Exhibit 1

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

V.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF SARAH ADELMAN

- 1. I, Sarah Adelman, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:
- 2. I submit this Declaration in support of the State of New Jersey's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through the New Jersey Department of Human Services' ("DHS") personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon DHS.
- 1. I am the Deputy Commissioner at DHS located in New Jersey. I have been employed as Deputy Commissioner since February 2018. In my capacity as Deputy Commissioner, I oversee the Division of Medical Assistance and Health Services ("DMAHS"), New Jersey's Medicaid and Children's Health Insurance Program ("CHIP"), the Division of Developmental Disabilities ("DDD"), and the Division of Aging Services "(DoAS"). These programs each manage federal funds including funding from the U.S. Department of Health and Human Services.

Impacts of Funding Termination

3. DHS is the largest state agency in New Jersey, serving about 2.1 million New Jerseyans, or one of every five state residents. DHS serves seniors, individuals and families with low incomes; people with developmental disabilities, or late-onset disabilities; people who are blind, visually impaired, deaf, hard of hearing, or deaf-blind; parents needing child care services,

and child support and/or health care for their children. DHS and its divisions provide programs and services designed to give eligible individuals and families the help they need to find permanent solutions to a myriad of life challenges. This is made possible through DHS's work to make strategic use of state and federal resources, establish community supports, and promote accountability among staff.

- 4. In FY2018, DHS received a total of \$10.7 billion in federal HHS funding to serve a variety of programs important for maintenance of the health and welfare of New Jersey residents.
- 5. From Medicaid alone, DHS received \$7.3 billion dollars in federal HHS funding in FY2018. Required State matching, which ranges from 10 to 50 percent, depending on the group served, totaled about \$4 billion. DHS also received over \$456 million in CHIP funding in FY2018. The State matched 12 percent of the federal funds, or about \$50 million. Collectively, Medicaid and CHIP programs in New Jersey are referred to as "NJ FamilyCare." Through these programs, DMAHS services over 1.7 million people in the State. Eligibility for NJ FamilyCare is based primarily on income level. The Affordable Care Act expanded Medicaid eligibility so that individuals and families with incomes up to 138% of the federal poverty level are eligible for the program.
- 6. DoAS received a total of \$85.8 million in HHS funding in FY2018, including around \$30.7 million under the Older Americans Act. New Jersey matches roughly 15 to 25 percent of the federal funds under the Older Americans Act. The funds allow older adults to live in the community as long as possible with independence, dignity, and choice. DoAS serves as the focal point for planning services for older adults through oversight of home and community-based programs. DoAS and DMAHS also provide funding to nursing facilities through Medicaid

and the Older Americans Act. Because such facilities would be required to accommodate the objections of any staff to certain procedures, and due to the unclear and broad scope of the Final Rule, DHS must be prepared to be held responsible for any breach of the rule by hundreds of facilities.

- 7. DDD received a total of \$850.9 million in federal HHS funding in FY2018. DDD funds and supports more than 600 agencies all across New Jersey providing education and other services for nearly 25,000 adults with developmental disabilities. Around 8,000 adults with developmental disabilities reside in more than 1,800 group homes across the State, funded by DDD.
- 8. DHS's Division of Family Development received a total of \$840 million in HHS funding in FY2018, including around \$400 million for Temporary Assistance for Needy Families, known as WorkFirst NJ ("WFNJ"). Approximately 40,000 individuals received WFNJ benefits including cash assistance, emergency housing assistance, child care, and job training and education supports in FY2018.
- 9. Given the size of these programs, it is very unlikely that adequate State funding would be available to offset a significant loss of federal dollars. Any significant federal reduction would require changes to eligibility requirements or the number of services offered. The reduction or cut-off in federal funding would mean a significant decrease in the number of individuals with low-incomes receiving health insurance benefits. It would also reduce the availability of DHS-administered services to families with low incomes, such as child care, work training, and cash assistance, as well as reduce the number of services available to older residents and individuals with disabilities. The viability of the state earned income tax credit, which many families depend on, would also be at risk under the Final Rule. A decrease in

funding to DDD would adversely affect the ability to provide comprehensive services to individuals with developmental disabilities in the State.

Immediate Impact of the Final Rule

- 10. Because the Final Rule threatens cuts in funding to recipients for the non-compliance of their sub-recipients, DHS understands that it would be expected to ensure that all sub-recipients are in compliance. Ensuring such compliance would likely require expending significant DHS resources to ensure that sub-recipients have policies and plans in place that enforce the Final Rule and plan for any religious or moral objections that may arise.
- 11. I anticipate that DDD, for example, would have to make complicated arrangements to ensure compliance of every one of its more than 120 group home providers. Group home providers are often responsible for scheduling medical appointments and providing transportation to and from medical services. The Final Rule would allow for nearly any group home employee to object to assisting in the performance of any services covered under the rule. Group homes, many of which are already short-staffed, would have to account for the possible objections of any one of their employees. Given that employers are restricted under the Final Rule from asking employees about objections more than once per calendar year and not before they are hired, group homes would have a difficult time ensuring that sufficient staff are present to transport individuals to reproductive care appointments. Additionally, DDD would have to institute measures to ensure that group homes are complying with the Final Rule and accommodating staff who are only tangentially associated with reproductive care, such as drivers and administrative staff. Such administrative burdens on DDD would divert time and resources away from overseeing facilities' treatment and care of individuals with disabilities.

- 12. For individuals with disabilities, this diversion of resources can be particularly harmful. Individuals with disabilities face an increased risk of sexual abuse and assault as compared to the general population. The need for reproductive care and the ability to make choices about their reproductive health is important. Prioritizing the objections of non-medical staff, such as drivers or administrative staff, over individuals' health choices made with the benefit of their health care professional, and in some cases their family and/or guardian, would put individuals with disabilities at risk.
- 13. The Final Rule is very broad and permits many individuals and entities to object without notice. I anticipate that DMAHS would likely have to overhaul Medicaid billing and contracting procedures to account for potential objections. Currently, 95 percent of NJ FamilyCare is delivered through Managed Care Organizations ("MCOs"). MCOs provide case management services and handle Medicaid billing. MCOs are required to cover, through Medicaid funds, ectopic pregnancies, miscarriage, and natural loss of pregnancy. Under the Final Rule, MCOs could object to covering such life-saving procedures. I anticipate that DMAHS would need to account for this possibility in advance, likely by shifting Medicaid billing for procedures related to loss of pregnancy to a separate billing structure. This likely would require DHS staff to expend significant time and resources to reviewing MCO contracts and restructuring billing to account for objections.
- 14. Additionally, because of the expansive definitions of who may be assisting in the performance of a medical procedure, DMAHS likely would also have to account for potential objections by its own administrative employees providing billing and support for therapeutic abortions, which are paid through State Medicaid funds, as previously described. The large pool of individuals covered by the Final Rule will likely complicate Medicaid's coverage structure

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and will likely require the expenditure of significant time and resources to ensure that coverage for health care is not compromised due to potential objections by various entities with widely varying levels of involvement in the actual health care services beneficiaries receive. This process could also delay the delivery of health services and unnecessarily involve patients in complicated billing procedures.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this // day of June, 2019

Sarah Adelman

Deputy Commissioner New Jersey Department of Human Services

Exhibit 2

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA. STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cy-04676-PAE

DECLARATION OF DR. NICOLE ALEXANDER-SCOTT

- 1. I, Dr. Nicole Alexander-Scott, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:
- 2. I submit this Declaration in support of Rhode Island's involvement as a Plaintiff in the above-captioned matter against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of HHS, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through state personnel who have assisted me in gathering this information from our institution, or on the basis of documents that were provided to me and that I reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Rhode Island Department of Health ("RIDOH").
- 3. My educational background includes undergraduate work at Cornell University, where I majored in Human Development and Family Studies, followed by SUNY Upstate Medical University at Syracuse in 2001. After completing a combined internal medicine-pediatrics residency at SUNY Stony Brook University Hospital in 2005, I finished a four-year combined fellowship in adult and pediatric infectious diseases at the Warren Alpert Medical School of Brown University. I later obtained a Master's Degree in Public Health from the Brown University School of Public Health. I have served as the Director of RIDOH since 2015. As Director, I have established the following three leading priorities for RIDOH: (1) addressing the socioeconomic

and environmental determinants of health; (2) eliminating disparities of health and promoting health equity; and (3) ensuring access to quality health services for all Rhode Islanders, including the state's vulnerable populations.

- 4. I bring relevant and valuable experience to my role as Director from (a) my work as a specialist in infectious diseases for children and adults, and (b) time spent in academia as an associate professor of pediatrics, medicine, and public health. I am board-certified in Pediatrics, Internal Medicine, Pediatric Infectious Diseases, and Adult Infectious Diseases. In 2018, I was elected by my peers to be the President of the <u>Association of State and Territorial Health Officials</u> ("ASTHO"), the national organization for state health directors.
- 5. Each incoming ASTHO President selects a Challenge as a focus for the year that s/he leads the organization. I chose "Building Healthy and Resilient Communities" as my Challenge because I wanted to help create tangible vehicles to support research and initiatives addressing the socioeconomic and environmental determinants of health in communities, such as education, housing, transportation, and employment, given that these and other community-level factors affect health outcomes most significantly.
- 6. RIDOH aims to give every person, in every community in Rhode Island, an equal opportunity to be as healthy as possible. Under my leadership, RIDOH has re-committed to addressing the socioeconomic and environmental determinants of health so that a person's health does not depend on his or her ZIP code, race, ethnicity, sexual orientation, gender identity, level of education, or level of income. I have had the distinct honor of being recognized for this work by numerous local and national organizations, including Grow Smart Rhode Island, the Rhode Island Chapter of the American Academy of Pediatrics, and the Kresge Foundation.

