even if the City could comply with the administrative burdens, the Rule's unqualified refusal rights would undermine the practical ability to provide prompt, non-

discriminatory, care in conformance with professional standards, and, thus, would force the City's medical providers to engage in the unethical practice of medicine.

2. The Rule interferes with the City's mandate to protect the public health.

152. The Rule requires providers to explicitly endorse the very stigma that the City has sought to eradicate from its public health system, and threatens to undo the holistic, trauma-informed approach to its public-health mission. Provider refusals under the Rule will result in denials of timely care to Baltimore residents, in City programs and elsewhere, which will result in significant harm for individual patients and for public health at the population level.

153. If health care staff refuse to treat patients for religious, moral or "other" reasons, based on either the services sought or the patient's identity, it would inherently communicate a sense of judgment to the individual. Such refusals will cause already traumatized patients to lose trust in their providers and in the City more generally, and to be deterred from seeking care in the future. Inevitably the Rule would undermine BCHD's reputation in hard-to-reach communities.

154. Patients who have faced a lifetime of discrimination will be particularly vulnerable to the stigma and psychological harms that a patient may suffer when denied care on the basis of who they are or the treatment they seek. Baltimore's trauma-informed approach to care relies on establishing trust with patients and patient communities over time. That trust which may take years to build, can collapse in the single moment it takes for a patient to be turned away because of who they are or the services they seek.

155. BCHD clinics display notices to patients that they will receive care without discrimination on the basis of their race, color, national origin, age, gender, sexual orientation, gender identity or expression, physical or mental disability, religion, ethnicity, language, or

inability to pay. However, if the Rule is permitted to take effect, Baltimore residents may view alongside such notice, a notice to health care employees that:

> **You may have the right under Federal law to decline to perform, assist in the performance of, refer for, undergo, or pay for certain health care-related treatments, research, or services (such as abortion or assisted suicide, among others) that violate your conscience, religious beliefs, or moral convictions.**

84 Fed. Reg. at 23,272 (Appendix A). While such notice is not required under the Rule, voluntary posting of "notice concerning Federal conscience and anti-discrimination laws" will be "non-dispositive evidence of compliance." 84 Fed. Reg. at 23,216. Given the risk of loss of federal funding, the City's clinics may feel no choice but to comply.

156. The Rule's recommended notice to healthcare employees would communicate to patients that they might be stigmatized and discriminated against at BCHD's clinics, potentially driving them away from care.

157. The stigmatizing effects of being denied care that one individual experiences will ripple out through word of mouth in that person's community, leaving others, once again, mistrustful of government health care programs and reluctant to seek care. Many in these vulnerable populations may forego necessary medical care for fear that they will be rejected or mistreated.

158. Because the BCHD's clinics are often facilities of last resort for Baltimore's most at-need residents, those turned away or scared away from its services would go without necessary medical care.

159. Even those who have access to health care elsewhere sometimes choose to come to the BCHD for services because they are too embarrassed to seek those services from their primary-care providers. If the Rule takes effect and more health care providers restrict access based on "conscience" objections, the numbers of individuals seeking care from BCHD may rise even

further. If BCHD can no longer provide judgment-free health care, these individuals will forgo necessary preventive and other health care, resulting in worse and more costly health outcomes.

160. Interference that impedes public-health efforts in marginalized communities can set programs back years, if not decades. Those setbacks could threaten the broader population with devastating harms, including increased prevalence of tuberculosis, HIV, sexually transmitted diseases, teen pregnancies, infant deaths, and opioid overdoses.

3. Failure to comply would inflict greater harm even than compliance.

161. If the costs of compliance are impossibly high, the potential costs of non-compliance are worse. An enforcement action under the Rule could result in a loss of funding that would cripple the City's ability to provide essential health services. Nearly 80% of BCHD budget comes from HHS, and Fire/EMS relies heavily on Medicaid reimbursements to fund emergency transports. Thus, the cost of interpreting the scope of the Rule's tolerance for stigma too narrowly is massive.

162. The Rule puts the City in a double bind: continue to rely upon federal funding but sacrifice provider's professional ethics and commitment to patient care, on one hand, or reject federal funding and be forced to close clinics and drastically reduce BCHD and Fire/EMT services, on the other. Under either option, public health is irreparably harmed. *See Baltimore v. Azar et al.*, 2019 WL 2298808 at *12 (finding irreparable harm where "should Baltimore City choose to comply with the Final Rule in order to retain Title X funding, its medical providers would be forced to contravene their ethical obligations to provide patient-centered, non-directive care.").

