

Exhibit 11

**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

CLARK DECLARATION

DECLARATION OF SARAH CLARK

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

2. I am the Chief Financial Officer for the Vermont Agency of Human Services (“AHS”). I oversee the Agency’s budget of \$2.6 billion, which includes \$1.4 billion in federal funds. I am responsible for budget development, federal financial reporting, federal cost allocation plans and managing the receipt and reconciliation of federal funds. I have worked in a financial capacity for the State of Vermont for 15 years. I have been the CFO of AHS for 4.5 years. I have a Masters’ Degree in Business Administration from the University of Maryland, and a Bachelor’s degree from American University.

3. I submit this Declaration in support of the State of Vermont’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”).

4. I make the statements set forth below based on my personal knowledge, through information obtained from other AHS personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me.

5. Medicaid is the national medical insurance program for the poor, which is jointly financed by state and federal government. Vermont’s Medicaid program operates pursuant to federal approval as a demonstration project under Section 1115 of the Social Security Act (SSA), 42 U.S.C. § 1315.

CLARK DECLARATION

6. Since 2005, Vermont has operated its Medicaid program under a Section 1115 waiver, using a public managed care-like model for health care delivery. Vermont Medicaid contracts directly with providers to deliver care to Medicaid members. Provider contracts stipulate that providers must be in compliance with all applicable state and federal laws. There are 17,189 individual providers enrolled in Vermont Medicaid. Providers include health care professionals working in solo or small practices, pharmacies, hospitals, residential treatment facilities, and specialists in numerous areas including obstetrics, pediatrics, and behavioral health.

7. Vermont's Medicaid program covers a wide variety of procedures and services, all of which must be medically necessary to qualify for Medicaid coverage. Covered benefits include, but are not limited to, the following: inpatient and outpatient hospital services; family planning services; Federally Qualified Health Center services; Rural Health Clinic services; transportation to necessary medical care; and services related to birth and pregnancy.

8. In state fiscal year 2018, Vermont spent \$1.06 billion in federal funds on services under its Medicaid program. This includes Administrative Costs and the State Children's Insurance Program. Vermont receives majority of federal funding for Medicaid from the Center for Medicare and Medicaid Services ("CMS") which is a program of HHS.

9. Medicaid recipients include numerous vulnerable populations: children, individuals with physical and cognitive disabilities, and individuals with complex, long term health conditions. Disruption of care and loss of established provider relationships for such individuals will greatly increase incidence of preventable illness and otherwise manageable symptoms of chronic illness, as well as increasing the risk of catastrophic health events and death.

10. To the extent that "health care entity" as that term is used in the Final Rule includes contracted providers (clinics, hospitals, practitioner groups), a single staff member or practitioner's

CLARK DECLARATION

decisions with respect to “assist[ing] in the performance” of care will not only disrupt the care of individual patients dependent on that provider, but also the contractual relationship between the contracted provider and Vermont Medicaid.

11. If contracted provider(s) refuse care to Medicaid members, Medicaid must cover care from an alternate provider. In many communities in Vermont, the number of potential providers for both primary and specialty care is limited. Refusals to provide care and attempts to accommodate those refusals when the Final Rule goes into effect would abruptly change the provider and Medicaid relationships in unpredictable and disruptive ways.

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

Executed on this 13th day of June, 2019



Sarah Clark
Chief Financial Officer
Vermont Agency of Human Services

CLARK DECLARATION

Exhibit 12

**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 HAWAII,
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
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SERVICES; ALEX M. AZAR II, *in
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STATES OF AMERICA,

Defendants.

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

DECLARATION OF LORI A. COYNER

COYNER DECLARATION

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

2. I am the Medicaid Director at the Oregon Health Authority (“OHA”), the state agency responsible for public health programs in the State of Oregon, including administration of Oregon’s Medicaid program. My educational background includes a Master of Arts degree in Statistics and over two decades of research, publication, and teaching in biostatistics and public health topics. Since 2000 I have worked in public, private, and academic settings in the field of public health policy and health administration. I served as Director of Health Analytics for OHA from 2013 to 2015 and as Medicaid Director from December 2015 to July 2017 and from February 2019 to the present.

3. I have over 20 years of experience in budgeting and developing programs in health care policy, public health, and clinical research, including structuring and implementing Oregon’s the Oregon Health Plan (“OHP”), Oregon’s managed care Medicaid program that includes coordinated care organizations (“CCOs”).

4. I submit this Declaration in support of the State of Oregon’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”).

5. I make the statements set forth below based on my personal knowledge, through information obtained from other OHA personnel who have assisted me in gathering this information

COYNER DECLARATION

from our institution, or on the basis of documents that have been provided to and/or reviewed by me.

6. The Oregon Health Authority operates a number of research, education, public health monitoring, and outreach programs, but the Oregon Health Plan is the fiscally largest OHA program and directly affects the lives of over 970,000 Oregonians across all thirty-six counties in the State. OHP members include families (including 400,000 children), people with disabilities, and people with severe long term illnesses such as HIV and Hepatitis C.

7. Medicaid is the national medical insurance program for the poor, which is jointly financed by state and federal government. OHP operates pursuant to federal approval as a demonstration project under Section 1115 of the Social Security Act (SSA), 42 U.S.C. § 1315.

8. Oregon has operated its Medicaid program under a Section 1115 waiver since the 1990s, and since July 2012 has operated using the coordinated care model for health care delivery. OHA contracts with CCOs and makes a capitated per member per month payment to each CCO for that CCO's OHP members. CCOs contract with providers to deliver care to OHP members. Providers include physicians, pharmacies, hospitals, residential treatment facilities, and specialists in numerous areas including obstetrics, pediatrics, and behavioral health.

9. OHA receives a majority of the funding for OHP (between \$4 billion and \$5 billion annually) from the Centers for Medicare and Medicaid Services ("CMS") which is an agency within HHS.

10. As of May 2019 there are 15 CCOs operating in Oregon. In the majority of Oregon counties there is only one CCO enrolling OHP members. Those CCOs in turn have limited numbers of providers, particularly in rural counties, with whom they contract to care for OHP members.

COYNER DECLARATION

11. CCOs enter into annual contracts, including the per member per month reimbursement rate, with OHA to cover care for OHP members. The contracts require the CCOs to comply with all applicable laws and regulations, including Medicaid regulations and Oregon insurance laws.

12. The rates themselves are set on a multi-year cycle using an actuarial process that takes into account the demographic and health characteristics of the covered population, and past cost and utilization data.

13. To the extent that “health care entity” as that term is used in the Final Rule includes contracted providers (clinics, hospitals, practitioner groups), a single staff member or practitioner’s decisions with respect to “assist[ing] in the performance” of care will not only disrupt the care of individual patients dependent on that provider, but also the contractual relationship between the contracted provider and the CCO.

14. If contracted provider(s) refuse care to OHP members, the terms of the CCO contracts require CCOs to cover care from an alternate provider. In many communities in Oregon, the number of potential providers for both primary and specialty care is limited. Refusals to provide care and attempts to accommodate those refusals when the Final Rule goes into effect would abruptly change the financial structure underlying the provider and CCO relationships in unpredictable and disruptive ways, thus destabilizing the entire OHP coordinated care structure.

15. To the extent the CCOs themselves are “health care entities” under the Final Rule, CCOs may seek to opt out of covering procedures, treatment, or prescriptions. Such refusal may conflict with Oregon laws regarding the coverage of certain procedures or conditions, and will also

COYNER DECLARATION

disrupt the rate setting process which depends on analysis of past costs and utilization combined with predicted costs and utilization across whole patient populations.

16. If any CCO declines to cover a procedure or course of treatment for an OHP member, that CCO may be in breach of Oregon law, the CCO/OHA contract, or both. Termination of a CCO agreement will result in all of that CCO's members losing coverage, and corresponding disruption of care, particularly in the majority of the state where there is no alternate CCO and few if any alternate providers.

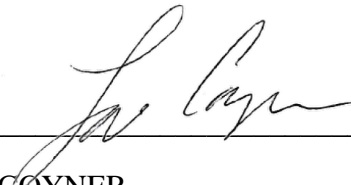
17. OHP members include numerous vulnerable populations: children, individuals with physical and cognitive disabilities, and individuals with complex, long term health conditions. Disruption of care and loss of established provider relationships for such individuals will greatly increase incidence of preventable illness and otherwise manageable symptoms of chronic illness, as well as increasing the risk of catastrophic health events and death.

18. The OHA does not have a means to replace whole provider networks or coverage in entire counties. In some areas and for some populations, OHA could move to a fee-for-service coverage model, but that would not solve the provider shortage in some areas, nor would it be possible to convert to fee-for-service on a large scale immediately in response loss of whole portions of the coordinated care network.

19. Losing the cost benefits of a coordinated care model of health care coverage and delivery would result in increased health care costs, including both direct care and ancillary costs in ways that it is presently difficult to quantify.

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

Executed on this 10th day of June, 2019



LORI A. COYNER

Medicaid Director, Oregon Health Authority

COYNER DECLARATION

Exhibit 13

**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 HAWAII,
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,

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UNITED STATES DEPARTMENT
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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 THOMAS M. DALY

1. I, Thomas M. Daly, FHFMA, 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 University Hospital personnel who have assisted me in gathering this information from our institution, 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 University Hospital.

Background

3. I am the Chief Financial Officer ("CFO") at University Hospital located in Newark, New Jersey. I hold a BBA in Accounting and have been employed as CFO since July 21, 2008. I am also a Fellow of the Healthcare Financial Management Association ("HFMA").

4. In my capacity as CFO, I oversee the hospital's Finance and Health Information Management departments. I am responsible for direct oversight of establishing and operating within budgetary constraints. Moreover, I regularly coordinate with University Hospital's Chief Human Resources Officer, who is responsible for the hospital's current conscience objection accommodation policy. I anticipate that the Final Rule, if it takes effect, would likely have immediate financial consequences impacting areas over which I have direct oversight and responsibility.

5. University Hospital is an academic medical center and one of three Level One Trauma Centers in New Jersey. The hospital has over 500 medical staff, 140 adjunct medical staff, and 603 residents. University Hospital is the principal teaching hospital for Rutgers Biomedical and Health

Sciences (“RBHS”). University Hospital educates a large number of students, including approximately 762 medical students and 420 dental students annually. In addition, University Hospital educates students from a number of other RBHS schools, such as the schools of Nursing, Pharmacy, and Health Professions.

6. University Hospital is the principal research partner for Rutgers New Jersey Medical School and is currently supporting over 100 open clinical trials, the vast majority of which are federally funded. These trials will likely have a material impact on future patient care in New Jersey and around the world.

7. University Hospital consists of numerous departments, including Emergency Medicine, Trauma, and Family Health Services. Among the services provided to patients are vaccinations, abortions, sterilizations, end-of-life care, gender affirmation surgeries, and counseling and referral. The hospital also supports 18 distinct clinical New Jersey Medical School departments functioning within University Hospital.

8. The hospital is a critical medical center for patients in New Jersey’s largest city. Over 16,000 patients are admitted to the hospital each year. The hospital has another 172,000 outpatient visits and more than 90,000 emergency room visits each year.

9. University Hospital is New Jersey’s only public hospital, operating as an instrumentality of the State, with an operating budget of over \$700 million per year. Approximately \$525 million of the hospital’s budget consists of a combination of federal and state funding. The hospital received a total of \$516 million in Medicare and Medicaid funding in FY2018, with a portion of Medicaid funding coming from state matching funds. Additionally, in FY2018, University Hospital received \$439,000 in federal grant funding to improve New Jersey’s ability to prepare for, respond to, and recover from an Ebola or other emerging infectious disease

event. University Hospital also received over \$700,000 for emergency preparedness and for state-wide medical coordination among its public health, healthcare, and emergency management systems. The Medical Coordination Center program took the lead in coordinating the responses to the Flight 1549 landing in the Hudson River, Hurricane Earl, Hurricane Irene, and Hurricane Sandy. Concurrently, it played a significant role in the development of several major statewide and regional plans including the Port Security Plan, Rail Security Plan, Prudential Center Plan, Newark Liberty International Plan, National Disaster Medical System Plan for Newark Liberty International Airport, and the Tropical Storm/Hurricane Plan. In light of the volume of federal funding received by University Hospital for these activities, discontinuance of or significant reduction in federal funding would have great adverse effects on the operation of the hospital, the ability prepare for emergencies and outbreaks, and patient care.

10. University Hospital is the largest provider of uncompensated care in the State. The funds received through HHS are crucial to the financial health of the hospital and its ability to provide equitable care to all of New Jersey's residents. Any reduction in funding to University Hospital could prove disastrous to the care provided to vulnerable and low-income populations in New Jersey.