- 7. Rhode Island received over \$2.1 billion in federal health care funding from HHS in the 2018 federal fiscal year for entities identified as being at the state level in the Tracking Accountability in Government Grants ("TAGG") System.
- 8. RIDOH receives an annual amount of federal funding totaling approximately \$7,118,423 for programs for arthritis, asthma, cancer registry, breast and cervical cancer, comprehensive cancer, colorectal cancer, diabetes, heart disease and stroke, and screening for heart disease.
- 9. RIDOH was awarded \$2,725,000 in Title X funds for family planning program services for project period April 1, 2016 through August 31, 2018. The number of clients served by Title X service sites in 2018 was 29,098.
- 10. These funds are essential to the functioning of RIDOH and maintaining public health within Rhode Island.
- 11. It is RIDOH's understanding that the Final Rule expands definitions of terms in ways that may affect how we function, specifically, the terms "assist in the performance," "discriminate or discrimination," and "health care entity."
- 12. "Assist in the performance" now means "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 23,236 (to be codified at 45 C.F.R. § 88.2). Under this definition, simply scheduling a medical appointment would constitute "assistance." RIDOH would be required to guess which routine procedures or referrals "may" constitute "assistance" that requires additional steps to accommodate workers or protect patients.

- 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. Providers would not be able to use alternate staff to provide any objected-to medical services if those efforts exclude an objecting staff member from their "field [] of practice" or require "any" additional action by that person. We also understand that any accommodation offered to an objecting employee must depend on that employee's willingness to accept that accommodation to avoid discrimination, regardless of the reasonableness of such accommodation. 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2). This runs contrary to Rhode Island law and RIDOH regulation. For example, RIDOH regulation requires reasonable accommodation by a pharmacy owner for licensed pharmacists who notify the pharmacy owner in writing of their ethical/moral/religious objection to filling certain prescriptions.
 - 14. RIDOH Regulation 216-RICR-40-15-1.15.2.
- 15. The term "health care entity" is expanded in such a way that would allow objections by human resources analysts, customer service representatives, data entry clerks, and numerous other who believe that analyzing benefits or answering a benefits-related question is inconsistent with their personal beliefs.
- 16. At the core of the Final Rule lies a detrimental lack of clarity as to the parameters of these terms and who may be subject to them, but RIDOH must prepare for compliance with the Final Rule or be at risk for losing, at a minimum, all federal health care funding.
- 17. As the State's health regulator, RIDOH is responsible for enforcing laws directly affected by the Final Rule. Such laws include: the requirement that every health care facility, including free-standing ERs, provide prompt treatment of patients (R. I. Gen. Laws § 23-17-26(a));

allowing license revocation for physicians who abandon patients (R. I. Gen. Laws §§ 5-37-4, 5-37-5.1, and 5-37-6.3); the requirement that a pharmacy owner create a reasonable accommodation, without creating undue hardship, for licensed pharmacists who notify the pharmacy owner in writing of ethical/moral/religious objections to filling certain prescriptions (RIDOH Regulation 216-RICR-40-15-1.15.2); the requirement that a physician or anyone working in a health care facility give written notice of objection to performing abortions or sterilization procedures (R. I. Gen. Laws § 23-17-11); and informed consent laws regarding abortion procedures (R. I. Gen. Laws § 23-4.7-2). The Final Rule interferes with our ability to enforce these laws.

- 18. For our State's health systems that operate ambulance fleets or contribute to fleets that respond to emergency calls, the Final Rule presents a Hobson's choice for RIDOH, other state agencies, and provider agencies: train and require EMS practitioners to assist in all emergency circumstances and face possible sanction for non-compliance with the Final Rule; or permit real-time objections from those personnel who could refuse to drive or assist in an emergency situation, either without the opportunity to provide other, non-objecting personnel or with the burden of spending significant resources to ensure such non-objecting personnel is readily available. This will create chaos in accessing critical, quality health care in life-threatening circumstances.
- 19. The Final Rule's expansion of the universe of objectors for religious, moral, or ethical reasons, its limits on requiring advance notice of such objection(s), and vagueness of definitions (e.g., "assist in the performance"), means RIDOH will have to expend significantly more resources and time to determine veracity of objections made by employees.
- 20. Compliance with the Final Rule is onerous, puts an undue burden on provider sites, and runs contrary to RIDOH's mission of ensuring access to quality health services for all Rhode Islanders.

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I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 7th day of June, 2019.

Nicole Alexander-Scott, MD, MPH

Director of Health

Rhode Island Department of Health

Exhibit 3

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

sTATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA. STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF CHARLES ALFERO

1. I, Charles Alfero, pursuant to 28 U.S.C. § 1746, hereby declare that the following is

true and correct:

- 2. I submit this Declaration in support of the State of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge or on the basis of documents I have reviewed.
- 3. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the people of southwestern New Mexico.
- 4. I am the executive director of the Center for Health Innovation (CHI), located in Silver City, Grant County, New Mexico. My educational background includes a masters in psychology from Western New Mexico University.
- 5. I have been employed as director of CHI since 2010. I am also the founder of Hidalgo County Medical Services (HMS), a Community Health Center providing primary medical, dental, mental health, family support, community development, and health policy services in southwestern New Mexico. CHI is a research, development and policy division of HMS and is working in 23 states on a variety of rural health workforce, public health improvements, integrated services and community/university collaborations.
- 6. I have been director of rural outreach for the University of New Mexico (UNM)

 Health Sciences Center and director of the Community Health Services Division in the New

 Mexico Department of Health (DOH) and am currently also director of the New Mexico Primary

 Care Training Consortium.

- 7. I have more than 41 years of experience in rural health policy, systems, and program development.
- 8. In my capacity at CHI, I am responsible for employing staff that serves remote counties in Southern New Mexico and statewide.
- 9. According to the U.S. Census Bureau, Hidalgo County, New Mexico's southernmost county, has a population estimated in 2018 as 4240 persons, 21% of whom are over 65. The population density was just over one person per square mile in the year 2010.
- 10. Grant County, also covered by health policy staff at our CHI center, has an estimated population of just over 27,000, almost 27% of whom are over 65. The population density is approximately 7 persons per square mile.
- 11. Understanding the diverse health and medical needs of persons in such a remote area requires sensitivity to many religious and ethical demands, and our area hospitals and clinics that provide direct services already struggle to meet such demands. Adding to the complexity of compliance with rules is likely to detract rather than enhance the services they already provide.
- 12. This is especially so as our medical entities cope with an aging population that will necessarily be facing end-of-life decisions made more complex by expansion of the conscience rules.
- 13. The right to life and health should not be based on religious beliefs in any area of health care.
- 14. The Final Rule's expansion of universe of objectors, its limits on requiring advance notice of objection, and vagueness of definitions (e.g., "assist in the performance"), means that direct services providers in the frontier area of New Mexico will need to expend more resources

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to determine veracity of objections made by employees, as well as resources to support any

potential litigation pursuant to decisions impacting the health and well-being of patients.

15. I know that New Mexico's health policy demands are already complex and that our

laws already require respect for religious diversity. Therefore, adding to the complexity of the

task of providing rural health care does not serve the needs of our sparse population.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true

and correct.

Executed on this 7th day of June, 2019

Charles Alfero

Executive Director

Center for Health Innovation (CHI)

Exhibit 4

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STA	ATE	OF	NEW	Y	ORK.	et	al
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Plaintiffs,

v.

19 Civ. 4676 (PAE)

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

DECLARATION OF GREATER NEW YORK HOSPITAL ASSOCIATION

- 1. I, Laura M. Alfredo, declare under penalty of perjury, pursuant to 28 U.S.C. § 1746, that the following is true and correct:
- 2. I am the Senior Vice President of Legal, Regulatory, and Professional Affairs and General Counsel at the Greater New York Hospital Association (GNYHA), where I have been employed since 2015. My responsibilities include policy development and technical assistance on a range of matters affecting the legal and compliance function of our member hospitals and health systems.
- 3. I am offering this declaration in support of the of the State of New York's litigation against the United States Department of Health and Human Services (HHS) regarding the recently

issued final rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority (Final Rule).

- 4. Founded in 1904, GNYHA is a trade association representing more than 160 hospitals and health systems in New York, New Jersey, Connecticut, and Rhode Island. In New York, GNYHA represents approximately 139 hospitals. All our members are either not-for-profit or public institutions.
- 5. Among the services that GNYHA provides to its members is technical assistance with developing best practices for the delivery health care services in a culturally competent manner that is consistent with local, State, and Federal anti-discrimination laws. This encompasses respect for the right of both health care workers and patients not to be unlawfully discriminated against. For example, we have assisted our members with understanding and implementing compliance programs in connection with Section 1557 of the Affordable Care Act and other anti-discrimination laws, including New York City and State statutes prohibiting public accommodations, including hospitals, from discriminating against those who use their facilities on the basis of sex, race, religion, and sexual identity, among other protected classifications.
- 6. GNYHA and its members have serious concerns about the recent regulatory changes contained in the Final Rule. These changes will increase the likelihood of a conflict between workers' and patients' rights and inappropriately emphasize the rights of workers over patients. It ignores the fact that hospitals and providers must comply with a host of anti-discrimination laws and regulations, in addition to laws like the Emergency Medical Treatment and Labor Act (EMTALA) and professional conduct standards prohibiting patient abandonment. HHS failed to take heed of comments, including GNYHA's, urging it to align the Final Rule with the existing "reasonable accommodation" framework that for decades has enabled hospitals to

balance worker and patient rights. Finally, the changes include ambiguous and potentially draconian compliance and enforcement provisions that could damage safety net hospitals, including many in New York State.