163. Baltimore has seen firsthand the effects of service interruptions in underserved communities. In the early 1990s, federal funding to the City's STD clinics was reduced, decreasing the number of medical professionals and outreach personnel on staff. This, combined with the rise

of crack-cocaine use and housing displacement of many poor residents, led to a 500 % increase in syphilis infections across Baltimore.

164. Without treatment, syphilis and gonorrhea may lead to infertility. Syphilis also causes blindness, pelvic inflammatory disease (causing extreme pain in women), miscarriages, stillbirths, and disabilities in infants. And HIV and Hepatitis C, if left untreated, can be deadly. The progress that BCHD has made in preventing and treating HIV and STDs could be undone by a rule allowing refusals to provide care, setting our public-health efforts back by 20 or 30 years.

165. Likewise, cuts to family planning services will lead to more unintended pregnancies and higher health costs. In 2010, services provided at Title X health centers in Maryland saved the state and federal government $147,766,000. These savings came from preventing unintended pregnancies, sexually transmitted diseases (including HIV), and cases of cervical cancer. At a national level, savings from Title X services totaled $7 billion that year. Jennifer Frost et al, *Return on Investment: A Fuller Assessment of the Benefits and Cost Savings of the US Publicly Funded Family Planning Program*, Wiley Periodicals, Inc, (2014).

166. Funding cuts or restrictions to the Title X program in Baltimore in the year 2017 alone would have resulted in 2,800 missed annual exams and 132 missed referrals to health services. Title X funding restrictions could have potentially left Baltimore City residents with undiagnosed and untreated cases of STDs and HIV, including: 8,746 cases of chlamydia, 18,925 cases of gonorrhea, 5,283 cases of syphilis, and 8,174 cases of HIV. This number of undiagnosed and untreated cases—which, left untreated, would likely have spread to even more patients—would have serious public health consequences for the Baltimore community.

167. In bypass grants through the state, the U.S. Department of Labor currently grants over $7 million each year to the City through the Workforce Innovation and Opportunity Act to

conduct job training and employment development. Without these funds the City's two American Job Centers would close, discontinuing vital one stop services for resume prep, job training and job matching services. Currently these Centers assist adults through 30,000 visits per year. Special services and outreach is offered for dislocated workers, and the City subgrants to at least five other providers to target 18 to 24 year olds. By the Rule's plain terms, this Labor Department funding could be at risk.

168. Thus, a regulation that grants health care employees the unqualified right to refuse to treat, assist, or refer patients for care and prevents employers from inquiring about potential refusals would undermine BCHD's years of work persuading Baltimore residents to seek and accept care—whether or not the City successfully implements it.

169. The consequences may be devastating, both for the innumerable individuals who rely on the City for health care services and for BCHD's ability to advance the well-being of Baltimore residents at the population level.

4. The Rule will harm the City as an insurer.

170. The City's coffers will suffer as health care costs for its employees, retirees, and their families increase as a result of the Rule. Stigmatizing refusals of health care nationwide will drive the City's insured away from preventive care and other appropriate treatment which can detect and treat infectious disease before it spreads or serious illness like cancer early. Early detection and treatment is less costly and results in better outcomes. Delays in accessing care will cause conditions to become acute and will increase costly emergency care and care for advanced conditions. These increased costs will be borne by the City.

CAUSES OF ACTION

COUNT I
VIOLATION OF APA; 5 U.S.C. § 706(2)(A)—CONTRARY TO LAW

171. The City incorporates the preceding paragraphs as if fully set forth here.

172. Defendants are subject to the APA, 5 U.S.C. § 551 *et seq. See* 5 U.S.C. § 703).

173. The APA requires that agency action that is "not in accordance with law" be held unlawful and set aside. 5 U.S.C. § 706(2)(A).

174. The Rule violates Section 1554 of the Affordable Care Act, which prohibits the Department from implementing any regulation that "(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114.

175. The Rule violates the Emergency Medical Treatment and Labor Act, which requires hospitals to provide emergency care. 42 U.S.C. § 1395dd.

176. The Rule conflicts with the Medicaid and Medicare statutes it purports to implement, which provide that with regard to informed consent, those statutes shall not "be construed to affect disclosure requirements under State law." 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); *see also* 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice).