University Hospital's Current Objection Policy

11. University Hospital is committed to providing quality, considerate, respectful, and comprehensive care to all patients. To that end, the hospital has developed a carefully considered policy to accommodate the religious beliefs and cultural values of its staff in a way that does not compromise patient care. The policy requires employees with a religious or moral objection to notify their supervisor in advance in writing if such objection may impact performance of their job duties. Except in an emergency setting, an employee may be excused from participating in any

specific patient care based on his or her cultural values, ethics, or religious beliefs. Under University Hospital's policy, participation means that an employee has direct involvement in the procedure or attendance in the room at the time of the procedure, and it specifically does not include pre- and post-procedure care, room cleaning, or record keeping. Under no circumstances does an employee have the right to refuse to care for a patient without prior approval, and any such refusal to provide care results in disciplinary action. In the event that University Hospital cannot accommodate an employee's objection, the employee is advised to seek a transfer to a department where conflict of care issues are less likely to occur. Finally, under the policy, University Hospital reserves the right to re-evaluate, revise, or revoke any accommodation if the department head determines that the current situation requires that the employee participate in previously excused procedures in order to provide appropriate patient care. Such circumstances can arise due to, among other things, emergencies, changes in staffing availability, or other hospital conditions.

12. University Hospital requires prior written notice of employees' objections for a number of reasons. First, in order to be compliant with applicable regulations and guidelines promulgated at the state and federal level, University Hospital must be able to predict its staffing needs with a reasonable degree of certainty. Having advance notice permits University Hospital to make informed staffing decisions to ensure quality patient care. This is especially important in University Hospital's operating rooms, which are staffed on night shifts by three-person teams consisting of a doctor, a nurse, and a scrub technician. During night shifts, the hospital has only two teams running the operating rooms. If an employee on an operating room team were to raise an objection without prior notification, patient care would most likely be compromised. For example, an operation could be interrupted or delayed and a patient placed at risk while staff searched for a doctor, nurse, or scrub technician who did not object to the procedure. Staffing a

large medical center like University Hospital is very complex. Allowing objections without prior notice would upend University Hospital's staffing plans and is not operationally, functionally, or financially feasible. Second, by requiring advance notice of objections, University Hospital is able to comply with New Jersey law, which requires that there be an "appropriate, respectful and timely transfer of care" if a health care professional declines to participate in withdrawing or withholding life-sustaining measures. N.J. Stat. Ann. § 26:2H-62(b). Such transfer of care can only be ensured if University Hospital has advance notice of objections and, therefore, the ability to staff its departments accordingly.

13. Additionally, University Hospital reserves the right to re-evaluate or revoke any accommodation in order to ensure patient care. For example, in the case of an emergency, an employee who previously objected to a certain procedure may nonetheless be required to participate in that procedure if he or she is the only employee available and a patient would be placed at risk were he or she not to participate. That is, while University Hospital strives to accommodate employees' cultural values and religious beliefs, patient care is the number one priority.

Immediate Impact of the Final Rule on University Hospital

14. The Final Rule, if it takes effect, likely will have an immediate and negative impact on University Hospital. For example, University Hospital will have to determine whether the Final Rule allows the hospital to maintain a policy that requires notice for objections, or if a staff member may object without prior notice. Because the Final Rule seems to allow objections without notice, University Hospital will have to take precautions in line with the assumption that staff may object without prior notice. It is our understanding that University Hospital would then be required to accommodate that objection even if it were to potentially place a patient at risk (for example, in a

case where an objection were raised for the first time during an emergency). As a critical provider of trauma services for the northern half of New Jersey, a liver transplant center, and the referral center for specialized Ophthalmology, Otolaryngology, Neurosurgery, and Orthopedic Care, University Hospital provides care in numerous emergency situations; objections made without prior notice would have a profound and detrimental impact on emergency patient care in New Jersey.

15. The Final Rule also may prohibit University Hospital from doing the following: disciplining employees who refuse to provide care based on sincerely held religious or moral objections without prior approval; inquiring about conscience objections prior to hiring; advising employees to seek transfer to a department where conflict of care issues are less likely to occur; or re-evaluating, revoking, or revising accommodations if the department head determines that the current situation requires the participation of previously-excused employees in order to provide appropriate patient care. Additionally, the Final Rule expands both the areas in which an employee can assert an objection on religious or moral grounds, as well as the overall number of covered employees, by allowing employees to object to emergency care, pre- and post- procedure care, scheduling, room cleaning and preparation. Ultimately, I expect the Final Rule to adversely affect University Hospital's ability to provide care to patients and to cost the hospital funds that could better be spent on improving patient outcomes.

16. ***Financial Costs of the Final Rule*** – The Final Rule will likely require University Hospital to over-staff in order to avoid a situation where the only available employee refuses to participate in an aspect of patient care. For example, University Hospital would likely need to ensure that more nurses or employees are on call and ready to respond were an individual to, without notice, assert a conscience objection. Double-staffing might not be enough, for example,

where the back-up nurse also asserts a conscience objection. Moreover, because of the Final Rule's expansive definitions of staff who participate in providing care, University Hospital will likely need to double-staff not just operating room staff, but also employees involved in the scheduling of procedures, in the provision of pre- and post-procedure care, and in the cleaning and prepping of rooms. The extremely broad scope of the Final Rule seems to implicate all areas of patient interaction, from the front door, to registration, to the front desk, to patient experience, to transport, counseling, and the provision of medical services. Such over-staffing will likely be unduly expensive and largely unworkable for University Hospital, the largest provider of uncompensated care in the State. Moreover, such over-staffing may nonetheless fail to both satisfy the Final Rule and ensure quality patient care; the hospital cannot account for every possible objection in every department. The level of redundancy required by the Final Rule is simply untenable and may even be impossible to achieve due the lack of available staff in the market and the enormous financial burden it causes.

17. *Effect on Patient Care* – Even if University Hospital were to take all of these expensive staffing precautions, the Final Rule likely would still adversely impact patient care. For example, if an employee asserts a conscience objection without notice, a procedure could be halted, perhaps at a critical time, while the employer searches for an employee that would not object. That delay could have negative consequences for the patient. Additionally, patient care will likely be negatively impacted when large amounts of funding that could have gone toward improving patient outcomes is re-directed to over-staffing positions to ensure backup in the event of a conscience objection. The hospital's primary mission is the provision of patient care. Prioritizing staff objections could impair physicians' and medical providers' (and, by extension, the hospital's) ability to effectuate that duty.

18. ***Effect on Hiring*** – The Final Rule also constrains University Hospital’s hiring practices by generally prohibiting questions regarding a potential employee’s conscience objections prior to hiring. As a result, University Hospital may fill a critical position with an employee who cannot perform the position’s core requirements (and the Final Rule also precludes University Hospital from then transferring this employee to another department). Consequently, University Hospital will likely need to hire additional people to ensure that it has employees available who are willing and able to provide comprehensive, quality health care to all patients. Again, patient care will likely be negatively impacted when funding for improving patient outcomes or improving a certain hospital department is diverted to over-staffing in order to accommodate the Final Rule’s requirements.

19. ***Impact on LGBTQ Care*** – University Hospital is committed to ensuring that all patients, regardless of sexual expression or gender identity, have access to high quality, comprehensive care. Moreover, University Hospital is working toward becoming a center for excellence for gender-affirming surgery. University Hospital will likely need to over-staff in order to ensure that care for patients who identify as LGBTQ is not interrupted or negatively impacted by an employee who, without notice, objects to providing care on religious or moral grounds. Again, such over-staffing will likely be unduly expensive for University Hospital.

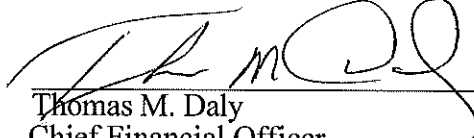
20. ***Impact on Enforcement of New Jersey Law*** – If the Final Rule goes into effect, University Hospital will face significant difficulties reconciling the Final Rule with New Jersey state law regarding pharmacies. The Final Rule allows health care entities, including pharmacists and pharmaceutical assistants, to object to assisting in the performance of a health service program. Conversely, New Jersey law requires pharmacy practice sites to “fill lawful prescriptions for prescription drugs or devices[,]” even if an employee of the practice objects to filling the

prescription based upon “sincerely held moral, philosophical, or religious beliefs.” N.J. Stat. Ann. § 45:14-67.1(a). University Hospital operates a pharmacy on site for immediate patient care that dispenses contraceptives, emergency contraception, and prescriptions that can be used for end-of-life care and in connection with gender affirmation surgery. In order to ensure compliance with the Final Rule, University Hospital will likely need to double-staff pharmacist and pharmaceutical assistant positions in order to ensure that it “fill[s] lawful prescriptions,” *id.*, even in the face of objecting staff. Such double-staffing is unduly expensive, generally unworkable for the hospital, and may not even be a satisfactory way to reconcile the Final Rule and New Jersey law.

21. ***Drafting a New University Policy on Objections*** – I anticipate that, if the Final Rule takes effect, University Hospital will need to update its policy on conscience objections to ensure that it comports with the Final Rule. The hospital intends to ensure its full compliance with state and federal law. To do so, it will need to re-write its existing objection policy. This requires a multi-disciplinary approach and the input of the hospital’s entire leadership team, including the Chief Executive Officer, Chief Medical Officer, Chief Nursing Officer, Chief Financial Officer, Chief Legal Officer, Chief Human Resources Officer, and Chief Operating Officer. Indeed, it is not clear that a new policy can be drafted that comports both with the Final Rule and pre-existing state law requirements in this area. Significant resource re-allocation will also be necessary to determine the veracity of any conscience objections and whether they are sincerely held.

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



Thomas M. Daly
Chief Financial Officer
University Hospital

Exhibit 14

**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,
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OF MASSACHUSETTS, STATE OF
MICHIGAN, STATE OF
MINNESOTA, STATE OF NEVADA,
STATE OF NEW JERSEY, STATE
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RHODE ISLAND, STATE OF
VERMONT, COMMONWEALTH
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UNITED STATES DEPARTMENT
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and Human Services*; and UNITED
STATES OF AMERICA,

Defendants.

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

DECLARATION OF REBECCA S. DINEEN, M.S.

1. I, Rebecca S. Dineen, 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 Maryland'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 Baltimore City Health Department personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Baltimore City Health Department.

3. I am Assistant Commissioner for the Bureau of Maternal and Child Health in the Baltimore City Health Department. I have held this position since January 2010.

4. The Baltimore City Health Department is responsible for addressing public-health challenges and administering public-health initiatives to protect and promote the health and well-being of Baltimore's more than 600,000 residents.

5. The Health Department's development and implementation of programs and its provision of healthcare services is informed by the unique vulnerabilities of the City's residents.

6. Historically, race discrimination, including discrimination by government-funded hospitals and healthcare providers, impeded black patients' access to healthcare. Likewise, black patients historically have been subjected to medical testing and study without their informed consent and in ways that grossly violate contemporary medical ethical standards.

7. Baltimore currently has high rates of poverty and violent crime, both of which disproportionately affect communities of color. Large numbers of Baltimore residents have

experienced trauma. Trauma may result from discrimination, poverty, homelessness, exposure to physical violence, child abuse and neglect, or involvement in the criminal-justice system, among other adverse experiences.

8. These experiences of historical marginalization, discrimination, and trauma—often at the hands of the government—have made many residents mistrustful of and reluctant to engage with medical providers and public officials offering healthcare services and related assistance.

9. This mistrust is compounded in parents suffering from substance-use disorders, who may hesitate to seek care for themselves and their children out of fear that the government will reduce their parental rights or take away their children altogether.

10. And many people from marginalized communities who have sought out healthcare services have been met with judgment and blame by providers, making them less likely to continue to seek care in the future.

11. When some members of the community don't trust the government to provide them with safe, judgment-free services, the overall public health suffers.

12. Thus, the Health Department is adopting a holistic, trauma-informed approach to its public-health mission that prioritizes breaking down the stigma of receiving care, building trust with individuals and communities, and ensuring that each person we serve is treated with dignity.

13. I am familiar with the new rule promulgated by the U.S. Department of Health and Human Services, entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("the Rule").

14. I have grave concerns that any regulation that may grant healthcare employees the unqualified right to refuse to treat, assist, or refer patients for care would undermine the Health Department's years of work persuading Baltimore residents to seek and accept care and would

threaten the overall public health. The consequences may be devastating, both for the innumerable individuals who rely on the Health Department for healthcare services and for the Health Department's ability to advance the well-being of Baltimore residents at the population level.

About Me

15. I have more than twenty years of experience in public health. I have worked in fourteen countries on three continents, in both the public and private sectors.

16. As an experienced project manager, I have the skills to strategically advance, design, implement, and evaluate public-health initiatives and programs to improve health outcomes.

17. I have expertise in the substantive areas of maternal and child health, family planning, HIV/AIDS, malaria, and primary healthcare. My work has involved policy and advocacy, training, behavioral change, and community mobilization.

18. The City Health Department's Bureau of Maternal and Child Health provides adolescent and family reproductive-health services and supports the health and well-being of pregnant women, infants, and children in Baltimore. As Assistant Commissioner for the Bureau, I am responsible for the development and implementation of all of its programs and initiatives.