- 7. One of the regulatory changes that GNYHA is concerned about is the definition of Discrimination in the Final Rule. The changes will ban pre-employment inquiries regarding an applicant's potential objection to assisting in certain health care activities. They will also prohibit exclusion or restriction on employment based on an employee's self-disclosure of religious or conscience objections.
- 8. These changes could deprive hospitals of effective mechanisms for avoiding conflicts between worker and patient rights and potentially place hospitals in the position of having to choose which laws to violate. Hospitals routinely ask job applicants whether they require any accommodations to complete the essential functions of the position. This question is often incorporated into the employment application and is intended to capture information about physical and other impediments to the performance of the job. Under the Final Rule, this question could be seen as discriminatory.
- 9. In addition, many hospitals maintain policies on conscience rights that advise workers of their right to proactively notify the hospital of any conscience or religious objections to assisting in certain procedures. This is consistent with New York State law, which provides for a process by which health care workers may provide a "prior written refusal" to assist in an abortion. NY CVR 79-i.
- 10. The purpose of these policies is to allow for appropriate planning to ensure that an objecting worker is not placed in an uncomfortable position while allowing the hospital to arrange for safe staffing. This may include the hospital's decision not to place the objecting employee in

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certain settings in which the objected-to conduct is likely to arise or where the consequences of a conflict between the worker's and a patient's rights could be dire, even if such a conflict were not likely to happen frequently.

- 11. The most obvious example of such a scenario is hospital emergency services. Many hospitals operate ambulance fleets and employ emergency medical technicians (EMTs) and paramedics. Hospital first responders augment the emergency corps operated by localities and are part of hospitals' critical sector role. In New York City, for example, the New York City Fire Department (FDNY) Emergency Medical Services operates the City's 911 system and dispatches FDNY or hospital assets, based on location, need, and other factors intended to optimize speed, efficiency, and patient safety and care.
- EMTs and paramedics whether they require reasonable accommodations to perform their duties, there will be a risk that an objecting worker, faced with the imperative to treat or transport a patient who requires care that such worker finds objectionable, could place the patient and other workers in jeopardy in the field. Ambulances are typically staffed with two workers, one who drives and one who tends to the patient. In most cases, it would be unsafe to transport a patient without an attendant. Therefore, the only option in the event that a worker objected to conducting the transport would be to dispatch another ambulance. Clearly, this is not optimal for patient care or the efficient use of resources. It is not clear that HHS would not penalize a hospital for taking action to discipline or even transfer such an employee who jeopardizes patient safety in that manner; indeed, from the text and tone of the Final Rule, it appears HHS would take the position that the hospital could take no action that could be perceived as "adverse" whatsoever, even where its employee jeopardized patient safety by failing to come forward with their objections in a timely manner.

- 13. This concern is only magnified when one considers the Final Rule's new definition of Assist in the Performance. In the preamble, HHS acknowledges that activities such as scheduling and preparing a room or instruments would fall within this definition. This represents a marked expansion of the pool of workers who could potentially object to certain procedures and activities. To illustrate, one health system peri-operative department inquires of certain direct care providers, mainly nurses and surgical technicians, whether they have any objection to assisting in an abortion. Workers who respond affirmatively are not placed on a call list that is used on nights and weekends, the purpose of which is to replace staff members who may object to assisting in an abortion procedure but who may not have previously self-disclosed their objection. While this process may not be at odds with the new provisions in the Final Rule, by virtue of the new definition of Assist in the Performance, the health system may now have to survey both direct and non-direct care workers, including schedulers, transporters, and those individuals who prepare the operating rooms. This would be an onerous process that would be difficult to operationalize and maintain.
- 14. GNYHA is also concerned about the Final Rule's new requirement for an assurance and certification that applicants for Federal financial assistance or funds will comply with the Final Rule. Our concern stems from the aforementioned challenges with operationalizing compliance with the Final Rule in the context of the other laws, regulations, and professional standards that hospitals must adhere to. It is difficult to give an assurance of or certify compliance where the regulations are vague and in opposition to other requirements.
- 15. New York State hospitals, like most hospitals, are reliant on Federal funding, in particular Medicare funding. New York State hospitals, in the aggregate, have one of the lowest operating margins in the United States. There are 26 voluntary (non-public) hospitals throughout

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New York State on a Department of Health "Watch List" for being at high-risk of closure because

they have less than 15 days' cash on hand, as well as other indicators of poor financial condition.

These hospitals are receiving approximately \$600 million in State operating subsidies to prevent

unplanned closures, while the facilities transform into more sustainable operating models and

transition to payment methodologies with payers that are value-based. Many of these hospitals

are in rural and underserved urban communities, where they are both the essential safety-net

healthcare provider and a major employer. These hospitals are particularly vulnerable to Federal

funding cuts and reimbursement losses and are thus potentially at particular risk under the Final

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Rule.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 10, 2019

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Exhibit 5

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

V.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DR. MACHELLE ALLEN

1. I, Dr. Machelle Allen, pursuant to 28 U.S.C. § 1746, hereby declare that the following

is true and correct:

- 2. I submit this Declaration in support of the City of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and the United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, NYC Health + Hospitals (herein after "Health + Hospitals" or "the System") personnel who have assisted me in gathering this information from the System, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon Health + Hospitals.
- 3. I am a Senior Vice President and the System Chief Medical Officer ("CMO") at Health + Hospitals, located in New York City. I am a graduate of Cornell University and the University of California, San Francisco, School of Medicine, and completed a residency in Obstetrics and Gynecology at Health + Hospitals/Jacobi. I have been employed as the System's CMO since April 2017. Prior to that date, I was the System's Deputy CMO since October 2013.

Background on the NYC Health + Hospitals; Receipt and Use of HHS Funds

- 4. Health + Hospitals is New York City's municipal hospital system and the largest public health care system in the United States. Health + Hospitals protects and promotes the health and well-being of 8.5 million diverse New Yorkers across all five boroughs, serving as the City's public safety net and health care system.
- 5. Health + Hospitals operates an integrated health care system consisting of: eleven acute care hospitals; five post-acute/long-term care facilities; "Gotham Health," a network of health clinics across the five boroughs offering primary and preventive care services; and "NYC"

Health + Hospitals/At Home," a certified home health agency offering expert services in Manhattan, Queens, Brooklyn, and the Bronx.

- 6. Health + Hospitals offers: "MetroPlus," a low to no-cost health insurance plan serving more than 500,000 New York residents; "OneCity Health," the largest Medicaid Performing Provider System in the City composed of hundreds of health care providers, community-based organizations, and health systems; and "Health + Hospitals/Correctional Health Services," one of the largest correctional health care systems in the nation, with over 43,000 annual admissions in jails across the City.
- 7. In addition to this range of facilities and programs, twenty-two Health + Hospitals facilities have been designated as "Leaders in LGBT Healthcare Equality" by the Human Rights Campaign Foundation. This designation is given to entities that train staff in the provision of LGBTQ health care, have LGBTQ-responsive policies, and make those policies available to the public and staff.
- 8. Health + Hospitals received approximately \$3.4 billion in fiscal year 2018 from HHS. In particular, Health + Hospitals received: \$5,933,864 for services covered by Child Health Plus; \$1,153,400,144 for services covered by Medicaid; \$29,459,286 in federal grants related to HIV/AIDS, Sexually Transmitted Disease Treatment and Prevention, Substance Abuse Treatment, Public Health and Prevention, Immunization, Biomedical and Behavioral Research; \$112,799,439 in other grants; \$978,233,262 in Medicaid supplemental payments; and \$1,114,354,374 for services covered by Medicare.
- 9. These federal funds allow Health + Hospitals to serve around one million patients annually and are essential to the functioning of our System and maintaining public health within our jurisdiction.