177. The Rule conflicts with Title VII of the Civil Rights Act of 1964, which prohibits discrimination in employment based on religious beliefs, and further provides that employers are not obligated to accommodate employees' religious beliefs where the accommodation would cause "undue hardship" on the employer. 42 U.S.C. § 2000e(j).

178. The Rule is therefore "not in accordance with law" as required by the APA. 5 U.S.C. § 706(2)(A).

179. The unlawful Rule will cause ongoing harm to the City and its residents.

COUNT II
VIOLATION OF APA § 706(2)(C) —EXCEEDS STATUTORY AUTHORITY

180. The City incorporates the preceding paragraphs as if fully set forth here.

181. The Rule violates the APA under 5 U.S.C. § 706(2)(C) because it is greatly in excess of statutory jurisdiction, authority, or limitation.

182. Under the APA, courts must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

183. Defendants only possess rulemaking authority to the extent conferred by statute. *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013).

184. The Rule exceeds Defendants' authority under the statutes it purports to implement because the Rule legislates and implements excessively broad definitions of statutory text, including "assist in the performance," "health care entity," and "discriminate or discrimination." 84 Fed. Reg. at 23,263-64.

185. In addition, the Rule's extraordinarily broad and vague enforcement scheme that would authorize the Department to withhold, deny, suspend, or terminate billions of dollars in federal health care funds to the City if, in Defendants' determination, there is a failure to comply

with the Rule or any of the underlying statutes, *see* 84 Fed. Reg. at 23,271-72, is not authorized by the relevant federal statutes.

186. The Rule's enforcement scheme authorizing the Department to withhold or suspend all federal financial assistance from the Department of Labor and Department of Education to the City if in Defendants' determination there is a failure to comply with the Rule or the Weldon Amendment, *id*., is not authorized by the relevant federal statutes.

187. The Rule is therefore "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," in violation of the APA. 5 U.S.C. § 706(2)(C).

188. The unlawful Rule will cause ongoing harm to the City and its residents.

COUNT III
VIOLATION OF APA; 5 U.S.C. § 706(A)—ARBITRARY, CAPRICIOUS, AND ABUSE OF DISCRETION

189. The City incorporates the preceding paragraphs as if fully set forth here.

190. The APA provides that courts must "hold unlawful and set aside" agency action that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

191. The Rule is arbitrary and capricious because Defendants' justification for its promulgation runs counter to the evidence before the agency, relies on factors Congress did not intend the agency to consider, and disregards material facts and evidence, including nationally recognized standards of care for medical professionals.

192. The Rule is arbitrary and capricious because its definitions of "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for," taken together, arbitrarily require Plaintiffs to guess whether routine procedures and services would require additional steps to accommodate workers or protect patients.

193. The Rule is arbitrary and capricious because HHS unreasonably ignored evidence in the rulemaking record that the definitions of "assist in the performance," "discriminate or

discrimination," "health care entity," and "referral or refer for" create an unworkable situation for the City and other healthcare providers and regulators.

194. The Rule is arbitrary and capricious because the Department conducted and relied on a flawed cost-benefit analysis, citing benefits the Rule would confer without any evidentiary basis, and failing adequately to account for the true costs the Rule will impose, including the significant costs to the City and to the public health and safety.

195. The Rule is arbitrary and capricious because it fails to consider important aspects of the problem, including by failing to provide any exception for medical emergencies, 42 U.S.C. § 1395dd(b)(1), or where refusal to provide services would cause "undue hardship," 42 U.S.C. § 2000e(j).

COUNT IV
VIOLATION OF APA; 5 U.S.C. § 706(B)—CONTRARY TO CONSTITUTIONAL RIGHT, POWER, PRIVILEGE, OR IMMUNITY

196. The City incorporates the preceding paragraphs as if fully set forth here.

197. Defendants are subject to the APA, 5 U.S.C. § 551 et seq. See 5 U.S.C. § 703.

198. The APA requires that agency action that is "contrary to constitutional right, power, privilege, or immunity" be held unlawful and set aside. 5 U.S.C. § 706(2)(B).

199. The Establishment Clause of the First Amendment prohibits the government from favoring one religion over another or favoring religion over nonreligion.

200. The Establishment Clause permits government to afford religious accommodations or exemptions from generally applicable laws only if, among other requirements, the accommodation (1) lifts a substantial, government-imposed burden on the exercise of religion and (2) does not impose on innocent third parties the costs or burdens of accommodating another's religious exercise.