19. I developed and oversee its flagship initiative, B'more for Healthy Babies, a broad-ranging, city-wide strategy to improve birth outcomes through direct services, education, community outreach, and policy, as well as the numerous programs that operate under it.

20. I lead a staff of 135 and oversee the efforts of more than 200 volunteers annually. I am responsible for the Bureau's annual operating budget of approximately \$29 million.

21. Before becoming Assistant Commissioner for the Bureau, I served as Bureau Chief for Maternal and Infant Care, overseeing the provision through home visits of healthcare services to pregnant women and women with infants.

22. Prior to my employment with the Health Department, I worked for several years at Jhpiego, an international nonprofit organization affiliated with The Johns Hopkins University, where I developed and oversaw the implementation of global health initiatives in the areas of maternal health, malaria, and HIV/AIDS in Africa and Asia, among other projects.

23. I have authored or co-authored numerous papers and delivered presentations on reproductive, maternal, and child health.

24. I earned a Master of Science in Health Policy and Management from the Harvard School of Public Health in 1998.

25. My curriculum vitae is attached as Exhibit A.

Public-Health Initiatives of the Bureau of Maternal and Child Health

26. Through its flagship initiative, B'more for Healthy Babies, the Bureau of Maternal and Child Health applies a trauma-informed approach in the provision of adolescent and family reproductive-health services; care for pregnant women; and care for mothers, infants, and children in Baltimore. Our programs are designed to improve health before pregnancy, including family planning and reproductive health; to ensure quality care during pregnancy; and to support families in raising healthy children. Our vision is a Baltimore in which all children are born healthy and grow and thrive in healthy families. We seek to reduce the teen birth rate; reduce the rates of fetal, infant, and maternal mortality; and reduce the number of child and adolescent deaths.

27. As a public-health entity, our mission is to provide population-level change. That is, in addition to providing services at the individual level, we seek to shape the health of entire

populations over time by making it easier for everyone to obtain care, using evidence-based approaches to improve the quality of services, mobilizing communities, and advocating for policies at all levels that improve access to care.

28. Our programs are also driven by racial, social, and economic justice. Black and Hispanic teens have birth rates three and four times higher, respectively, than white teens. And black babies die at twice the rate of white babies. We seek to eliminate the racial and economic disparities in the incidence of poor outcomes and inequities in the overall provision of care.

29. We rely on more than 100 partners to carry out our programs and achieve our goals, including city agencies, corporate healthcare entities, academic institutions, and nonprofit organizations, including a number of small, grassroots organizations.

30. All of our programs, whose descriptions follow, are funded in whole or in part by federal financial assistance administered through the U.S. Department of Health and Human Services. Some of our funding comes directly from the federal government, but much of it is passed through the State of Maryland. This includes funds through Title V and Title X of the Public Health Services Act, Head Start, the Office of Adolescent Health, the Centers for Disease Control and Prevention, and Medicaid reimbursements.

Family-Planning and Reproductive-Health Clinics

31. The Bureau of Maternal and Child Health funds and operates three clinics that offer family-planning and reproductive-health services: the Druid Family Planning Clinic in West Baltimore, the Eastern Family Planning Clinic in East Baltimore, and the Healthy Teens and Young Adults Clinic. The family planning and reproductive health clinics provide care to one-third of Baltimore women.

32. The mission of these clinics is to reduce unintended pregnancies and to improve pregnancy outcomes by providing family-planning and reproductive-health services to women and men ages 25–50. The Druid Clinic also hosts the Healthy Teens and Young Adults Clinic, which offers these same services to young women and men ages 10–24.

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

34. The clinics operate weekdays during normal business hours, with some extended hours offered at the Druid Clinic each week. In addition to appointments, both clinics offer blocks of walk-in hours each week.

35. The clinics provide their services on a sliding scale and do not turn away patients based on an inability to pay. For many patients, clinic visits are the primary or sole source of reproductive or related healthcare.

36. More than 5,000 people receive care at these clinics each year.

37. The Health Department employs approximately 25 people at these three clinics, including one physician, two nurse practitioners, one nurse, and 20 administrative and other staff. Spanish-speaking staff is available. The staff members are all full-time employees of the Health Department.

38. The Bureau's clinics receive funding through Title X of the Public Health Services Act and through HHS's Office of Adolescent Health.

39. In addition to operating its own family-planning and reproductive-health clinics, the Health Department also provides subgrants to four other clinics throughout Baltimore that provide similar services.

School Clinics

40. The Health Department operates clinics at seven schools in Baltimore. The clinics operate during school hours and have dedicated full-time staff. These clinics offer the same family-planning and reproductive-health services as the other three clinics, including the provision of contraceptives; STD screening; options counseling for pregnant patients, including referrals for abortion; and other counseling services.

41. The school clinics offer their services for free to students who are unable to pay.

42. The school clinics receive Title X funding through the Bureau of Maternal and Child Health. These clinics are operated by the Bureau of School Health.

Immunization Clinics

43. The Health Department operates an immunization program to help prevent vaccine-preventable disease, to conduct disease surveillance, and to provide and monitor immunization-related health education and community outreach.

44. The Health Department operates "T.I.K.E." (To Immunize Kids Everywhere) Clinics, which provide free immunizations to children and adolescents, with an additional limited number of adult immunizations. Services through T.I.K.E. Clinics are available to those without a healthcare provider or whose insurance does not cover immunizations.

45. The clinics offer all immunizations clinically recommended for children and adolescents, including measles, mumps, and rubella; chicken pox; diphtheria, tetanus, and pertussis; and Hepatitis B. The clinic also offers influenza vaccinations.

46. In addition to immunizations, the T.I.K.E. Clinics offer lead testing for pregnant women and for children ages nine months to six years old.

47. The clinics operate out of the Health Department's Druid and Eastern Health Centers during selected hours throughout the week. The clinics are available by appointment or on a walk-in basis.

48. The Immunization Program also collects data and conducts outreach. Its Immunization Registry Project collects and securely discloses vaccination records for children, adolescents, and young adults. And the program provides education and outreach targeted at families with children who are delayed in their recommended immunizations and to neighborhoods at risk for under-immunization.

49. The Immunization Program is funded through the Maryland Department of Health with funds from the Centers for Disease Control and Prevention.

Home-Visiting Services

50. Through its Maternal and Infant Care Program (M&I), the Health Department provides support services to pregnant women and women with young children in Baltimore through a home-visiting program and group-based interventions.

51. M&I operates the Nurse Family Partnership Program, an evidence-based intervention method that is commonly used by public-health entities nationally and internationally. This prescriptive model employs nurses to provide home care to low-income, first-time-pregnant women. Baltimore's NFP program caters particularly to teens and pregnant women up to 24 years old. Clients often possess chronic medical conditions that may complicate their pregnancies, along with mental-health or substance-use disorders. The program serves approximately 100 women at any given time. Visits focus on six domains: personal and environmental health; life courses

involving family planning, education, and job skills; parenting and attachment; interpersonal relationships with family and friends; and referrals to other health and human services. The program is supported by federal funds from HHS's Maternal, Infant, and Early Childhood Home Visiting Program.

52. M&I also operates two group programs for parents: Circle of Security, which provides parenting groups for its clients and in other community settings, and B'more Fit for Healthy Babies, which offers postpartum stress management, fitness, and nutrition guidance. Both programs are operated in English and Spanish. These sessions serve 10–25 women on average each week, and B'more Fit has served over 800 women since its inception in 2012. Baltimore Medical Systems, a federally qualified health center, partners with the City Health Department and M&I on the NFP program, Circle of Security, and B'more Fit. The Health Department also provides subgrants to partner organizations that operate home-visiting and center-based services.

53. With funding from the Baltimore City Health Department, the Family League of Baltimore oversees five organizations that implement the Healthy Families America home-visiting model for more than 400 families annually. Healthy Families America is an evidence-based model through which nonmedical staff, supervised by social workers, provide home visits. The model begins with prenatal visits and continues through early childhood, with a focus on bonding, school readiness, and referrals to other support services.

54. In addition to the Family League, the Health Department provides supplemental funding to Baltimore Healthy Start, which provides home-visiting and center-based services to approximately 1,000 mothers, fathers, and infants each year.

55. The care provided through home visiting is intensive and the services wide-ranging.

56. The home visitors offer counseling and coaching, referrals into other healthcare services as necessary, education on parenting, and assistance connecting women to other core social services, like housing and G.E.D. programs. The home visitors also evaluate women with infants and young children for signs of post-partum depression, make referrals for other healthcare services, offer breastfeeding support, and provide counseling on family planning.

57. The frequency of visits is consistent with the needs of the clients, stage of pregnancy or developmental milestones of infants, and the guidelines of both the NFP and Healthy Families America models. Visits may occur weekly, biweekly, or monthly. If a client is in crisis or facing a health complication, visits may be more frequent. Home visitors also remain in contact with their clients by phone and text message.

58. All programs are provided at no cost to those receiving the services.

Teen Pregnancy Prevention

59. The Teen Pregnancy Prevention Program seeks to reduce teen births by increasing access to family-planning clinical services, health education, and information.

60. In addition to the work of the Healthy Teens & Young Adults Clinic and School Clinics, the Health Department conducts outreach to outside providers to determine what services are offered and to recommend improvements to the quality of services provided. Specifically, the Health Department coordinates with clinics to determine what methods of contraception they offer and to advocate that they make the full range of contraceptives available, to the extent that they are not already doing so.

61. The Teen Pregnancy Prevention Program also operates the U Choose: Know What U Want campaign, which seeks to deliver sexual and reproductive-health education to adolescents and teens through age-appropriate messaging, with a particular focus on addressing the myths and

commonly held misconceptions surrounding reproductive health. The Program likewise partners with middle schools and high schools to provide reproductive-health education in Baltimore schools. Each year, more than 10,000 students receive sexual-health education informed by this program.

Support for Children with Developmental Delays

62. The Baltimore Infants and Toddlers program provides support services to families of developmentally delayed infants and children up to two years old or infants and children who have been diagnosed with a condition that is likely to affect development. These are mandated services under Part C of the Individuals with Disabilities Education Act.

63. Once enrolled, the children are assessed to identify early-intervention needs in the areas of speech and language; physical, cognitive, and psycho-social development; and self-help skills. Through the program, the Health Department offers diagnosis, speech pathology and audiology, occupational therapy, physical therapy, psychological services, health services related to other early-intervention services, education and counseling, and case management services.

64. Approximately 2,000 infants and toddlers receive early-intervention services annually. The Health Department is the lead agency designated by the Mayor's Office to provide services to infants and toddlers with special needs. The Department coordinates the care for all of these families and contracts with the Baltimore City School System and private entities to offer the required clinical and developmental services.

65. Where not otherwise covered through Medicaid or other insurance, the program is provided at no cost to the families receiving the services, made possible by HHS funding.

Nutrition Support

66. The Health Department operates the Women, Infants, and Children program, through which participants receive Electronic Benefits Transfer Cards to purchase healthy foods. Program participants also receive nutrition education and counseling, as well as health screenings, including growth and weight assessments for pregnant women and infants and children. Through the program, 15,275 women and children receive nutrition and related support annually. In the future, the Bureau of Maternal and Child Health hopes to expand this program to provide screening and referrals for substance use, mental health, and other conditions.

Philosophy of Care, Successes, and Ongoing Challenges

67. Over the last several years, the Baltimore City Health Department has made significant strides in improving reproductive healthcare and care for pregnant women, infants, and children in Baltimore.

68. In the last ten years, the teen birth rate has decreased by 55%. In the same time, the infant mortality rate has decreased by 36%. Infant mortality is now the lowest it has been since we began recording its rate in the 1950s. Racial disparities in health outcomes are also decreasing. We have seen a 38% decrease in the black-white disparity in infant mortality over the last ten years. And the black-white disparity in the teen birth rate has dropped by 76%.

69. In addition to the evidence-based, high-quality clinical care and services we provide, we operate with the understanding that our programs can improve public-health outcomes only if the men, women, and children for whom they are designed actually use the programs to obtain care. Therefore, we operate our programs based on—and attribute much of our success to—a philosophy that prioritizes access to care.

70. First, we recognize that many Baltimore residents have experienced various types of physical, psychological, or emotional trauma, leading them to be mistrustful of the government and reluctant to seek out or accept care from the Health Department. Our trauma-informed approach recognizes that before we can provide care, we must earn the trust of Baltimore residents.

71. The trauma-informed care approach touches on all aspects of the patient experience. It means creating an environment at our clinics that is welcoming and does not appear overly institutionalized or penal; that has clear signage and is easy for the patient to navigate; and that offers instructions and paperwork in simple terms, with pictures where possible, and in multiple languages.

72. Trauma-informed care also shapes patient interactions with employees, from the intake clerk to the medical provider. It means the administrative and intake staff treat patients kindly and with patience if they, for example, do not have their IDs or required paperwork in order. It means that providers characterize patients' health issues—specifically as to substance abuse—not as something the patient *did*, but rather as something that happened *to* the patient. It means ensuring that patients understand that they are entitled to privacy and confidentiality with respect to the care they receive. It means linking patients to other healthcare and social services.