Existing Health + Hospitals Policies Addressing Religious Objections

- 10. Health + Hospitals has robust anti-discrimination policies that are tailored to comply with the existing requirements of our state and local laws on religious accommodation. Foremost among these, Health + Hospitals has an Equal Employment Opportunity ("EEO") Program and a Religious Accommodation Policy. Attached hereto as Exhibit A are true and correct copies of Operating Procedure No. 20-32, Equal Employment Opportunity Program ("EEO Policy"). Attached hereto as Exhibit B are true and correct copies of Operating Procedure No. 20-18, Corporation Policy with Respect to Requests for Religious Accommodation ("Religious Accommodation Policy").
- 11. The EEO Policy emphasizes its commitment to providing equal employment opportunities to all employees and applicants for employment without regard to, among other bases, their actual or perceived religion or creed. *See generally*, EEO Policy.
- 12. In the context of religious accommodations, Health + Hospitals "grant[s] requests by employees and prospective employees for a reasonable accommodation of the employee or prospective employee's religious beliefs, practices or observance." Religious Accommodation Policy at 1; *see also* EEO Policy at 3 (prohibiting the denial of reasonable accommodations for "sincerely held religious beliefs, observances, and practices").
- 13. An accommodation would not be available if it would impose an "undue hardship" on the particular facility or department. *Id.* at 7; Religious Accommodation Policy at 3. A requested accommodation may cause an "undue hardship" if it would be significantly difficult or unduly costly to implement, may affect patient care, or would fundamentally change the nature or operation of Health + Hospitals. *Id.*
 - 14. The Religious Accommodation Policy likewise explains that,

A request for a religious accommodation will be denied only if, after exploring reasonable alternatives, the network/facility where the employee works or has applied to work determines that granting the request will cause an undue hardship to the operation of the applicable network/facility either because it would interfere significantly with the safe and efficient operation of the network/facility (including, without limitation, its ability to care for patients in a unit or division affected by the request) or would result in significant expense in relation to the size and operating costs of the network/facility.

Religious Accommodation Policy at 1–2.

- 15. Requests for religious accommodations should be made in writing to a Senior Manager and be made as far in advance as possible. Religious Accommodation Policy at 2.
- 16. In determining whether to grant a religious accommodation request, the Senior Manager will engage in an interactive dialogue with the employee's department to discuss the effects of the accommodation on the department, and when appropriate, alternative accommodations with the employee. EEO Policy at 7–8.
- 17. The Religious Accommodation Policy requires the Senior Manager to give written decisions on the religious accommodation requests. The Religious Accommodation Policy also provides higher levels of review that offer additional opportunities for exploring alternatives not yet considered. Religious Accommodation Policy at 3–4.
- 18. Absent plain reason to believe otherwise—such as inconsistency of practice—the Senior Manager accepts the employee's assertion of the sincerity of his or her religious belief. Religious Accommodation Policy at 4.
- 19. Health + Hospitals's policies are modeled on a reasonable accommodation and undue hardship framework in order to balance a variety of interests, at times competing, that surface in the workplace. The desire to balance these interests is motivated in part by Health + Hospitals's fundamental mission to provide care to all as well as the need to operate a financially

sustainable public hospital system. Health + Hospitals employs tens of thousands of employees in a variety of patient care environments who utilize complex and highly-specialized skill sets. They work together to deliver care to some of the most vulnerable and underserved patients. It is therefore imperative that the System maintain planned and adequate staffing levels so that care can be delivered in a predictable and safe manner. The current model of evaluating requests for reasonable accommodations, which accounts for the burden on Health + Hospitals, allows the System to guarantee that patient safety is not negatively affected.

Immediate Impact of the Final Rule Upon Health + Hospitals

- 20. It is Health + Hospital's understanding that the Final Rule expands definitions of terms in ways that affect how we function, specifically: "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for."
- 21. There is a lack of clarity as to who or what falls under these terms, yet Health + Hospitals must prepare for compliance with the Final Rule.
- 22. **Staffing costs.** Health + Hospitals must expend time, resources, and effort by: modifying hiring practices; double or triple-staffing emergency functions in light of limits the Final Rule places on requiring advance notice of objections; and training staff on what behavior is now permissible from objectors and how to work around objections not planned in advance.
- 23. For example, in the context of a hysterectomy at least twelve different employees are involved in delivering direct care to the patient. This includes nurses, operating room technicians, and others. If clerical staff and housekeepers are included in that figure, the number increases to at least fifteen different people. Many of those individuals are scheduled to perform services weeks or months in advance. It may be impossible to perform the procedure when even one of them—for example, a scrub nurse or certified registered nurse anesthetist—lodges a last minute objection to providing care. In such an instance, the procedure may not be able to be

rescheduled for weeks or months. This could result in harm to the patient or could discourage the patient from coming back to have the procedure performed.

24. Hiring additional staff to act as alternate providers is impracticable for Health + Hospitals. As shown below, in fiscal year 2018, Health + Hospitals directly employed the equivalent of 35,860 full-time and part-time staff; 8,433 affiliate and temporary staff persons; and 700 staff persons who provided hourly services. These salaries amounted to over \$4 billion.

FY18	H+H (Full Time & Part Time Staff)	Affiliate	Allowances	Overtime	Temporary Staffing	FY18 Total
Full Time Equivalent (FTEs)	35,860	5,657	700	2,144	2,776	47,138
Health + Hospital Corp (\$ in 000s)	\$2,588,661	\$1,208,964	\$51,931	\$155,881	\$155,529	\$4,160,966

- 25. Additional staffing would be costly. It is not clear Health + Hospitals can feasibly comply with the Rule without compromising patient care.
- 26. **Emergency care.** As a result of the Rule, and the risk that any employee may now refuse to provide patient care without advance notice to the hospital, Health + Hospitals must attempt to create contingency staffing plans to ensure that more than one of each necessary professional is available at all times in its emergency rooms.
- 27. Health + Hospitals operates under enormous budgetary constraints and does not have additional staff to perform essential functions required for a patient experiencing an emergency.

- 28. For example, a woman who arrives at a Health + Hospitals emergency room with a miscarriage or ectopic pregnancy will typically encounter at least fifteen staff members during her course of treatment.
- 29. These staffers include: Registration Clerks; Triage Nurses; Patient Care Associates; Laboratory Techs; ER Doctors; OR Technicians; Clerical Staff; Radiologists; Radiology Technicians; Staff Nurses; Housekeeping Staff; Scrub Nurses; Circulating Nurses; Anesthesiologists; and Certified Registered Nurse Anesthetists.
- 30. Just as hiring additional staff for non-emergency services would be cost prohibitive, hiring additional staff for emergency services is not realistic.
- LGBTQ health care. In order to better meet the needs of the estimated 750,000 LGBTQ individuals living in the City of New York, Health + Hospitals began collecting sexual orientation and gender identity ("SOGI") demographic information at the System's facilities. This data—identifying when, where, and why LGBTQ individuals seek medical treatment—will help the System better allocate resources. This, in turn, creates an affirming experience for LGBTQ patients at Health + Hospitals, thus reducing barriers to equitable care and improving patient outcomes.
- 32. The Final Rule threatens our effort to improve patient care. It deters LGBTQ individuals from disclosing information for fear that a System employee may refuse them services. It may even cause LGTBQ individuals to delay or refuse to seek care altogether due to stigma and discrimination in the health care setting.
- 33. *Contractual relationships.* Health + Hospitals must review contractual relationships with subcontractor institutions that are used to deliver health services in order to

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ensure that such institutions are in compliance with the Rule. In doing so, Health + Hospitals must devote substantial time and resources to this immense undertaking.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed on this 7th day of June, 2019

Machelle Allen, M.D.

Machelle all my

Senior Vice President and Chief Medical Officer NYC Health + Hospitals

Exhibit 6

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF YORK. **STATE NEW** OF COLORADO, **STATE** OF CONNECTICUT, **STATE** OF DISTRICT DELAWARE, **OF** COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, **STATE** MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, **STATE** OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION of JOHN ANDAZOLA, M.D.

1. I, John Andazola, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

- 2. I submit this Declaration in support of the State of New York's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge or on the basis of documents I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the people of southwestern New Mexico.
- 3. I am the program director of Southern New Mexico Family Medicine Program, the president of the New Mexico Primary Care Training Consortium, a board member of the New Mexico Academy of Family Physicians and a board member of the Southwest Center for Health Innovation.
- 4. I have taught medicine for 18 years and have aided in the training and placement of approximately 60 family physicians in southern New Mexico. Others have gone on to hospitals and clinics in numerous other states.
- 5. I have served in my current role as program director of the Southern New Mexico Family Medicine Program at the Memorial Medical Center in Las Cruces NM, a 199-bed acute care facility and level-four trauma center serving the State's Mesilla Valley, for the past 10 years.
- 6. I have thorough acquaintance with the Title VII mandates requiring excusal of medical students and medical residents based on religious objection. In a previous position, I experienced the consequences of existing civil rights protections when I was a provider in an environment where religious objections to abortion-related procedures led to a patient's being required to carry a nonviable pregnancy to term.

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7. I understand the current law and believe its application to those who have religious

objections to certain reproductive procedures and/or end-of-life decisions is adequate.

8. Adding to the number of persons whose objections can affect patient care gives me

great concern. It seems likely that allowing clerical staff to object to making appointments for

procedures with which they have conscience objections could inject chaos in an already complex

system of care, especially in areas such as southern New Mexico where there are few doctors and

access to any care can become a challenge.

9. Further, I am concerned about legal conflicts that could lead to sacrificing our much-

needed emergency services in order to preserve federal funds: I fear that our training hospital could

be forced to curtail Emergency Medical Treatment and Labor Act (EMTALA) emergency services

instead of risking federal funds compliant with conscience protections provided in the Final Rule.

The inherent conflict between EMTALA's mandate to provide care despite personal religious

objections in life-threatening situations and the Final Rule's mandate, 84 Fed. Reg. at 23,272, to

observe the conscience objections even in life-or-death circumstances could reasonably result in a

decision to stop providing emergency services. I believe that our hospital's provision of emergency

medical care is essential in geographic area where patients have few alternate medical sources, yet I

could also understand why our hospital could elect to stop providing emergency care rather than

sacrificing federal funds because of an application of the Final Rule.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and

correct.