201. The Rule fails both requirements and therefore violates the Establishment Clause.

202. The Rule creates expansive religious exemptions for healthcare employees at the expense of third parties, namely, Plaintiffs, providers, and, crucially, patients. In so doing, Defendants have used their rule-making authority for the primary purpose of advancing and endorsing religious beliefs and permitting same to be privileged over secular beliefs as a basis for denying medically necessary information, referrals, and services, including emergency healthcare and healthcare guaranteed under federal and state laws.

203. In accommodating an employee's religious objections, the Rule places an undue burden on third parties—patients seeking healthcare and healthcare providers seeking to fulfill their ethical mandates to provide such care. *Burwell*, 134 S.Ct. at 2781 n.37 (requiring consideration of the burden placed on third parties by a religious accommodation).

204. The Final Rule violates the Spending Clause of the Constitution because it coerces state and local governments to adhere to the Final Rule or lose millions of dollars in federal funds. *See Sebelius*, 567 U.S. at 581 (Congress cannot use threat to withdraw funding as a "gun to the head").

205. The Final Rule violates the Spending Clause of the Constitution because it does not provide adequate notice of what specific action or conduct, if engaged in, will result in the withholding of federal funds and constitutes unlawful post-acceptance conditions on federal funds. *See Halderman*, 451 U.S. at 17.

206. The Final Rule violates the Spending Clause of the Constitution because it is not rationally related to the federal interest in the program that receives the federal funds. *See South Dakota v. Dole*, 483 U.S. at 207.

207. The Rule is therefore "contrary to constitutional right, power, privilege, or immunity" in violation of the APA. 5 U.S.C. § 706(2)(B).

208. The unlawful Rule will cause ongoing harm to the City and its residents.

COUNT V
EQUITABLE RELIEF TO PRESERVE REMEDY

209. The City incorporates by reference the foregoing paragraphs as if fully set forth.

210. The Rule becomes effective on July 22, 2019, unless it is enjoined. The City is entitled to a full, fair, and meaningful process to adjudicate the lawfulness of the Rule before being required to implement its far-reaching requirements, which threaten to undo decades of public health progress.

211. The City will suffer irreparable injury by being required in advance of implementation to spend countless staff hours reviewing and revising employment policies and procedures. Once deployed, the Rule will cause irreparable harm to individual patient health and to the public health more generally by requiring Plaintiffs to violate patients' rights, subjecting patients to stigmatizing and re-traumatizing health care denials, and delaying or denying them access to care. These health care experiences will erode hard-won trust between vulnerable patients and health care providers—trust that was sensitively nurtured over decades of developing patient-centered and trauma-informed care—with devastating and long-lasting public health consequences. Accordingly, to ensure that Plaintiffs receive meaningful relief should they prevail in this action, the Court should preliminarily and permanently enjoin Defendants from implementing the Rule.

212. In addition, the City will be harmed if the Rule is not enjoined nationwide, as the City insures individuals who live and seek health care across the country.

REQUEST FOR RELIEF

The City requests that the Court grant the following relief:

a. Enter a declaratory judgment pursuant to 28 U.S.C. § 2201(a) and 5 U.S.C. § 706(a) that the Rule is contrary to law, in excess of statutory authority, and is arbitrary and capricious;

b. Issue and order vacating and setting aside the Rule in accordance with the APA;

c. Issue a preliminary injunction with nationwide effect enjoining Defendants from implementing and enforcing the Rule;

d. Issue a permanent injunction with nationwide effect enjoining Defendants from implementing and enforcing the Rule;

e. Award the City attorneys' fees, costs and expenses and other disbursements for this action; and

f. Award any further and additional relief that this Court deems just and proper.

CERTIFICATION AND CLOSING

Under Federal Rule of Civil Procedure 11, by signing below, I certify to the best of my knowledge, information, and belief that this complaint: (1) is not being presented for an improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation; (2) is supported by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law; (3) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery; and (4) the complaint otherwise complies with the requirements of Rule 11.

RESPECTFULLY SUBMITTED this 5th day of June, 2019.

By: /s/ Andre M. Davis
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CERTFICIATE OF SERVICE

I hereby certify that this document will be served on the Defendants in accordance with Fed. R. Civ. P. 4.

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