73. Second, we try to remove as many structural and administrative barriers to care as possible. For example, our home-visiting program allows pregnant women and women with infants to receive care—including some clinical services—at their homes. For many, including those who are fearful of going to a clinic or unable to do so because of disability or other limiting factors, this service is the difference between receiving care and not. Similarly, our School Health clinics are located at Baltimore schools. Students who may not be willing or able to go to a separate

location to receive reproductive healthcare are able to receive this care in a more convenient and familiar setting.

74. Finally, a core component of B'more for Healthy Babies is its centralized intake system, through which more than 4,000 Medicaid-eligible pregnant women and families with infants are referred to providers each year. Care coordinators work telephonically with families to make referrals. And to support our most vulnerable families and those who are harder to reach, the Health Department employs dedicated pregnancy-engagement specialists, who are stationed in hospital and provider waiting rooms to connect with pregnant women and women with infants. The pregnancy-engagement specialists provide options counseling and make referrals to Health Department programs.

75. The Health Department likewise partners with healthcare providers and community organizations to link women to programs for which they may be eligible.

76. Community outreach is a particularly important component of getting women into care. Thus, the Health Department engages in door-to-door canvassing in targeted neighborhoods to identify women and families who are eligible for care. The Health Department also partners with community organizations to create neighborhood-based hubs through which families may feel more comfortable seeking out information, referrals, and care. Though still few, these local organizations have close ties to the communities that they are serving. Our partnerships with these groups are another means through which the Health Department seeks to build trust within Baltimore communities.

77. Notwithstanding our successes over the last several years, there is much still to do to provide population-level improvements in reproductive, fetal, maternal, and child health. The teen birth rate in Baltimore is still twice as high as that of Maryland and three times the national

average. And while the rate of infant mortality in Baltimore has decreased, it remains higher than the national average. And despite recent improvements, disparities in health outcomes persist along racial and ethnic lines.

78. Likewise, although we have made great strides in building trust in communities through our trauma-informed approach to care, we still are doing the work of building trust, reducing stigma, and encouraging people to seek and accept care.

79. Early-childhood care continues to be an undervalued public-health issue, neglecting the critical first five years of a child's life, during which brain development and adverse childhood experiences will determine health outcomes later in life.

80. Our overall annual funding has remained flat for the past ten years. Even on our current budget, many of our programs are already understaffed and otherwise underfunded.

Potential Harms Stemming from Refusals of Care

81. Any rule permitting healthcare employees to refuse to treat, assist, or refer Baltimore residents seeking care would impose administrative and logistical hurdles, impede individuals' access to care, and threaten the mission of the Bureau of Maternal and Child Health and its work to protect and improve public health in Baltimore.

82. Compliance with any such rule would create nearly insurmountable logistical and administrative hurdles. The Bureau's clinics and other services would not be able to accommodate multiple refusals. The clinics and other programs are leanly staffed with healthcare workers. For some programs, including home visiting and door-to-door outreach, a single Health Department employee is assigned to cover various neighborhoods or households. An employee who refuses to perform certain services at a clinic or refuses to complete home visits for a certain demographic would create a significant lapse in care. If the Health Department were unable to replace or reassign

that employee, the only way for operations to proceed as normal would be to hire additional employees to fill the gaps in service. This putative workaround would be essentially impossible in practice. The Health Department's clinical and other programs are already understaffed and utterly lack the financial resources to fill duplicate positions.

83. Refusals under such a rule would result in denials of timely care to Baltimore residents, and it is hard to overstate the harms that would follow, both for individual patients denied care and for public health in Baltimore at the population level.

84. For many individuals who receive services through us, the Health Department provides services of last resort. Likewise, Health Department services may be the only source of care that a vulnerable patient trusts. This means that a person turned away from a Health Department clinic or program likely cannot or will not receive care elsewhere.

85. The Maternal and Child Health Bureau provides fundamental services at pivotal moments in the lives of their patients: sexual health education and contraceptive care for the teenager who becomes sexually active; options counseling for the pregnant teenager; basic prenatal care and referral to a provider for the pregnant woman who needs assistance maintaining a healthy pregnancy; and nutrition education and support services for the first-time mother and her infant child.

86. Disruption in the provision of these services may have serious consequences for the woman and her child. A woman who lacks access to reproductive healthcare and options counseling may have an unwanted pregnancy and an unwanted child. Statistically, the rates of child abuse and neglect are much higher for children who are the result of unwanted pregnancies. Likewise, without a home visit, a pregnant woman's preeclampsia may go undiagnosed. Untreated, this condition can be fatal to the mother and baby. And without intervention, a pregnant woman

with a substance-use disorder may give birth to a baby with neonatal abstinence syndrome, posing a number of serious and potentially long-lasting health risks.

87. Just as fundamentally disruptive are the stigma and psychological harms that a patient may suffer when denied care. Patients with a history of trauma and who have faced a lifetime of discrimination will be particularly vulnerable to those harms. Our developing trauma-informed approach to care relies on establishing trust with patients and patient communities over time. That scaffolding, which sometimes takes years to build, can collapse utterly in the single moment it takes for a patient to be turned away because of who they are or the services they seek.

88. Take, for example, the case of a preteen girl at a Baltimore public school. It took almost a year of outreach and trust-building by Health Department employees at the school before the girl felt comfortable enough to go to a clinic for an STD test, where she ultimately tested positive for chlamydia and received treatment. Imagine that the girl arrived at the clinic, only to be told by the intake clerk that she could not obtain STD testing because the intake clerk objected on religious or moral grounds to preteens having sex. The likelihood is very low that this girl would bother to make another appointment or, indeed, seek out services from the Health Department in the future.

89. And the stigmatizing effects of being denied care that one person experiences may ripple out into that person's community, leaving others, once again, mistrustful of government healthcare programs and reluctant to seek care.

90. In short, the outcomes that denials of timely care would allow are diametrically contrary to the goals of client care based on building trust and lasting relationships in the community. Further, while each of the examples I have given demonstrate harm to individual

patients seeking clinical care, from a public-health perspective the cumulative effect would be to reverse years of progress.

91. The consequences of forgoing federal funding, or of losing funding because of alleged or threatened noncompliance, would be equally drastic. We would be forced to stop almost all of our operations. The vast majority of the funding that I oversee comes from the U.S. Department of Health and Human Services.

92. As an experienced public-health official, I foresee serious impediments to the efforts of the Bureau of Maternal and Child Health to carry out its mission to provide population-level care in the areas of reproductive health and care for pregnant women, infants, and children in Baltimore.

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

Executed on this 13th day of June, 2019, in the State of Maryland.



Rebecca S. Dineen, M.S.

Exhibit 15

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 HAWAII,
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 SHEREEF M. ELNAHAL, M.D., M.B.A., COMMISSIONER

1. I, Shereef M. Elnahal, M.D., M.B.A., Commissioner, 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 New Jersey Department of Health ("NJDOH") personnel who have assisted me in gathering this information from our institution, 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 NJDOH.

3. I graduated summa cum laude with a B.A. in biophysics from Johns Hopkins University. Thereafter, I received a dual-degree M.D. and M.B.A. with Distinction from Harvard University, and worked as a physician in training at Brigham and Women's Hospital and Johns Hopkins Hospital. Prior to leading the New Jersey Department of Health, I worked as a physician executive in the United States Department of Veterans Affairs ("VA"), serving as the Assistant Deputy Under Secretary for Health ("ADUSH") for Quality, Safety, and Value in the Veterans Health Administration. At the VA, I led efforts to improve the quality and safety of healthcare delivery to veterans. In addition, I spearheaded unprecedented efforts around transparency and standardized best practices that prevent opioid dependency, improve women's healthcare, and enhance access to care for veterans.

4. I currently serve as the Commissioner at NJDOH and have served in this position since January 25, 2018. In my capacity as Commissioner of Health, I oversee all budgetary, financial, programmatic, and regulatory duties of the Department of Health. NJDOH is committed to providing access to high quality, affordable, culturally competent, and trauma-informed care, as

well as reducing and eliminating disparities in health outcomes across all health care services. NJDOH's priorities align with evidence-based, national best practices, including the Institute of Medicine's six dimensions of quality health care: safety, timeliness, patient-centeredness, effectiveness, efficiency, and equitability.

The Grave Impacts of Funding Termination

5. The Final Rule imposes new conditions on millions of federal dollars that NJDOH relies on to ensure access to health care for patients. The Final Rule allows for the termination of HHS funding if at any point HHS determines that NJDOH or one of its sub-recipients has failed to comply with any of the Final Rule's many requirements.

6. In Fiscal Year 2018, NJDOH received approximately \$243,384,739 in funding from HHS.

7. For example, NJDOH received over \$41 million in HHS funding through the Ryan White CARE Act, supplemented by over \$20.5 million in state funding, in Fiscal Year 2018. That funding enabled New Jersey to provide medical care and services to over 10,000 residents with HIV. New Jersey used the funding to, among other things, provide free or subsidized HIV medication to low-income residents and provide support services that assist with treatment compliance, such as mental health treatment, case management, housing, transportation, and nutrition services.

8. If HHS funding through the Ryan White CARE Act were terminated, I anticipate that the State would not be able to make up the lost \$41 million in funding. New Jersey would not be able to provide residents with HIV medication, treatment, or supportive services to the same extent as the State does now. This could lead to an increase in HIV infection rates and, potentially, a public health crisis with nationwide ramifications.

9. Also in Fiscal Year 2018, New Jersey received \$11,460,935 in funding from HHS through the Maternal & Child Health Block Grant, along with \$8.6 million in matching State funds. New Jersey used this funding to support and improve the health of over 285,000 women, infants, and children, including children with special needs. For example, the Maternal & Child Health Block Grant funds the Healthy Women, Healthy Families Initiative, which addresses infant and maternal mortality; Fetal Alcohol Syndrome and Sudden Infant Death Syndrome prevention efforts; outreach and education for women experiencing post-partum depression; intensive case management for children and families with special health care needs, such as autism and cleft palate; school wellness and oral health initiatives; and lead screening, including case management and environmental assessments.

10. If New Jersey were to lose this funding, I anticipate that it would not be able to make up the more than \$11 million shortfall. Instead, services would need to be cut. For example, cuts to the Healthy Women, Health Families Initiative likely would result in upwards of 17,000 women not being screened for pregnancy risks and thousands of women losing access to referral services that link them to local organizations aimed at reducing infant and maternal mortality.

11. Additionally, in Fiscal Year 2018, NJDOH received over \$3 million in funding from HHS to combat the opioid epidemic. That funding helped to improve public health surveillance in the State and to bolster data infrastructure regarding opioid use disorder (“OUD”) and substance use disorder (“SUD”). The funding also expanded access to evidence-based treatment and prevention for OUD and SUD. Previous CDC funding—through, for example, the Data-Driven Prevention Initiative (CDC-RFA-CE16-1606), the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality (CDC-RFACE16-1608), and the Cooperative Agreement for Emergency Response: Public Health Crisis Response—Opioid Epidemic (CDC-

RFA-TP18-1802)—has been critical to establishing New Jersey’s robust surveillance system, bolstering the Office of the Chief State Medical Examiner, enhancing the quality and sharing of data among state agencies, strengthening our prescription drug monitoring program, launching data tools such as New Jersey’s Opioid Data Dashboard, connecting public health and law enforcement through “Operation Helping Hand,” supporting harm reduction centers (syringe access programs), linking EMS first response with treatment and recovery support, and promoting education around opioid prescribing in our health systems. For example, funding allowed the Department of Health’s Division of Epidemiology, Environmental and Occupational Health to expand New Jersey’s syndromic surveillance capabilities in order to focus opioid interventions in those geographic areas where they are most needed. This targeted response is a cost-effective way of fighting the opioid epidemic and reducing harms to the individual and society as a whole.

12. If New Jersey were to lose federal HHS funding, I anticipate that it would not be able to make up the budget shortfall with state funds. As a result, New Jersey’s opioid surveillance and opioid data infrastructure, initiatives to enhance linkages to care among EMS teams and local public health departments, and efforts to enhance non-punitive neo-natal abstinence screening would all face severe cuts, which would negatively affect the health and welfare of New Jersey residents, especially those suffering from substance-related disorders.