Executed on this 10thth day of June, 2019

John Andazola, M.D.

Director, Southern New Mexico Family Medicine

Program, Memorial Medical Center

Exhibit 7

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF BRUCE S. ANDERSON, PH.D.

1. I, Bruce S. Anderson, Ph.D., pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

- 2. I submit this Declaration in support of the State of Hawai'i's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through State of Hawai'i Department of Health personnel who have assisted me in gathering this information from our agency, or on the basis of documents I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Department of Health ("DOH").
- 3. I am the Director of Health for the State of Hawai'i Department of Health located in Honolulu, Hawai'i.
- 4. The mission of the Department of Health is to protect and improve the health and environment for all people in Hawai'i. DOH's philosophy is that health, that optimal state of physical, mental, social, and environmental well-being, is a right and responsibility of all of Hawai'i's people. The goals of the department are to: 1) promote health and well-being; 2) prevent disease and injury; 3) promote healthy lifestyles and workplaces; and 4) promote the strength and integrity of families and communities.
- 5. During the fiscal year that ended June 30, 2018, the DOH expended a total of \$83,713,419 of federal funding awards, and \$34,124,619 of the total was passed through to subrecipients for health and human services programs.
- 6. These funds are essential to the functioning of the DOH and maintaining public health within Hawai'i.

The implementation of Final Rule will have a devastating impact on the many, many services provided to Hawai'i's people by the Hawai'i Department of Health.

7. If the Final Rule is allowed to become effective, the DOH will have to expend immense time, resources, and effort to implement it in many ways, including: modifying hiring practices; hiring double-staff for emergency functions in light of limits the Final Rule places on requiring advance notice of objections, a task that is especially difficult because Hawai'i has a considerable healthcare provider shortage, especially on the Neighbor Islands; training staff on what behavior is now permissible from conscience objectors; and determining how to work around objections not planned for in advance.

The following paragraphs describe in particular the effect the Final Rule would have on DOH's provision of care for the citizens of Hawai'i.

8. The Harm Reduction Services Branch of the DOH ("HRSB"), is deeply concerned about the potential negative impact of this Final Rule. HRSB provides safety-net services for the screening and treatment of sexually transmitted infections ("STIs"), including HIV, and HRSB works to enhance the capacity of community-based medical providers to provide STI and HIV services. To the extent that the Final Rule would result in any primary care providers refusing to provide STI screening, treatment, or prevention services, or medical care related to the prevention or treatment of HIV, or any medical providers refusing to provide any type of medical care to persons living with HIV, or to lesbian, gay, bisexual, or transgender persons, this could lead to increases in the rates of STIs, including HIV, and increased morbidity and mortality from delays in diagnosis and treatment. Moreover, even the perception among populations at increased risk of STIs/HIV that medical providers might refuse to treat them based on moral or religious beliefs would create a barrier to engaging and retaining some individuals in medical care. At this point in the HIV epidemic there are medications that are highly effective in preventing individuals from contracting HIV, and highly effective treatments that maintain the

health of individuals living with HIV and prevent them from transmitting HIV to others. The safety-net services that HRSB has implemented in Hawai'i help to ensure that cost and lack of insurance are not significant barriers to treatment. In Hawai'i, the biggest challenge to realizing the potential of these interventions to end the HIV epidemic is stigma. If implemented, the Final Rule risks individuals delaying or forgoing medical care due to the fear of discriminatory treatment by medical providers.

- 9. The Emergency Medical Services and Injury Prevention System Branch of the DOH ("EMSIPSB") provides a variety of services including Emergency Medical Services ("EMS"), Administration of the State Trauma System, bariatric transfer oversight, and the Hawai'i Poison Center. Invocation of this rule would adversely affect these services for Hawai'i's residents and visitors.
- 10. EMSIPSB contracts with agencies in the 4 counties to provide 911 emergency service: in Hawai'i County: Hawai'i County Fire/EMS; in Kauai County: American Medical Response ("AMR") Kauai; in Maui County: AMR Maui; and on Oahu: City and County of Honolulu EMS. 911 helicopter services are provided on Maui and Hawai'i County. The Maui unit serves all of Maui County including Kalaupapa, the infamous Hansen's disease refuge on the island of Molokai. Given the emergent nature of the 911 response including life, limb, and death, implementation of this rule would have devastating consequences for both residents and visitors. EMSIPSB's resources are currently stressed to the limit and therefore, it does not have the ability to dispatch a second ambulance if the original unit was not at full capacity because of application of the Final Rule.
- 11. In addition, EMSIPSB contractually provides support to Kapiolani Community College. EMS students have clinical rotations. They learn by observing and participating in

providing care for all emergency medical situations. This rule would cause confusion and adversely impact patient care as well as the students' ability to obtain their degrees if they were able to object to participating in a patient's care with no advance notice.

- transfers statewide. EMSIPSB medical directors approve the transfer and then interface with Coast Guard flight surgeons for final approval. C130s are used as the "flying ambulance" and the patient is served by the federally supported Disaster Medical Assistance Team ("DMAT"). The DMAT has a limited number of volunteer personnel and could not easily substitute personnel if assigned personnel invoke the Rule without having given notice. Invocation of this rule could be catastrophic.
- 13. DOH, through EMSIPSB, administers the Trauma System. There are eight, soon to be nine, Trauma Center hospitals and eleven critical access hospitals receiving contractual support in the State. Several of the hospitals allocate portions of this funding to support salaries for physicians and nurses. Trauma care is time sensitive. Trauma response health care providers applying this rule would cause delays in treatment and care that would adversely affect trauma care for the State's residents and visitors.
- 14. The Hawai'i Poison Center ("HPC") provides 24/7 poison emergency help from specially trained nurses, pharmacists, and physicians via tele-health. HPC personnel are not unlimited. Calls are received from the public and health care professionals. Approximately 70% of calls from the public can be managed through the call alone, thus saving hospital and EMS health care dollars. The HPC accomplishes this through its ability to make follow-up calls. Poisoning exposures, including suicide attempts, can be life threatening. Hospitals depend on

the HPC service to provide medical consultations for managing acutely poisoned patients.

Invocation of this rule could adversely affect patient care for residents and visitors.

- 15. The Final Rule gives an emergency health care provider an opportunity to object for practically any reason. Here are some examples of the possible scenarios if the Final Rule is made effective that could have life threatening consequences: 1) EMS or hospital personnel refuse to treat and transport an opioid addict (or any person with a drug related condition); 2) EMS refuses to treat and transport a septic HIV patient; 3) EMS refuses to treat and transport a patient after an attempted self-induced abortion; 4) Trauma center personnel refuse to treat a terrorist post a terror event; 5) Trauma center refuses to treat a person arrested for using their car to run over pedestrians (vehicular homicide); 6) Hospital personnel refuse to treat an Ebola patient; or 7) Poison center personnel refuse to assist suicidal caller because suicide is against their beliefs.
- 16. Recently EMS was asked to transfer a bariatric (morbidly obese) patient with multiple medical conditions overwhelming a neighbor island hospital. The patient had recently been arrested for an alleged murder. The patient was transported safely, but his care could easily have been jeopardized by any healthcare provider invoking the Final Rule, along the way.
- 17. The Public Health Nursing Branch ("PHNB") immunization clinics are staffed based on the number of appointments and the number of vaccinations clients will be receiving. If staff are not willing to counsel or vaccinate children, this will impact PHNB staffing to support that clinic. They may not be able to locate additional staff, as many are in the field on other assignments. If this occurs, PHNB may need for staff to work overtime or double up on staffing. They may need to turn clients away if they cannot provide overtime, and clients may not return. This can impact vaccination rates and community safety. With regard to family planning and

abortions, PHNB provides information and counseling to clients on pre-conception care, options during pregnancy, and other family planning options. Due to the high risk nature of PHNB's clients, if someone asked about abortion and the nurse refused to provide information, the professional client-nurse relationship would be adversely impacted and so could patient care. PHNB will have nurses supporting the Department of Human Services' ("DHS") First to Work contract in fiscal year 2020. The contract's target population is pregnant women and those with children 0-5 years of age. These clients will need counseling for pre-conception care. If this rule goes into effect, DOH may need to amend its memorandum of agreement with DHS.

18. The DOH's Developmental Disabilities Division provides services for nearly 3,000 people with moderate to severe intellectual and developmental disabilities. Primary funding is through the Medicaid 1915 (c) Home and Community Based Services ("HCBS") Waiver. The State could not operate services for this population without considerable burden without Medicaid funding. Services are provided to help people to integrate into the community in lieu of institutional care. Many of the services are provided to ensure health and safety for an extremely vulnerable population, including people with complex medical needs and behavioral issues. Many in the population need nursing care, delegated nursing services, personal assistance to perform activities of daily living, behavioral supports, supervision, and services to ensure their health, safety and protection. If funding were affected or if a waiver provider had religious or moral objections to performing a required function or working with a certain type of client, that client's health and safety could be compromised. Especially in rural areas and with lack of adequate workforce in a number of areas, this would heavily impact the ability to provide services necessary to ensure the health and well-being of the population. It would also impact the ability to meet compliance with federal requirements for community integration for HCBS

programs, and the likelihood for reverting back to care in institutions for this population would increase.