13. Moreover, partial or full loss of federal funds will hinder NJDOH’s capacity to deliver the “10 Essential Public Health Services” identified by the Centers for Disease Control and Prevention.¹ Underfunding of the public health surveillance functions of NJDOH will likely adversely impact data quality, benchmarking, and comparisons across jurisdictions, as well as accurate accounting of disease burdens within New Jersey and nationwide. Examples of

¹ Centers for Disease Control and Prevention, *The Public Health System & the 10 Essential Public Health Services*, <https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html>.

surveillance activities supported through federal funds include opioid surveillance supported through CDC grants and cancer surveillance supported through the National Institutes of Health's National Cancer Institute and CDC funds. Likewise, CDC funding for environmental public health tracking helps support the NJ State Health Assessment Data System, which provides on-demand access to public health datasets, statistics, and information on the health status of New Jerseyans. NJDOH's capacity to diagnose and investigate health hazards is supported through the Agency for Toxic Substances and Disease Registry funds for hazardous site evaluations and the epidemiological and laboratory capacity are funded through HHS. Furthermore, NJDOH's Division of Public Health Infrastructure, Laboratories & Emergency Preparedness would be gravely impacted by any partial or full loss of HHS funds, which support the Hospital Preparedness Program (approximately \$5.1 million) and the CDC Public Health Emergency Preparedness grant program (approximately \$16 million).

Compliance Burdens Imposed by the Final Rule

14. NJDOH distributes HHS funds to a number of recipients and sub-recipients, including 24 Federally Qualified Health Centers ("FQHCs") across 117 current satellite locations and 77 hospitals. FQHCs provide primary and preventive care to underserved areas, delivering high quality health care regardless of a patient's ability to pay. FQHCs serve the uninsured, as well as patients with NJ FamilyCare (New Jersey's publicly funded health insurance program, which includes CHIP, Medicaid, and Medicaid expansion populations), Medicare, and private insurance. FQHCs provide a wide range of services, including comprehensive primary care, women's health services, behavioral and mental health services, and HIV/AIDS counseling and testing. Both FQHCs and hospitals provide family planning, abortions, sterilization procedures, counseling and referral services, and end-of-life care. NJDOH monitors FQHCs' and hospitals'

compliance with various federal and state laws. If the Final Rule takes effect, NJDOH will need to take a number of immediate steps to educate and inform all of these FQHCs and hospitals about the Final Rule so that they comply with it and NJDOH does not risk losing vital HHS funding.

15. For example, I expect that NJDOH will need to draft and disseminate guidance documents to all of its roughly 630 funding recipients and sub-recipients to ensure (i) that they understand the contours of the Final Rule and (ii) that they remain in compliance with the Final Rule. Such guidance is especially necessary given that FQHCs and hospitals provide the types of services implicated by the Final Rule, including abortions, sterilization procedures, counseling and referral services, and end-of-life care. In order to ensure compliance, I expect that NJDOH would need to review all of its recipients' and sub-recipients' HR policies to ensure that they appropriately accommodate conscience objections. NJDOH does not currently have the capacity to review all such HR policies; thus, I expect that the Final Rule, if it takes effect, will require NJDOH to hire additional staff.

16. Currently, it takes survey staff 196 survey hours to complete one Federal recertification of a Skilled Nursing Facility, 63 survey hours to complete one Federal recertification of an Ambulatory Surgical Center, and 276 survey hours to complete one Federal recertification of a Hospital. Modifying the inspection process to account for a facility's compliance with the Final Rule likely will increase these hours, and NJDOH's survey staff is already overstretched.

17. It will also be difficult to harmonize the Final Rule with New Jersey state laws protecting patient safety and choice. New Jersey emergency care rules have more restrictions than the federal Emergency Medical Treatment & Labor Act. NJDOH regulations only permit hospitals to transfer an emergency patient if the hospital does not provide the service the patient requires.

N.J. Admin. Code § 8:43G-4.1(a)15. Further, a patient can only be transferred from an emergency department to another health care facility for “a valid medical reason or by patient choice.” N.J. Admin. Code § 8:43G-12.7(p). I anticipate that the Final Rule will make it prohibitively expensive and very difficult for hospitals to comply with both the Final Rule and New Jersey’s emergency care laws. It may require hospitals to double-staff certain positions to ensure that staff are available to perform potentially-objected-to procedures so that patients are not unnecessarily transferred to other hospitals in contravention of NJDOH’s regulations. For example, if (i) a patient presented with an ectopic pregnancy, (ii) the only physician at a hospital that provided emergency prenatal services refused to perform an abortion, citing conscience objections, and, consequently, (iii) a patient were transferred to a different hospital as a result, this would directly contravene N.J. Admin. Code § 8:43G-12.7(p). The Final Rule privileges conscience objections over patient care.

18. The Office of Women’s Health oversees New Jersey’s family planning program. Ensuring compliance with the Final Rule would be especially difficult within the family planning program because the services it provides are the very services to which the Final Rule permits objections. Recognizing that the Final Rule allows family planning clinic staff to opt-out of job functions including the provision, discussion, referral, and/or scheduling of contraceptive services, abortions, and sterilization services, full compliance with the Final Rule may require family planning providers to double-staff positions to ensure that a back-up employee is available should another employee raise a conscience objection. This would place a significant strain on program resources. Moreover, individuals may present for care with insurance plans that are affected by conscience objections protected by the Final Rule. This could result in decreased reimbursement for the program, which, in the worst case scenario, could result in the program having to turn patients away. This is just one example of the potentially disastrous ramifications of the Final

Rule. It is likely that other departments and divisions that support marginalized populations directly and indirectly through grant programs would suffer similar negative repercussions.

19. Given the broad scope of the Final Rule, NJDOH itself may also need to overstaff in order to accommodate any conscience objections that may be made. The Final Rule would be especially burdensome for certain departments, for example, those that facilitate services or research related to reproductive and sexual health, end of life care, and issues specific to LGBTQ, minority, or other specialty populations.

The Final Rule Impedes Health Care Access and Quality

20. The Final Rule will inhibit the provision of health care in a manner that harms public health in New Jersey and likely falls more heavily on the shoulders of vulnerable populations. Faced with a broad array of potential conscience objections from any employee, under the Final Rule, health care providers have strong incentives to cease offering procedures like abortion or gender transition-related therapies or surgeries in order to avoid any possibility of the loss of all federal health care funding, which could potentially close a health care provider's doors. Additionally, the Final Rule likely will reduce health care access for lower-income New Jersey residents by permitting an expanded group of individuals and institutions to decline to provide necessary care.

21. Such a net reduction in the medical care offered by health care providers would harm public health in New Jersey generally. And the Final Rule will likely inflict a disproportionate amount of harm on women of color specifically. By way of example, a growing number of New Jersey patients receive care from facilities affiliated with the Catholic Church, and Catholic hospitals are prohibited from providing many types of care, including, in some Catholic hospitals, treatment for pregnant women experiencing miscarriages, even if the woman's life is at

risk. Women of color comprise 50% of women of reproductive age in New Jersey, yet represent 80% of births at Catholic hospitals. The lack of notice requirements or an emergency exemption in the Final Rule could compromise the safety of expectant mothers—especially expectant mothers of color at Catholic hospitals—experiencing, for example, ectopic pregnancies. Those mothers could face catastrophic delays in care or refusals of care were staff to raise previously undisclosed objections, as permitted under the Final Rule.

22. The Final Rule will also likely lead to the elimination or reduction of family planning providers, which would disproportionately impact lower-income New Jerseyans, especially women of color. Limited, delayed, and denied access to reproductive and family planning services has far-reaching economic consequences. Long-term impacts include constrained participation in the workforce, limited intergenerational economic independence, and hindered participation in public life. Sub-optimal health outcomes are linked to these economic impacts.

23. In addition to undermining access to care, the Final Rule likely would undermine the quality of care that is provided. Conscience objections can yield substandard care that deviates from evidence-based best practices. For example, NJDOH is concerned about refusals to administer vaccinations, to fill prescribed pharmaceuticals, and to provide medical aid in dying in conformance with New Jersey law.

Informed Consent Frustrated by Final Rule

24. The State of New Jersey has affirmed its commitment to the principle of informed consent in medical care, which includes a patient's right to advice and information from their provider about available, alternative treatments and options.

25. NJDOH promotes communication of clear, timely, unbiased medical information designed to inform and empower New Jersey's health consumers. The American Medical Association's Code of Medical Ethics (Opinion 2.1.1) makes clear: "Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."² Quality health care delivery in New Jersey requires implementation of such principles.

26. The Final Rule, however, allows health care providers to deny information and counseling on topics and services they find objectionable, and it does not require that a patient be informed that a health care provider is refusing to counsel them about, or refer them to, certain health care services. In this way, the Final Rule undermines the physician-patient relationship; erodes trust in the medical profession; and contradicts longstanding principles of informed consent.

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

Executed on this 6th day of June, 2019



Shereef M. Elnahal, M.D., M.B.A.,
Commissioner, New Jersey Department of Health

² American Medical Association, *Code of Medical Ethics Opinion 2.1.1*, <https://www.ama-assn.org/delivering-care/ethics/informed-consent>.

Exhibit 16

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 HAWAII,
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 KATHARINE ESHGHI

I, Katharine Eshghi, do hereby depose and state the following:

1. I am Senior Vice President and General Counsel at UMass Memorial Health Care (“UMass Memorial”). I am responsible for overseeing all aspects of legal affairs for the UMass Memorial health care system, including working closely with the system’s corporate boards, executive leadership and clinical and operational teams to identify and mitigate legal risks and to develop strategic solutions to complex legal and business challenges.

2. I am familiar with the Final Rule entitled “Protecting Statutory Conscience Rights in Health Care; Delegation of Authority” (“Final Rule”).

3. 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 Senior Vice President and General Counsel at UMass Memorial.

4. UMass Memorial is the largest health care system in central Massachusetts with approximately 13,000 employees, 1,700 physicians on the active medical staff and 1,125 hospital beds. The health care system includes three hospitals: UMass Memorial Medical Center, UMass Memorial HealthAlliance-Clinton Hospital and Marlborough Hospital. All of the hospitals operate 24/7 emergency departments. The UMass Memorial hospitals are recognized as Essential MassHealth hospitals and disproportionate-share hospitals serving as the safety net provider for a high percentage of low income and elderly patients in the service area. In addition, UMass Memorial includes: UMass Memorial Medical Group, a large multi-specialty physician group; Community Healthlink which provides a wide range of behavioral health and substance use disorder services; home health and hospice programs; and a range of ancillary care services through joint ventures, affiliations and other arrangements. UMass Memorial operates the only Level I Trauma Center for adults and children in

Central Massachusetts, and provides a full range of clinical services including heart and vascular care, orthopedics, transplant services, cancer care, surgery, newborn intensive care, children's services, women's services, emergency medicine and trauma services. Included in the services provided by UMass Memorial are induced termination of pregnancy, emergency contraception, sterilization, blood transfusions, vaccinations and end-of-life care. UMass Memorial is a private, non-profit charitable organization.

5. UMass Memorial is the clinical partner of the University of Massachusetts Medical School. Under this partnership, students, residents, and faculty physicians provide all levels of health care, and conduct research activities, at UMass Memorial hospitals. The academic physicians are employed by both UMass Medical School and the UMass Memorial Medical Group. These students, residents, and faculty are subject to the policies of both UMass Medical School and UMass Memorial.

6. Because UMass Memorial and UMass Medical School are so intertwined, any disruption to the operation of one will inevitably harm the operation of the other. UMass Memorial relies upon UMass Medical School faculty and residents to carry out its charitable mission of delivering clinical services and improving the health of the populations it serves. At the same time, support of the UMass Medical School academic mission, including research and education, is central to UMass Memorial's own charitable purpose.

7. Federal funding is critical to the operation of UMass Memorial. In fiscal year 2018, UMass Memorial billed \$2,832,376,991 in Medicare charges and \$1,461,520,174 in Medicaid charges. Specifically, for emergency department services in fiscal year 2018, the three UMass Memorial hospitals billed over \$530,413,000 in Medicaid charges and over \$1,020,000,000 in Medicare charges. UMass Memorial also receives other direct and indirect funding from the Department of Health and Human Services, including Health Resources and Services Administration

grants for the UMass Memorial behavioral health and substance use disorder provider Community Healthlink.

8. The Final Rule threatens UMass Memorial's continuing eligibility for this funding. For this reason, UMass Memorial has expended time and resources reviewing and determining how to comply with the Final Rule.

9. UMass Memorial recognizes the importance of conscience protections for health care providers. UMass Memorial believes that all patients, without regard to diagnosis, disability, age, race, color, religion, creed, gender, national origin, sexual orientation, gender identity and gender expression are entitled to comprehensive and individualized quality care. UMass Memorial workforce members are expected to perform within the scope of their training and expertise whatever duties are necessary and appropriate to ensure quality patient care and treatment. UMass Memorial also recognizes the right of a workforce member, in certain circumstances, to request to be excused from participating in certain aspects of patient care due to religious or ethical concerns. UMass Memorial has policies and procedures in place for workforce member requests to be excused from participating in certain aspects of patient care or treatment due to a conflict with the workforce member's ethics or religious beliefs and to ensure that when such a request may be granted the patient will not be affected negatively. Under the applicable policy and procedure, a workforce member requesting to be excused must follow specific requirements with respect to advance, written notice to their supervisor. While all such requests will receive consideration, patient care or other requirements may make it infeasible to grant a workforce member's request, or feasible to grant it only from time to time, depending on patient care needs. If, after consideration, the request is not granted, the workforce member is expected to fulfill the assigned patient care duties. If the employee refuses to provide care, disciplinary action up to and including

termination may be taken. A workforce member's request will not be approved if it is based solely on the patient's diagnosis (unless the employee's personal physician has provided written direction to avoid certain diagnoses because of a danger to the workforce member's existing health condition) or any aspect of the patient's demographic status.

10. Similarly, the Medical Staff Rules and Regulations of UMass Memorial Medical Center set forth a process to preserve patient safety and continuity of care while permitting members of the Medical Staff to request not to participate in certain aspects of patient care or treatment due to a conflict with their cultural values, ethics or religious beliefs. Specifically, within the scope of their expertise, Medical Staff members must treat all patients in accordance with generally accepted standards of care and failure to do so may subject them to disciplinary action up to and including revocation of clinical privileges. Under the Medical Staff Rules and Regulations, when requesting an exception to not participate in certain aspects of patient care or treatment, the Medical Staff member must maintain ongoing coverage of the patient by promptly arranging for care by another Medical Staff Member in the same department or by asking their Chair/Chief to make such arrangements to assure that continued appropriate medical care is provided for the patient in question.

11. The Final Rule is inconsistent with this balanced approach.

12. If the Final Rule were permitted to go into effect, it would place UMass Memorial in an untenable position. UMass Memorial could not effectively comply with the Final Rule without jeopardizing core clinical operations and its financial stability, and without violating other applicable legal, professional and ethical obligations. The Final Rule is overbroad, vague and unclear in defining what is required and/or permissible in the context of direct and indirect conflict between the Final Rule and other statutory and regulatory schemes, including the Emergency Medical Treatment

and Labor Act, informed consent requirements, and Federal anti-discrimination statutes such as Section 1557 of the Affordable Care Act and Title VII of the Civil Rights Act of 1964.

13. The Final Rule would significantly restrict UMass Memorial's ability to require advance notice from its workforce of any potential religious and moral objections or to make staffing decisions necessary to ensure that personnel can perform the essential core functions of their positions including critical clinical functions. If members of the workforce, at any time and without advance notice, are permitted to refuse to participate in or assist with the delivery of clinical services in urgent or emergent situations, or in other circumstances where continuity of care is compromised, patients may be harmed. If members of the workforce are permitted to assert a religious or moral objection to providing or assisting with the provision of services based on the race, religion, disability, diagnosis, gender identity, gender expression or sexual orientation of a patient, patients may be harmed. If UMass Memorial is required to staff individuals in positions where they are unable to perform core functions due to asserted religious or moral objections, delivery of safe, medically necessary care may be significantly impaired and patients may be harmed. Under the Final Rule, UMass Memorial may be required to call upon other available staff without notice or advance planning to cover for employees who are refusing to provide services, creating additional disruption to the delivery of care throughout the facility. To mitigate these unacceptable risks to patient care under the Final Rule, UMass Memorial would be required to hire untold numbers of additional staff in anticipation of potential workforce objections at significant cost to the system. Expenditures on duplicative, and otherwise unnecessary and unproductive staffing, would necessitate budget cuts in other areas of operations potentially jeopardizing vital clinical services for Central Massachusetts.

14. The Final Rule would significantly restrict the ability of the Medical Staff to require Medical Staff members, and for UMass Memorial to require its employees, to ensure ongoing


coverage for patients or continuity of care when they refuse to participate in certain aspects of patient care or to provide services to certain patients. Such a situation may result in harm to patients, and expose UMass Memorial to legal liability for patient abandonment, violations of civil rights laws, and medical malpractice for any resulting adverse outcomes.

15. The Final Rule would subject UMass Memorial to conflicting legal, regulatory, ethical and professional obligations. If UMass Memorial cannot require members of its workforce to provide care to patients regardless of race, religion, diagnosis, disability, gender identity, gender expression or sexual orientation, UMass Memorial can neither fulfill its charitable mission to improve and protect the health of the diverse populations it serves nor comply with applicable civil rights laws. If UMass Memorial cannot require members of its workforce to provide full and complete information regarding the range of treatment options available, UMass Memorial cannot ensure that its legal and ethical obligations with respect to informed consent are met or that its patients are receiving safe, appropriate, culturally competent and medically necessary care.

16. Failure to comply with the Final Rule would place critical federal funding at risk. UMass Memorial would not be able to continue to operate without federal funding and, as a result, Central Massachusetts would lose access to critical health care services not otherwise available in the region.

PURSUANT TO 28 U.S.C. § 1746, I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on this 10th day of June, 2019



Katharine Eshghi
Senior Vice President and General Counsel
UMass Memorial Health Care

Exhibit 17

**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. NGOZI O. EZIKE

1. I, Dr. Ngozi O. Ezike, 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 Illinois'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 Illinois Department of Public Health ("IDPH") personnel who have assisted me in gathering this information from our institution, or on the basis of documents I have reviewed. I have also familiarized myself with the Final Rule in order to understand its potential impact upon IDPH.

3. I am the Director of IDPH. I graduated with honors from Harvard College with a concentration in chemistry. I received my medical degree from the University of California at San Diego and a management certificate from Harvard Business School. I completed my internship and residency at Rush Medical Center in Chicago. I am board certified in both internal medicine and pediatrics. I have been the Director of IDPH since February 2019. Prior to my appointment, I was the Medical Director of Cook County Juvenile Detention Center, Medical Director of Austin Health Center, and provided inpatient care at Stroger Hospital.

I. Background on IDPH

4. The mission of IDPH is to protect the health and wellness of the people of Illinois through the prevention, health promotion, regulation, and the control of disease and injury. IDPH has an annual budget of more than \$600 million in state and federal funds with headquarters in Springfield and Chicago plus seven regional offices. IDPH is organized into six offices that each address an area of public health.

5. Office of Women’s Health and Family Services (“OWHFS”) is one of the six offices within IDPH. OWHFS’s responsibilities include overseeing the health and services for women and girls throughout their lifespan as well as family services that address the health and well-being of pregnant women, infants, children and adolescents through child and adolescent health, perinatal health, and school health programs. OWHFS addresses breast and cervical health, heart disease and lifestyle choices, adolescent health, infant mortality, school health, and family planning.

6. The Division of Infectious Diseases is part of the Office of Health Protection at IDPH. The mission of the Division of Infectious Diseases is to protect people from infectious diseases through disease surveillance, analysis, immunization, and education. The Division is organized into the sections of Communicable Diseases, HIV/AIDS, Sexually Transmitted Diseases, and Immunization.

7. As evidenced in the attached chart, IDPH has received approximately \$192 million from HHS since April 1, 2017 to the present. Attachment A.

8. Since August 1, 2018, IDPH has distributed \$20,000 in HHS funding to the Chicago Department of Public Health to implement, evaluate, and disseminate strategies that address injury and violence issues including: child abuse and neglect, traumatic brain injury, motor vehicle crash injury and death, and intimate partner/sexual violence.

9. Since July 1, 2018, IDPH has distributed \$1.1 million in HHS funding to the Cook County Department of Public Health for responding to public health threats, including infectious diseases, natural disasters, and biological, chemical, nuclear, and radiological events. Since July 1, 2018, IDPH has also distributed \$148,683 in HHS funding to the Cook County Department of Public Health to respond to large public health emergencies needing life-saving medicines and medical supplies.

10. HHS funds are essential to the functioning of IDPH and maintaining public health across the state of Illinois.

II. Final Rule May Preempt Existing IDPH Policies

11. IDPH's current policies are tailored to comply with existing Illinois laws on religious accommodation, which provide that:

- a. Individuals with conscience objections are not relieved of their obligations to provide emergency medical care under 210 ILCS 70/1; 210 ILCS 80/1; 745 ILCS 70/6; and 77 Ill. Adm. Code 545.35;
- b. Abandoning a patient is grounds for disciplinary action, including license revocation under 225 ILCS 60/22(A)(16);
- c. Health care providers must give patients information concerning their condition and proposed treatment under 410 ILCS 50/3;
- d. Health care providers conducting HIV testing must first obtain informed consent from individuals undergoing testing under 410 ILCS 305/3;
- e. Certain agencies must deliver specified services either directly on-site or by referral, including contraception and other reproductive health care services under 77 Ill. Adm. Code 635.90; and
- f. Insurers must provide coverage for contraception under 215 ILCS 5/356z.4.

12. Compliance with the Final Rule could frustrate IDPH's ability to comply with the aforementioned Illinois laws. Therefore, under the Final Rule, IDPH would be forced to choose between following Illinois law and the Final Rule.

III. Immediate Impact of Final Rule on IDPH

A. Family Planning Title X Grant

13. The Family Planning Title X Block Grant is an HHS program developed to provide funding for a broad range of high-quality family planning services for underserved individuals.

14. IDPH has received \$4 million from the Family Planning Title X Block Grant since April 1, 2019. Attachment A.

15. Services funded with Title X dollars in Illinois include:

- a. FDA-approved methods of contraception;
- b. Pap tests;
- c. Screening tests for sexually transmitted infections (“STI”);
- d. Pregnancy tests as indicated and according to nationally recognized standards of care and non-directive counseling upon a positive pregnancy test;
- e. Contraceptive management, client counseling, and education;
- f. Pre-conception care; and
- g. Counseling and referrals for pregnancy planning, including assistance with infertility.

16. OWHFS distributes Title X funding to 63 local health departments, health centers, school-based health centers, and hospitals in 43 counties in Illinois.

17. Since October 2018 to June 2019, OWHFS has distributed \$204,238 in Title X funding to the Cook County Department of Public Health for the provision of free mammograms, breast exams, pelvic exams, and Pap tests to eligible women.

18. In 2017, Title X subgrantees served 46,103 patients, 94% of which were female and 82% were at or below the poverty level.

19. Women and adolescents with incomes of less than 250% of the federal poverty level are the target population of Title X funding. Women with incomes below 100% of the federal poverty level receive free services funded by Title X.

20. The majority of clinics that receive Title X funding from IDPH are in rural areas of Illinois and are the sole source of quality comprehensive family planning services in those areas. Title X funds permit IDPH to work with local health departments to bridge a gap in services, prevent unwanted pregnancies, and reduce the rate and incidence of STIs.

21. It is possible that IDPH employees or employees of Title X subgrantees will raise conscience objections to the services provided under Title X funding considering that some individuals have conscience objections to contraception, STI testing, pregnancy counseling, and pregnancy planning.

22. However, the Final Rule does not explain how IDPH can adequately accommodate and protect conscience objectors, such as those that could arise in Title X programs, or how HHS will assess whether a recipient of HHS funding like IDPH has violated the federal statutes wielded in the Final Rule. Thus, IDPH's HHS funding is at risk because IDPH is unable to decipher how HHS will enforce the Final Rule.

23. If HHS determines that IDPH or one of its subgrantees violates the Final Rule, IDPH could lose millions of HHS funding under the funding termination scheme, including over \$4 million in Title X funding. As a result of loss of Title X funding, thousands of Illinoisans would have no access to comprehensive family planning services, basic infertility services, pregnancy diagnosis, STI diagnosis and treatment, HIV education, and screenings for breast, cervical, and testicular cancers.

24. Moreover, any reduction or revocation of Title X funding to IDPH would disproportionately injure women, individuals living in rural areas, and those living below the poverty line.

B. Maternal and Child Health Title V Grant

25. The Maternal and Child Health Title V Block Grant is one of the largest federal block grant programs and is a key source of support for promoting and improving the health and well-being of the nation's mothers, children (including children with special needs), and their families.

26. IDPH has received approximately \$31.75 million from the Maternal and Child Health Title V Block Grant since October 1, 2017. Attachment A.

27. IDPH services funded with Title V dollars in Illinois include:

- a. Care for children with specialized health care needs;
- b. School-based health centers;
- c. Regionalized perinatal health centers;
- d. Adolescent health programming;
- e. Fetal infant mortality review;
- f. Dental sealants for underserved children;
- g. Home visiting service integration for pregnant and postpartum women and children;
- h. Infant and early childhood mental health consultation;
- i. Maternal and neonatal quality improvement initiatives in hospital settings;
- j. Improving communication and collaboration among health care providers for mothers and newborns impacted by opioids;
- k. Maternal mortality review;
- l. Improving and increasing perinatal depression screening;

- m. Addressing adolescent suicide;
- n. Improving intrapartum health; and
- o. Statewide perinatal depression hotline.

28. Since July 1, 2017, OWHFS has distributed a total of \$9 million in Title V funding to the Chicago Department of Public Health for maternal and child health services. This includes \$4.51 million for integration of home visiting services for pregnant and postpartum women and their children. OWHFS has also distributed \$60,000 in Title V funding to the Chicago Department of Public Health for dental sealants for underserved children since July 1, 2018.