- 19. The Adult Mental Health Division ("AMHD") has very strong concerns about the possible negative impacts of this Final Rule on the adults served by both State-operated Community Mental Health Centers and contracted community purchase-of-service providers. These consumers have severe mental illnesses and are therefore very fragile and vulnerable. Having a staff member refuse to provide services to them could have devastating consequences. Continuity of care is vital for this population. If AMHD cannot know at hiring, or at least when hired, that its staff have some objections to providing certain types of care or care to certain types of people, it would not be able to ensure that staff is available to serve its consumers. It also may not be able to prevent consumers from overhearing that a staff member does not want to provide a service to that person. Additionally, Hawai'i has a severe shortage of mental health service providers, especially psychologists and psychiatrists, and this shortage is especially dire on the neighbor islands and in rural areas. If one provider has religious or moral objections to providing a certain service or to providing a service to a certain person, there may be no other options for that consumer.
- 20. For the consumers who AMHD serves, stigma is a significant barrier to receiving services. The Surgeon General of the United States identified stigma as "the most formidable obstacle to future progress in the arena of mental illness and health." The deleterious effects of labeling someone with mental illness are pervasive and widely acknowledged, and mental illness stigma has been associated with discrimination in multiple systems (e.g., education, housing, work-force, health, mental health, and judicial). Though mental illness stigma has been described as a contributor to social and sexual isolation, recent evidence suggests that it also may

increase sexual risk behaviors. Because the majority of people in psychiatric care worldwide are sexually active and people with mental illness have sharply elevated rates of HIV infection compared to the general population in most regions where they have been examined, studies of the ways in which mental illness stigma impinges on the sexuality and sexual behaviors of people with psychiatric illnesses have emerged. It is a significant health risk. The Final Rule increases the negative effects of stigma on this population; it does not "do no harm."

21. The AMHD is also required by law to provide services to persons ("defendants") who are involved in the criminal justice system who are found to be unfit to proceed to trial or to be not penally responsible for their charged crimes due to physical or mental disease, disorder, or defect (also known as "forensically encumbered"). AMHD is required by State law to provide services to these consumers including forensic examinations, fitness restoration services, therapy services, psycho-social rehabilitation services, medication management, case management, and other relevant mental health and substance abuse services. Many of these consumers have multiple mental and physical health issues, along with co-occurring substance abuse disorders. Their needs are complex, and the Final Rule would make the provision of services to this forensically encumbered population more complex than it already is. The mental health provider pool in our State is not sufficiently robust to accommodate providers who refuse to provide a service they were hired or contracted to provide, or who refuse to provide a service to all of the patients they were hired or contracted to serve. This is especially true if these providers are able to object without providing advance notice, and if AMHD has no ability to offer reasonable accommodations that the providers must accept. AMHD's consumers will be the ones suffering the harms caused by the Final Rule. Forensically encumbered consumers are part of the criminal justice system and they have constitutionally protected rights. The Final Rule will cause a risk of overburdening Hawai'i's criminal justice system's duty to provide timely forensic evaluations and fitness restoration services, due process, and other constitutional rights to defendants if it allows providers in the system to object to providing services. The Final Rule would hamper Hawai'i's ability to ensure that forensically encumbered defendants receive the timely and appropriate services they need from AMHD.

- 22. The Child and Adolescent Mental Health Division ("CAMHD"), is the carve-out Medicaid provider for all plans for the most severely affected youth and adolescents who have behavioral and mental health issues. CAMHD serves approximately 2,500 youth a year with a broad spectrum of system of care services ranging from outpatient evaluations, to intensive inhome therapy, to residential and hospital-based programming. Inherent in the etiology of many, if not the majority, of our clients are Adverse Childhood Events (ACEs) that have contributed to the behavioral manifestations and symptoms that these youth display. The familial and societal condemnation of these youth and adolescents often contributes to their eventual diagnosis. One of the most common situations for this condemnation arises when a child discovers that he or she is gay or gender non-conforming and as a result is rejected by family or society for religious reasons. Alienation from family or community can and often does result in low self-esteem, guilt, feelings of loneliness, despair, and depression, which in children is often manifested in behaviors like running away, self-mutilation, substance abuse, criminal behavior, and attempted and sometimes realized suicide. Suicide is the leading cause of death for Hawai'i residents ages 10 to 19 years old; surpassing traffic crashes, cancers, drownings, and heart disease. The teenage suicide rate in Hawai'i exceeds the national rate.
- 23. In our own experience here in Hawai'i, up to 60% of those incarcerated at the Hawai'i Youth Correctional Facility, (HYCF) had genuine mental health diagnoses. Fortunately,

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in recent years, we have been hugely successful in diverting over 50% of that former inmate

population into mental health treatment, with the thinking that emotional supports rather than

incarceration, which often only reinforces societal rejection, is a better alternative for the lives of

these youth. As mentioned in the section regarding AMHD above, mental health care providers

are in very short supply in Hawai'i. The suggested rule change would further restrict access to

care, but more importantly, it would reinforce the rejection these youth feel, thus making their

problems and behaviors snowball. It is CAMHD's belief that acceptance, not rejection, can best

help these youth to feel like they belong, enhance their self-esteem, and help them to better

integrate as adults into society. To send them the message that they are unacceptable is both

professionally unethical and counter-therapeutic.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and

correct.

Executed on this <u>/</u> day of June, 2019.

Bruce S. Anderson, Ph.D.

Smuchhaderson

Director of Health State of Hawai'i

Exhibit 8

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF SHARON C. BOYLE

I, Sharon C. Boyle, do hereby depose and state the following:

- I am General Counsel at the Massachusetts Executive Office of Health and Human Services ("EOHHS").
- 2. Prior to being named General Counsel in 2018, beginning in 2003 I served in a variety of roles at the Executive Office of Health and Human Services including Deputy General Counsel, Chief MassHealth Counsel and First Deputy General Counsel.
- 3. I am familiar with the Final Rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegation of Authority" ("Final Rule").
- 4. I have either personal knowledge of the matters set forth below or, with respect to those matters for which I do not have personal knowledge; I have reviewed information gathered for me in my capacity as General Counsel.
- 5. EOHHS is a cabinet-level department responsible for providing health and human services to eligible individuals in Massachusetts. It is comprised of twelve agencies and directly manages the Commonwealth's Medicaid program, called MassHealth.
- 6. The MassHealth program provides health care benefits to one in four Massachusetts residents, either through its fee for service programs or through its contracted managed care providers.
- 7. EOHHS also oversees public health programs—including infectious disease and substance abuse programs—that impact every community in the Commonwealth. EOHHS agencies are also responsible for licensing and regulating most health care professionals and facilities in Massachusetts.

- 8. EOHHS also manages a network of health care providers including a network of public hospitals. The four public hospitals operated by the Department of Public Health alone employ more than 1,500 staff members and provide acute and chronic medical care to thousands of residents across the Commonwealth each year.
- 9. Federal funding is essential to EOHHS's ability to continue to provide critical services and protect public health in Massachusetts.
- 10. In federal fiscal year 2018, the EOHHS received approximately \$11B in federal funds from the Medicaid and CHIP programs. In fiscal year 2019, EOHHS agencies estimate receiving additional federal grants for approximately \$208.1M in federal funds for public health and prevention, \$124.7M for substance abuse prevention and treatment, \$3.2M in biomedical and behavioral research, \$2.2M for STD treatment & prevention and \$6.75M for immunizations.
- 11. The Final Rule affects the terms and conditions for this funding. As a result, EOHHS must expend time and resources reviewing and determining how to comply with the Rule while also continuing to fulfill responsibilities and mandates under state law.
- 12. If the Final Rule goes into effect, it would interfere with EOHHS agencies' ability to carry out their regulatory functions and operate health care programs and facilities consistent with Massachusetts laws and regulations.
- Department of Public Health (DPH) hospitals, which must continue to provide high-quality, non-discriminatory care and services to patients consistent with Massachusetts laws and regulations. Existing DPH policies and practices balance conscience protections for health care workers with other important factors including patient care and safety and the operational needs of its hospitals. The final rule does not provide similar balancing protections and adopts a different

approach to consciousness objections, including by limiting DPH's ability to make staffing

decisions to ensure that employees can carry out critical job requirements, are not placed in

circumstances that conflict with moral and religious beliefs, and do not jeopardize patient care.

14. Additionally, MassHealth's regulations prohibit providers from engaging in any

practice that constitutes unlawful discrimination under any state law or regulation on the basis of

race, color national origin, sex (including pregnancy, gender identity and sex stereotyping) age or

disability. 130 CMR 450.202 (B)

15. MassHealth's regulations also prohibit MCOs, Accountable Care Partnership

Plans, Primary Care ACO's, PCC's, the behavioral health contractor, SCOs and ICOs

(collectively, Managed Care Entities or MCEs) from unlawfully discriminating and using any

policy or practice that has the effect of unlawfully discriminating on the basis of health status,

need for health care services, race, color, national origin, sex, sexual orientation, gender identity,

or disability. 130 CMR 450.202(C).

16. Violation of 130 CMR 450.202(B) and (C) may result in administrative action –

including monetary sanctions or contract termination or referral to the state Commission Against

Discrimination.

17. The Final Rule jeopardizes MassHealth's ability to enforce its regulations as set

forth above.

PURSUANT TO 28 U.S.C. § 1746, I DECLARE UNDER PENALTY OF PERJURY THAT THE

FOREGOING IS TRUE AND CORRECT.