29. OWHFS also distributes Title V funding to:

- a. The University of Illinois Chicago Division of Specialized Care for Children to provide care for children with special health care needs;
- b. Schools, local health departments, federally qualified health centers, and hospitals to operate school-based health centers;
- c. 10 academic health centers to operate regionalized perinatal health centers;
- d. 12 local health departments, community organizations, and statewide organizations to increase adolescent visits;
- e. The University of Chicago Hospital to conduct fetal infant mortality review;
- f. The IDPH Office of Health Promotion to provide dental sealants throughout the state of Illinois;
- g. The Lurie Children's Hospital to provide infant and early childhood mental health consultation to public health programs at two county health departments;

- h. The Illinois Perinatal Quality Collaborative located at Northwestern University to provide quality improvement training and technical assistance at birthing hospitals in Illinois to improve maternal and neonatal outcomes;
- i. The Agency for Human Potential to improve communication and collaboration across state agencies and local providers for mothers and newborns impacted by opioids;
- j. The University of Illinois Chicago to: conduct severe maternal mortality reviews and to provide data to IDPH; provide assistance in abstracting maternal deaths for review by IDPH and its committees for maternal mortality review; and provide training and implement screening protocols to increase perinatal depression screening;
- k. The IDPH Office of Health Promotion to have a graduate intern to focus on adolescent suicide efforts within their efforts on suicide prevention;
- l. Everthrive to develop and distribute toolkits for health care providers to improve intrapartum health; and
- m. Northshore Hospital to operate a statewide peripartum depression hotline.

30. It is possible that IDPH employees or employees of Title V subgrantees will raise conscience objections to the services provided under Title V funding.

31. The Final Rule does not provide guidance on how IDPH can adequately accommodate and protect conscience objectors, such as those that could arise in Title V programs, or how HHS will assess whether a recipient of HHS funding like IDPH has violated the federal statutes wielded in the Final Rule. Thus, IDPH faces a risk of losing HHS funding under the Final Rule.

32. If HHS determines that IDPH or ones of its subgrantees violates the Final Rule, IDPH could lose millions of HHS funding under the funding termination scheme, including over \$31.75

million in Title V funding. As a result of any reduction or loss of Title V funding, the health of women and children in Illinois would face worse outcomes.

C. AIDS Drug Assistant Programs

33. The Division of Infectious Diseases uses over \$31.62 million in HHS funding to run AIDS Drug Assistance Programs across Illinois (“ADAP”), which provide HIV-related prescription drugs to low-income persons living with HIV who have limited or no prescription drug coverage. In Calendar Year (“CY”) 2018, an average of 13,517 clients were enrolled in ADAP, of which ADAP served an average of 8,010 clients monthly. The total number of ADAP clients served in CY 2018 was 13,517, which consisted of direct purchase, insurance, and Medicare Part D clients. In CY 2018, total ADAP expenses for HIV medications were almost \$63 million, which include dispensing fees on average of \$1.2 million. Total expenses for insurance costs (excluding Medicare Part D) for CY 2018 were \$11.5 million. Medicare Part D costs were \$2.6 million.

34. It is highly likely that some IDPH employees and subgrantees will have conscience objections to ADAP because some individuals hold religious or conscience objections to treating individuals living with HIV or AIDS. However, the Final Rule does not explain how IDPH can adequately accommodate and protect conscience objectors, such as those likely to arise in the context of ADAP, or how HHS will assess whether a recipient of HHS funding like IDPH has violated the federal statutes wielded in the Final Rule. Thus, IDPH faces a risk of losing all HHS funding under the Final Rule if an individual raises conscience or religious objections to providing care to individuals with HIV or AIDS through ADAP.

35. My understanding is that under the Final Rule, if HHS finds that IDPH or any of its subgrantees are in violation of the Final Rule, IDPH could lose millions of HHS funding under the

funding termination scheme, including over \$31.62 million in HHS funding for ADAP. As a result of any reduction or loss of HHS funding for ADAP, thousands of Illinoisans living with HIV or AIDS who have limited or no prescription drug coverage would be deprived of the life-saving drugs provided by ADAP.

D. Pre-Exposure HIV Treatments

36. The Division of Infectious Diseases receives approximately \$350,000 in HHS funding that funds staff overseeing pre-exposure prophylaxis medication (“PrEP”) grants to 97 local health departments across the state of Illinois. IDPH employees monitor and provide oversight for the grants to these local health departments.

37. PrEP are daily medicines that lower the chances of HIV infection. PrEP can stop HIV from taking hold and spreading throughout the body. It is highly effective for preventing HIV if used as prescribed, but it is much less effective when not taken consistently. Daily PrEP reduces the risk of getting HIV from sex by more than 90%. For people who inject drugs, it reduces the risk by more than 70%.

38. IDPH employees or subgrantees may have conscience objections to PrEP as some individuals believe it condones illicit drug use, homosexuality, and risky sexual behavior like unprotected sex. However, the Final Rule does not explain how IDPH can adequately accommodate and protect conscience objectors, such as those likely to arise in the context of dispensing PrEP, and still provide necessary care. Nor does it explain how HHS will assess whether a recipient of HHS funding like IDPH has violated the federal statutes wielded in the Final Rule. Thus, IDPH faces a very real risk of losing all HHS funding under the Final Rule, particularly due to an alleged violation in the context of dispensing PrEP.

39. As a result of any reduction or loss of the approximately \$350,000 in HHS funding that IDPH receives for PrEP, Illinoisans at high risk of HIV infection would be deprived of the crucial PrEP provided by IDPH and some would likely become infected with HIV.

E. Impact on non-Hispanic Blacks

40. HIV disproportionately affects non-Hispanic blacks in Illinois. In Illinois from 2009 to 2013, non-Hispanic blacks accounted for 50% of all new HIV disease diagnoses despite accounting for less than 15% of the population. The HIV diagnoses rate in Illinois among non-Hispanic blacks (47.7 per 100,000 population) was three times higher than among Hispanics (15.9 per 100,000 population), the group with the next highest incidence rate. Moreover, the HIV mortality rate among non-Hispanic blacks is almost ten times higher than among non-Hispanic whites.

41. Thus, if HHS finds IDPH or any of its subgrantees are in violation of the Final Rule and revokes any or all of the HHS funding for ADAP as a result, non-Hispanic blacks in Illinois would be disproportionately injured.

F. Impact on Men Who Have Sex with Men

42. As seen nationally, the majority of new HIV disease diagnoses in Illinois have occurred among males who have sex with males (“MSM”). From 2011–2015, 4,976 MSM in Illinois were diagnosed with HIV disease, accounting for 74% of all new HIV disease diagnoses in Illinois where a transmission risk category was reported.

43. Thus, if HHS finds IDPH or any of its subgrantees are in violation of the Final Rule and revokes any or all of IDPH’s HHS funding for ADAP as a result, MSM in Illinois would be disproportionately injured.

G. Impact on IDPH Grant Process and Monitoring

44. With its lack of specificity and finite directions on what constitutes adequate accommodation and protection of conscience objectors, the Final Rule has an immediate and damaging impact upon IDPH and the state of Illinois.

45. It is my understanding that the Final Rule expands definitions of terms, such as “assist in the performance,” “discrimination,” and “health care entity,” such that any IDPH employee or subgrantee must be permitted to refuse to perform a task due to a conscience objection without providing IDPH or a subgrantee notice of their objection. This would profoundly affect how IDPH functions.

46. These defined terms are vague and do not provide sufficient guidance for IDPH as to how to comply.

47. It is also my understanding that the Final Rule prohibits any restrictions upon the ability of individuals to object to assisting in the performance of any procedure they find objectionable on religious or moral grounds. For example, it is not clear whether IDPH can require a conscientious objector to provide a service or treatment in an emergency as is required under Illinois law. 745 ILCS 70/6.

48. As a result of the Final Rule and the risk that any individual may now refuse to provide patient care at any time, IDPH must create contingency staffing plans to ensure that more than one of each necessary professional is available at all times. In many cases, this requires hiring additional staff rather than “substituting” existing staff into other roles. In other cases, this requires extensive staff training on what behavior is now permissible from conscience objectors and how to work around unplanned conscience objections.

49. My understanding is that Final Rule makes IDPH responsible for non-compliance by subgrantees that receive HHS funds through IDPH.

50. Accordingly, the Final Rule would force IDPH to reconfigure every current and future grant that distributes HHS funding to ensure every subgrantee complies with the Final Rule to avoid reduction or revocation of HHS funding. The Final Rule would also force IDPH to monitor all subgrantees of HHS funding to ensure continued compliance with the Final Rule to avoid reduction or revocation of HHS funding.

51. Such changes to IDPH's grant process and increased compliance monitoring for subgrantees would be a significant burden on IDPH because it would require additional staff training, legal advice, and potentially hiring new staff.

IV. HHS Questionnaire

52. On December 14, 2018, Luis E. Perez, the Deputy Director of the Conscience and Religious Freedom Division in the HHS Office for Civil Rights sent a letter and questionnaire (collectively, "Questionnaire") to the Illinois Governor, Attorney General, and Department of Financial and Professional Regulation. Attachment B. The Questionnaire served as a "notice of investigation" by HHS into allegations that "the State of Illinois has violated the conscience rights of health care providers or has discriminated against them on the basis of religion." *Id.* The Questionnaire further stated that HHS's investigation was proceeding under authority granted by the Weldon Amendment, Coats-Snowe Amendment, and Church Amendments. *Id.*

53. The HHS investigation described in the Questionnaire relies on the same federal statutes wielded in the Final Rule. *See* 84 Fed. Reg. at 23,170, *passim* (to be codified at 45 C.F.R. § 88.2). Thus, HHS could revoke any or all of Illinois's HHS funding under the Final Rule if it goes into effect for any alleged violation it finds in the investigation described in the Questionnaire.

54. The Questionnaire asked Illinois to list and describe several categories of HHS funding that it receives, including: Medicaid; CHIP; HHS's appropriation within HHS, the Departments of Labor and Education, and the Related Agencies Appropriations Act; the Public Health Service Act; the Patient Protection and Affordable Care Act; Preventive Health and Health Services Blocks Grant; Substance Abuse Prevention and Treatment Block Grants; the Community Mental Health Services Block Grant; and the Maternal and Child Health Block Grant.

55. The Questionnaire also asked whether Illinois has enforced or intends to enforce amendments to the Illinois Health Care Right of Conscience Act that have been challenged in state and federal litigation. Attachment B.

56. On February 25, 2019, Illinois responded to the Questionnaire. Attachment C. In this response, Illinois stated: "Since July 29, 2016, the State of Illinois received approximately \$28.5 billion from Medicaid and approximately \$780 million from CHIP." *Id.* Illinois also provided a chart listing hundreds of millions in HHS funding it receives through the other specified funding streams. *Id.* Illinois's response noted that a federal court had preliminarily enjoined the amendments to the Illinois Health Care Right of Conscience Act and that Illinois "has no intention of enforcing the statute while the injunction remains effective." *Id.*

57. I believe that if the Final Rule goes into effect, HHS may move to strip IDPH of some or all HHS funding in light of the Questionnaire and HHS's ongoing investigation into alleged religious discrimination in Illinois. Thus, IDPH faces a real and imminent threat of loss of millions of dollars of HHS funding should the Final Rule go into effect.

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

A handwritten signature in blue ink, appearing to read "Ngozi O. Ezike", is written over a horizontal line.