Executed on this / 2day of June, 2019

Sharon C. Boyle

General Counsel

Executive Office of Health and Human Services

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Exhibit 9

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF JANET BRANCIFORT

1. I, Janet Brancifort, pursuant to 28 U.S.C. § 1746, hereby declare that the following

is true and correct:

- 2. I submit this Declaration in support of the State of Connecticut's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule" or "Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through the Connecticut Department of Public Health ("DPH") personnel who have assisted me in gathering this information from our agency, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon DPH.
- 3. I serve as a Deputy Commissioner for DPH, the State of Connecticut's lead agency for public health policy and oversight. DPH provides coordination and access to federal initiatives, training and certification, technical assistance and oversight and specialty public health services that are not available at the local level.
- 4. I am a Registered Respiratory Therapist and have a Master of Public Health degree. I have 41 years of experience in health and human services, including clinical, research and management experience. I have 13 years of experience in public health administration at DPH. I served as a manager in the Maternal Child Health Section at DPH for seven years prior to being appointed as a Deputy Commissioner in 2014.

I. The Role of Connecticut DPH in Serving the Health and Wellness of Connecticut's Residents

5. DPH is a lead state agency in a comprehensive network of public health services in Connecticut. DPH works in partnership with local health departments to coordinate and access federal initiatives, training and certification, technical assistance and oversight, and specialty public health services. It maintains up-to-date Connecticut health information and analytics which are

used by the Governor of Connecticut, the Connecticut General Assembly, the federal government and local communities to monitor the health of Connecticut's residents, to set health policy priorities and evaluate the effectiveness of health policy. DPH focuses on assuring quality and safety in health care to achieve positive health outcomes. It also seeks to streamline the administrative burden on regulated personnel, facilities, and programs.

- 6. DPH's mission is to ensure equitable access to resources and high quality health services for all of Connecticut's residents, to address the unique health needs of vulnerable populations living in our State, and to do no harm. Connecticut General Statutes § 19a-4j establishes an Office of Health Equity within DPH to improve the health of all Connecticut residents by working to eliminate differences in disease, disability and death rates among people of different races, ethnicities, ages, genders, socioeconomic position, immigration status, sexual minority status, language, disability, homelessness, mental illness or geographic area of residence. DPH's health equity policy is focused on achieving improved health outcomes for these groups across the State.
- 7. The majority of Connecticut's public health programs and services are supported by federal funds. For fiscal year 2019, DPH administered a budget of approximately \$306 million. Forty-three percent of DPH's 2019 budget, or \$132 million, was federal grant funding from various agencies including: HHS, the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Department of Homeland Security (DHS), and the Social Security Administration (SSA). The remainder of DPH's budget is comprised of state allocations (39%) and private or other sources including state approved bonding (18%).
 - 8. DPH received approximately \$52,632,185 in funds from HHS in Fiscal Year 2018.

- II. Connecticut's Department of Health Passes Through HHS Funds to Sub-Recipients to Support Programs that are Critical to Maintaining and Improving the Health and Wellness of Connecticut's Residents
- 9. DPH passes through substantial amounts of the HHS funds to third parties, such as private healthcare providers. In total, DPH has 135 contractual and inter-agency relationships with sub-recipients that DPH uses to deliver health services. A few of the critical programs DPH administers with HHS funds are described below.
- DPH passes HHS funds to Planned Parenthood for the DPH Family Planning program that prevents unintended pregnancy and decreases the birth rate among girls age 15-17 and provides them with primary reproductive health care. This program provides preventive reproductive health care, pregnancy prevention and testing/treatment of sexually transmitted disease and Human Immunodeficiency Virus (HIV) testing at 12 Planned Parenthood centers across Connecticut, and at four subcontracting sites, primarily to low income men and women of reproductive age. The program also provides training and educational programs for professionals serving this group.
- 11. DPH passes HHS funds through to the Personal Responsibility Education Program (PREP). PREP is an evidence-based, teen pregnancy, HIV, STD prevention program for at-risk youth ages 13-19 and pregnant or parenting youth up to age 21 delivered in school and/or community-based settings. PREP's prevention strategies are tailored to youth with histories of abuse, neglect, and trauma. In particular, PREP serves youth in the child welfare or juvenile justice systems who are at a greater risk for unplanned pregnancies and Sexually Transmitted Infections (STIs).
- 12. DPH passes HHS funds through to the School Based Health Centers (SBHC) program. SBHC provides health services to students at or near schools. SBHC services are

focused on, but not limited to, students who do not have access to a family doctor, or whose families have little or no health insurance. The comprehensive health care provided by SBHC helps Connecticut's students remain in school, stay healthy and be ready to learn.

- 13. DPH passes HHS funds through to the Children & Youth with Special Health Care Needs (CYSHCN) program. CYSHCN provides services for children who have, or are at increased risk for, a chronic physical, developmental, behavioral or emotional condition. CYSHCN provides medical home care coordination networks, coordination of services, information and referrals, provider and family outreach and parent-to-parent support, and access to respite and extended services. All of these services are tailored to children who require more health and social services than the general population.
- 14. DPH passes HHS funds through to the Office of Injury Prevention Intentional Injury Prevention Program. This program is a collaborative effort between DPH and the Connecticut Suicide Advisory Board (CTSAB) and the Child Maltreatment Domestic Violence Collaborative. The program seeks to reduce violence-related deaths and injuries caused by homicides, assault, suicide and suicide attempts, domestic violence, child abuse, and sexual violence. DPH's partners in this program have developed specific initiatives related to suicide prevention, fall prevention, concussion and traumatic brain injury prevention, sexual violence prevention, and opioids and prescription drug overdose prevention.
- 15. DPH passes HHS funds through to the Connecticut Breast and Cervical Cancer Early Detection Program (CBCCEDP). CBCCEDP is a comprehensive screening program available throughout Connecticut for women who are medically underserved. The program seeks to significantly increase the number of women who receive breast and cervical cancer screening, diagnostic and treatment referral services. The program services, which are provided

free of charge through DPH's statewide health care provider network, include: office visits, screening and diagnostic mammograms, breast biopsies, breast ultrasounds, fine needle aspirations, pap tests, colposcopies and colposcopy-directed biopsies, loop electrosurgical excision procedure (LEEP), surgical consultations, and clinical breast exams.

- 16. DPH passes HHS funds through to the Newborn Hearing Screening Program. This program seeks to reduce the loss to follow-up/loss to documentation about infants who have not passed a physiologic newborn hearing screening examination prior to discharge from the newborn nursery by utilizing specific, targeted and measurable interventions. Infants who do not pass newborn hearing screening and do not consistently receive follow-up testing are at risk for speech, language, social, and other delays.
- 17. DPH passes HHS funds through to Family Wellness Healthy Start (FWHS). FWHS provides care coordination, health education, referral and follow-up services and support during pregnancy and for up to two years postpartum to low income women and their babies in Hartford and New Britain, Connecticut. FWHS seeks to improve access to women's wellness visits; promote quality services; strengthen family resilience; achieve collective impact; and increase accountability through quality improvement, performance monitoring and evaluation.
- 18. DPH passes HHS funds through to Perinatal Case Management (PCM). PCM serves very high risk pregnant and parenting teens, including those with a history of substance abuse, mental illness, child welfare involvement, low income, unstable housing/homeless, and those at-risk for school drop-out and domestic violence. PCM provides intensive case management, home visits, parenting support and education, referrals and follow-up to mental health providers, health care, shelters, and substance abuse treatment to this group.

- 19. DPH passes HHS funds through to providers for HIV testing in clinical and non-clinical health settings. These HHS funds enable effective behavioral interventions, syringe services, condom distribution, social marketing, pre-exposure prophylaxis (PrEP) navigation services, health insurance premium assistance, CT AIDS Drug Assistance Program, treatment adherence, medical case management, early intervention services, outpatient ambulatory services, substance abuse treatment, mental health treatment, nutritional therapy, medical transportation, housing, oral health services and emergency financial assistance.
- 20. DPH passes HHS funds through to hospitals and local health departments to provide comprehensive testing and treatment for infected clients and those exposed to any Sexually Transmitted Disease (STD). These STD program funds pay for referrals for other services that clinicians determine to be needed.
- 21. The programs described in these preceding paragraphs—which are just a sampling—are absolutely essential to maintaining and improving public health in Connecticut. The loss of funding for any of these programs would be extremely detrimental to the health and well-being of Connecticut's residents.

III. The Final Rule Poses a Very Real Financial and Programmatic Risk to DPH and Its Sub-Recipient Entities

- 22. My understanding of the Final Rule is that the risk of loss of funds for DPH is both real and very hard for DPH to predict or prevent. DPH is at risk of losing all HHS funds if one of the 135 sub-recipients fails to comply with the Rule; but DPH's ability to control the actions of a sub-recipient is limited.
- 23. Even if DPH expends the substantial resources that would be needed to educate sub-recipients about the Final Rule, DPH may not be able to ensure that steps have been taken by

the sub-recipients to comply with the Final Rule. I am not sure how DPH will be able to adequately monitor sub-recipients on an ongoing basis for compliance.

- 24. Moreover, if one or more employees of a sub-recipient declines to perform a job, without notice, DPH will not be able to adequately assess whether any potential sub-recipient can actually provide the services contemplated by an award of funds. If the Final Rule prevents DPH from even screening sub-recipients for their ability to perform the procedures contemplated by an award of funds, then residents of Connecticut may not receive necessary care. The risk posed by an employee's refusal to provide care is especially acute for small-scale providers who will find it more difficult to double-staff to provide required care. In the long term, this may result in fewer awards to small-scale providers by DPH and a decrease in the number of services available to Connecticut's residents.
- 25. If HHS strips Connecticut's DPH of all of its funding because of an action of a sub-recipient, I am reasonably certain DPH will not be able to fill the gap to continue many, or maybe any, of these critical programs.

IV. Existing State Regulations and Policies Protect Connecticut Employees' Rights to Refuse to Provide Non-Emergency Care Based Upon Religious, Moral or Ethical Objections

- 26. My understanding is that Connecticut health care providers are already given protection to refuse to provide care to which they have an ethical, moral or religious objection. In Connecticut, existing regulations permit a healthcare provider who has an ethical, philosophical, or religious objection to certain procedures to decline to treat a patient, but require that the provider must turn over care of the patient without delay to another provider.
- 27. For example, a healthcare provider is not required to implement a "do not resuscitate order," but must turn over care to another provider who will implement the order and,

pending the assumption of care by another provider, must honor the order. See Regs. Conn. State Agencies § 19a-580d-9(a).

- 28. Connecticut law also allows an individual to refuse to assist in a non-emergency abortion if doing so would violate his or her judgment, philosophical, moral, or religious beliefs. *See* Regs. Conn. State Agencies § 19-13-D54.
- 29. I am also aware that some healthcare providers that receive HHS funds through Connecticut also have internal policies that address religious objections. For example, the University of Connecticut Health Center has an existing policy that permits an individual to raise a religious objection to participating in a procedure. The individual must do so in writing, and there is a procedure for evaluation of the request in light of the needs of the patient.

V. <u>If Healthcare Providers in DPH Funded Programs Are Empowered to</u> Refuse Care Without Prior Notice, Connecticut Residents Will Be Harmed

- 30. My understanding of the Final Rule is that it expands definitions of terms in ways that affect how DPH will function in the future. In particular, the Final Rule's definition of "assist in the performance" increases the number of individuals who may raise religious objections to go beyond covering healthcare providers who directly participate in a medical procedure. Under the Rule, as I understand it, now clerical staff and others who only indirectly aid a patient by scheduling a procedure or referring a patient to a specific healthcare provider can refuse to perform those functions. I am also concerned about the expanded or uncertain scope of the terms "discrimination" and "health care entity."
- 31. The lack of clarity as to who or what services fall under the Rule's terms creates a situation where the State of Connecticut, through DPH and other state agencies, must prepare for compliance with the Rule without a clear understanding of who the Rule applies to or how tangential their behavior may be and still fall under the Rule.

- 32. DPH must expend time, resources, and effort to comply with the Rule. DPH may have to modify hiring and contracting practices, as well as double-staff programs and services and other functions where there is a higher likelihood of an objection.
- 33. If a healthcare provider refuses to provide care, this will result in poorer health outcomes for Connecticut residents. These poor health outcomes are very serious and include increased infant HIV mortality rate, increased neonatal abstinence syndrome, increased HIV, HCV, STD and overdose related morbidity and mortality rates for populations in Connecticut. The risk of poor health outcomes will be exacerbated if a provider does not even need to provide notice of a refusal prior to refusing to provide care.

VI. If Providers Are Empowered to Refuse Care, the Final Rule Could Have An Especially Negative Impact on the Most Vulnerable Residents of Connecticut

- 34. Many of DPH's programs described above in Section II provide life-saving services to populations most in need, such as infants, youth, LGBT persons, women and families with limited income, and individuals who are at higher risk for HIV, STD, and opioid related overdoses in Connecticut.
- 35. The STD Control Program is a good example of the serious risk posed by a provider's refusal to provide care, without notice, even once. The STD Control Program receives funding from HHS to prevent, monitor the prevalence of, and control three major STDs: chlamydia, gonorrhea and syphilis. Disease Intervention Specialists (DIS) who work in this program are specially trained epidemiologists who link individuals testing positive for syphilis with treatment and help to locate their partners. Their work prevents further spread of the disease. DPH must be able to ensure that providers in this area are willing to actually fulfill the duties of the program.

- 36. There has been a significant increase in STDs in recent years across Connecticut, especially in young adults and adolescents, pregnant women and men who have sex with men. These individuals are often co-infected with other STDs, which makes them more susceptible to HIV. The STD Control Program helps to get these individuals into care and treatment as early as possible to protect them and the public at large.
- 37. Though easily treatable, untreated STDs can have lasting and devastating impacts, such as neurological and ocular syphilis, infertility in women and congenital syphilis which can lead to poor pregnancy outcomes, including miscarriages, premature births, stillbirths, or death in newborns. Babies exposed in utero can have deformities and delays in development. Connecticut had two cases of congenital syphilis in 2018. Just these two cases will have significant effects and indicate that DPH needs to increase testing and treatment of pregnant women.
- 38. If a patient is denied care or treatment for these, and other diseases, even one time, or if funding for these programs is stripped, the health of Connecticut's residents will be harmed. As a result, the State will almost certainly incur increased health care costs from delayed or denied treatment.

VII. The Final Rule's Threatened Loss of Funds Will Especially Impact Connecticut's Most Vulnerable Residents

39. The loss of HHS funds to the State due to non-compliance by a sub-recipient would result in negative health outcomes to the citizens of Connecticut because it could substantially reduce the ability of the State to provide healthcare to its citizens. Connecticut is facing another budget crisis and it is uncertain whether the Connecticut legislature would be

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willing and able to allocate sufficient funds to programs impacted by a loss of HHS funds by

DPH.

40. If Connecticut is stripped of HHS funds then it will not be able to provide the

same quality healthcare services like HIV-related services to the LGBT population. An

adequately funded HIV workforce is necessary to continue to provide critical prevention

education to youth, routine HIV testing, linkage to care, and treatment services. If funding for

HIV programs is lost, these patients and clients will be further marginalized and have poorer

health outcomes. Ultimately, the State of Connecticut will incur some or all of the cost for this

failure to provide adequate care.

I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true

and correct.

Executed on this 12th day of June, 2019

JANET BRANCIFOR

DEPUTY COMMISSIONER.

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

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Exhibit 10

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF. RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, and COOK COUNTY, ILLINOIS,

Plaintiffs,

V.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES OF AMERICA,

Defendants.

CIVIL ACTION NO. 1:19-cv-04676-PAE

DECLARATION OF DEANNA CHAREST

1. I, Deanna Charest, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

- 2. I submit this Declaration in support of the State of Michigan's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of the United States Department of Health and Human Services, and United States of America regarding the recently issued rule entitled Protecting Statutory Conscience Rights in Health Care; Delegations of Authority ("Final Rule"). I have compiled the information in the statements set forth below either through personal knowledge, through Michigan Department of Health and Human Services personnel who have assisted me in gathering this information from our institution, or on the basis of documents that I have reviewed. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Michigan Department of Health and Human Services.
- 3. I am the Reproductive Health Unit Manager within the Division of Maternal and Infant Health, Bureau of Family Health Services at the Department of Health and Human Services located in Michigan. I have a Master's in Public Health and more than fifteen years' experience in family planning and reproductive health, of which thirteen years has been with the Michigan Family Planning Program.
- 4. The MDHHS Family Planning Program has serious concerns related to the United States Department of Health and Human Services Final Health Care Refusal Rule. The Final Rule would significantly expand the ability of health care providers to withhold treatment, counseling, or medical information based on their religious or moral beliefs.
- 5. As an HHS Title X funded program, the Rule could jeopardize the MDHHS Family Planning Program's ability to meet the requirements of the Title X program, including providing services without discrimination, assuring access to a broad range of contraceptive methods, and providing services to minors.

- 6. The Rule would allow providers to withhold information about FDA approved contraceptive methods, counseling and referrals to abortion services, emergency contraception information, and vaccinations such as HPV and sterilization services.
- 7. The Rule could also allow providers to deny services to entire Michigan populations, such as minors, unmarried clients, clients living with HIV/AIDS, and LGBTQ people.
- 8. Clients who are low-income, uninsured or under-insured, or who live in rural communities could be disproportionately affected as alternative health care providers are not readily accessible.
- 9. The Final Rule does not consider the needs of Michigan clients and could create confusion about the rights and responsibilities of health care providers, entities, and clients and jeopardize the trusted client-provider relationship.
- 10. Withholding information from clients could also impact their ability to give informed consent for some health care services.
- 11. The Final Rule will have impacts for Michiganders and MDHHS in other areas outside the scope of the Family Planning Program, such as end-of-life care, blood transfusions, vaccinations, substance use disorders, civil rights laws related to employers, and likely many more.
- 12. Given that health care institutions owned and operated by Michigan will have no notice if one of their staff objects to the provision of a particular service or activity, those institutions will have to dramatically increase the staff available to serve patients in order to ensure that care is delivered.
- 13. The cost of this parallel staff will be unduly burdensome to the State institutions and to Michigan itself.

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14. This is especially true in areas in which there are few other health care providers, such as rural areas, and in areas in which other providers are more likely to be religious and have objections of their own to the provision of certain types of care.

Executed on this 6 day of June, 2019

Deanna Charest

Reproductive Health Unit Manager Division of Maternal and Infant Health, Bureau of

Family Health Services

Michigan Department of Health and Human Services