Dr. Ngozi O. Ezike

Director of the Illinois Department of Public Health

Exhibit 17

Attachment A

Description	Start date	Amount	CFDA #
State Loan Repayment	9/1/2018	861,307.00	93.165
Rural Health Care	7/1/2018	183,763.00	93.913
Primary Health Care	4/1/2019	270,028.00	93.130
Behavioral Risk - Internet Survey	3/29/2019	260,855.00	93.336
Rural Hospital Flexibility Program	9/1/2018	877,006.00	93.241
ELC DEPT 08	8/1/2018	40,000.00	93.323
WiseWoman	9/30/2018	500,000.00	93.436
Bioterrorism Hospital Preparedness	7/1/2018	8,601,678.00	93.074
Bioterrorism	7/1/2018	14,375,853.00	93.074
Ebola Preparedness	5/18/2015	1,954,126.00	93.817
Bioterr.-Cities Readiness Initiative-CRI	7/1/2018	1,885,757.00	93.074
SHIPS-Small Rural Hospital Improv.	6/1/2018	589,860.00	93.301
Reduce Opioid Overdose in Illinois	9/30/2018	724,647.00	93.243
ELC HAI DETECTION. PREVENTION AND STEWAR	8/1/2018	1,424,349.00	93.323
Vision & Hearing Surveillance	7/1/2018	150,000.00	93.314
Opioid-Involved Morbidity and Mortality	9/1/2018	860,462.00	93.136
Rape Prevention	2/1/2019	1,231,121.00	93.136
Cancer Registry Enhancement	6/30/2018	1,100,000.00	93.898
State Asthma Plan	9/1/2018	700,000.00	93.070
State-Based Birth Defects Surv.	2/1/2019	210,000.00	93.073
OPPS OPIOID CO-AG	9/1/2018	2,080,430.23	93.354
Public Health Approaches Quitline	8/1/2017	639,440.00	93.735
MCH Block Grant Title 5	10/1/2017	21,129,026.00	93.994
MCH Block Grant Title 5	10/1/2018	10,616,119.00	93.994
Preventive Health Services	10/1/2017	3,756,818.00	93.991
HEART DISEASE	9/30/2018	961,011.00	93.426
Illinois MCH Data Use Academy	12/1/2018	100,000.00	93.110
DIABETES	9/30/2018	961,011.00	93.426
Childhood Lead Poisoning	9/30/2018	567,383.00	93.197
Core State Violence & Injury Grant	8/1/2018	249,989.00	93.136
Refugee	7/1/2018	501,661.00	93.566
Refugee Preventive Health	8/15/2018	149,200.00	93.576
Medicare	10/1/2018	12,733,509.00	93.777
Clinical Laboratory Improv. Act	10/1/2018	740,271.00	93.777
Comprehensive Cancer	6/30/2018	344,221.00	93.898
IDPH Manufactured Food Regulatory Prgm	9/1/2018	300,000.00	93.367
National Syndromic Surveillance	9/1/2018	322,079.00	93.283
National Retail Food Regulatory Program	7/1/2018	63,841.00	93.103
PPHF	8/1/2015	1,704,900.00	93.521
PPHF	8/1/2016	1,242,512.00	93.521
PPHF	8/1/2017	770,577.00	93.323
NON PPHF-ELC	8/1/2018	2,469,962.00	93.323
ELC Zika	8/1/2017	839,398.00	93.323
Epidemiology & Laboratory Capacity	3/31/2015	3,134,720.00	93.815
OHP OPIOID CO-AG	9/1/2018	1,594,059.74	93.354
TB Control	1/1/2019	1,481,231.00	93.116
Cancer Prevention & Control	6/30/2018	7,000,000.00	93.898
AMCHP CoIIN Contract	4/1/2018	22,000.00	93.110
Immunization	4/1/2017	7,338,577.00	93.268
Childhood Vaccination	4/1/2017	11,301,980.00	93.268
STD	1/1/2019	2,246,838.00	93.977
Block Grant Title 20	7/1/2018	1,400,000.00	93.667
Title X Family Planning	4/1/2019	4,000,000.00	93.217
Tobacco Control	3/29/2019	1,243,632.00	93.305
Oral Health Workforce Activities	9/1/2018	399,789.00	93.236
Comprehensive HIV Prevention	1/1/2019	4,152,892.00	93.940
Morbidity & Risk Behavior Surv.	6/1/2018	430,291.00	93.944
AIDS Surveillance	1/1/2019	813,285.00	93.940
HIV Care-Ryan White	4/1/2019	9,549,487.00	93.917
MAI-Ryan White	4/1/2019	456,274.00	93.917
HIV Care-Ryan White	4/1/2019	29,693,840.00	93.917
ADAP Supplemental	4/1/2019	6,000,000.00	93.917
	Total:	192,303,065.97	

Exhibit 17

Attachment B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Voice - (800) 368-1019
TDD - (202) 619-3257
Fax - (202) 619-3818
<http://www.hhs.gov/ocr>

Office for Civil Rights
200 Independence Avenue, S.W.,
Room 509F
Washington, DC 20201

December 14, 2018

SENT VIA CERTIFIED U.S. MAIL, RETURN RECEIPT REQUESTED

Governor Bruce Rauner
207 Statehouse
Springfield, IL 62706

Lisa Madigan, Esq.
Illinois Attorney General
500 South Second Street
Springfield, IL 62701

Secretary Bryan A Schneider
Illinois Department of Financial & Professional Regulation
320 West Washington, 3rd Floor
Springfield, IL 62786

Re: OCR Transaction Numbers 17-282111, 18-292352, 17-282092, 18-293480, and
18-304777

Dear Governor Rauner, Attorney General Madigan, and Secretary Schneider:

The U.S. Department of Health & Human Services Office for Civil Rights ("OCR") has received multiple complaints, enclosed herein, alleging the State of Illinois has violated the conscience rights of health care providers or has discriminated against them on the basis of religion. OCR has jurisdiction to enforce certain Federal laws that protect religious nondiscrimination rights in health and human services programs and to protect the conscience rights of health care providers who refuse to perform, accommodate, or assist with certain health care services.

Federal regulations designate OCR to receive and handle complaints based on Federal laws protecting conscience and preventing coercion, including the Weldon Amendment,¹ the Coats-Snowe Amendment,² and the Church Amendments.³ OCR has reviewed the complaints

¹ Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, Div. H, Tit. V, § 507(d), 131 Stat. 135, 562 (2017).

² 42 U.S.C. § 238n.

³ *Id.* § 300a-7.

and has determined that it has sufficient authority and cause to investigate the allegations under one or more of these laws.

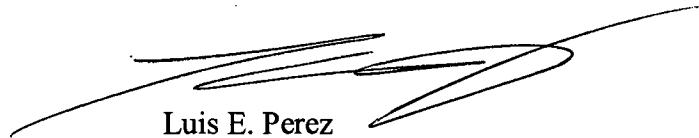
Under the Freedom of Information Act, we may be required to release this letter and other information about these cases upon request by the public. In the event OCR receives such a request, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

This letter is notice of an investigation and does not constitute a finding of violation. We look forward to your cooperation with the investigation. Section 1001 of 18 U.S.C. makes it a crime for any person knowingly and willfully to make any materially false, fictitious, or fraudulent statements or representations to a department or agency of the United States as to any matter within its jurisdiction. You should not destroy, modify, remove, transfer, or make inaccessible documents that are potentially responsive to the questionnaire, or that may be related to this matter.

Within thirty (30) days of the date of this letter, please submit your responses to: Mandi Ancalle (contractor), U.S. Department of Health & Human Services Office for Civil Rights, 200 Independence Ave. S.W., Washington, D.C. 20201, Mandi.Ancalle@hhs.gov.

Please be advised that communication by unencrypted e-mail presents a risk of disclosure of the transmitted information to, or interception by, unintended third parties. Please keep this in mind when communicating with us by e-mail.

Sincerely,



Luis E. Perez
Deputy Director
Conscience and Religious Freedom Division

Enclosures

OCR Transaction Nos. 17-282111, 18-292352, 17-282092, 18-293480, and 18-304777

Date: December 14, 2018

QUESTIONNAIRE

For each of the questions to which you respond yes, please provide your substantive response in a separate attachment.

1. Has the State of Illinois, or any of its instrumentalities, implemented or enforced 745 Ill. Comp. Stat. Ann. 70/6-6.2 of the Illinois Health Care Right of Conscience Act?
No Yes
2. Does the State of Illinois, or any of its instrumentalities, intend to implement or enforce 745 Ill. Comp. Stat. Ann. 70/6-6.2 of the Illinois Health Care Right of Conscience Act?
No Yes
3. Please indicate whether, and to what extent, the State of Illinois considers the U.S. Supreme Court's decision in *National Institute for Family and Life Advocates v. Becerra*, 585 U.S. ___, 138 S. Ct. 2361 (2018), to have impacted the constitutionality or enforceability of the Illinois Health Care Right of Conscience Act.
4. Please indicate whether the State of Illinois, or any of its instrumentalities, has been a recipient or sub-recipient of Federal financial assistance from HHS from July 29, 2016, to the present. If yes, please describe the awarding HHS component (or non-Federal organization receiving Federal financial assistance from HHS), dates the financial assistance was received and when it first began, the purpose of the assistance, and the dollar amount of the assistance.
5. Please indicate whether the State of Illinois, or any of its instrumentalities, participate in Medicaid and/or CHIP programs, and if so, please provide an approximate amount of funding from the program from July 29, 2016, to the present.
6. Please indicate whether the State of Illinois, or any of its instrumentalities, received funding through any of the programs or mechanisms listed below from July 29, 2016, to the present, and *if it has, please provide the amount received, the date received, the program under which the funding was received, and any grant, contract, loan, loan guarantee, interest subsidy, award or health plan numbers associated with the funding, as applicable.*
 - The U.S. Department of Health and Human Services' appropriation within the **Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act.**
 - **Public Health Service Act** (42 U.S.C. §§ 201 *et seq.*), whether by grant, contract, loan, or loan guarantee.

- **Patient Protection and Affordable Care Act** (Pub. L. No. 111–148 (2010)), as amended, whether for federally-qualified health plans or otherwise.
- **Biomedical or Behavioral Research Grants or Contracts**, under any program administered by the Secretary of the U.S. Department of Health & Human Services.
- **Health Service Program or Research Activity Funds**, under a program administered by the Secretary of the U.S. Department of Health & Human Services.

7. Please indicate whether the State of Illinois, or any of its instrumentalities, received funding or other assistance as a recipient or sub-recipient through any of the grant programs listed below from July 29, 2016, to the present, and *if it has, please provide the amount received, the date received, and any grant, grantee, or provider numbers, as applicable.*

PROGRAM NAME	U.S.C.	CFDA #
Preventive Health and Health Services Block Grant	42 U.S.C. 300w-7	93.991
Substance Abuse Prevention and Treatment Block Grants	42 U.S.C. 300x-57	93.959
Community Mental Health Services Block Grant	42 U.S.C. 300x-57	93.958
Maternal & Child Health Services Block Grant	42 U.S.C. 708	93.994



September 11, 2017

Via E-Mail and U.S. Mail: OCRCComplaint@hhs.gov

Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, DC 20201

RECEIVED
SEP 12 2017
HHS/OCR HQ

Re: Complaint of Discrimination in Violation of Federal Statutes

Dear Sir or Madam:

Alliance Defending Freedom represents Tina Gingrich, MD and Tina M.F. Gingrich, M.D., P.C. d/b/a Maryville Women's Center, who have been subjected to unlawful discrimination by the Illinois Department of Financial & Professional Regulation, a state agency subject to the Church Amendments (42 U.S.C. § 300a-7), the Public Health Service (PHS) Act (§ 245 (42 U.S.C. § 238n)), and/or the Weldon Amendment (Continuing Appropriations Resolution, Pub. L. No. 113-164, Sec. 101(a) (Sept. 19, 2015)) by virtue of its status as a recipient of federal funding.

Dr. Gingrich is an Illinois Ob/Gyn who practices medicine in conformance with her religious convictions that all human life should be respected in all stages of life, included life within the womb. These convictions prohibit her from performing, assisting in, referring for, or participating in any way with abortion or abortion-causing drugs. She does so at her private Ob/Gyn practice, Maryville Women's Center, and also as medical director for a pro-life pregnancy center. The rights of Dr. Gingrich, Maryville Women's Center, and the said pro-life pregnancy center to offer medical assistance to women in need without compromising their religious convictions relating to abortion or abortion-causing drugs are protected by the First Amendment to the United States Constitution, the Constitution of the State of Illinois and the Illinois Healthcare Right of Conscience Act, 745 ILCS 70/1 *et seq.*, in addition to the federal conscience clauses named above.

Pursuant to Illinois Senate Bill 1564, signed into law by Governor Bruce Rauner July 29, 2016, "healthcare entities" such as Maryville Women's Center and others similarly situated are required to "adopt written access to care and information protocols that are designed to ensure that conscience-based objections will be addressed in a timely manner to facilitate patient health care services." SB 1564, § 6.1. The safeguards of the state's Healthcare Right of Conscience Act, 745 ILCS 70/1, only apply if conscience-

Centralized Case Management Operations
U.S. Department of Health and Human Services
Complaint of Discrimination
September 11, 2017
Page 2

based refusals are asserted in accordance with these protocols. *Id.* The mandated protocols must, at a minimum, require health care facilities, physicians and health care personnel to inform a patient of “legal treatment options” in a timely manner, § 6.1(1), and if such treatment is contrary to their conscientious beliefs, arrange for others in the entity to provide the service or refer or transfer the patient to other health care providers whom they know will do so. § 6.1(3).

Because SB 1564 violates their right to practice medicine according to their conscience and religious beliefs, Dr. Gingrich, Maryville Women’s Center and others brought suit in the United States District Court for the Northern District of Illinois. The attached Complaint, *The National Institute of Family and Life Advocates, et al., v. Rauner*, Case No. 3:16-cv-50310, filed Sep. 29, 2016 (attached as Exhibit A), contains the factual and legal descriptions of this violation of our clients’ rights. On July 19, 2017, the court enjoined the application of SB 1564 to Dr. Gingrich, Maryville Women’s Center and the other plaintiffs in the lawsuit, holding the plaintiffs had “demonstrated a better than negligible chance of showing that a law compelling the health care provider with conscience-based objections to abortion to serve as the source of information about the legal treatment option of abortion and to serve as a directory of health care providers performing abortions is not narrowly tailored to achieve a substantial government interest.” See attached Order Granting in Part Motion for Preliminary Injunction at 9 (attached as Exhibit B).

Please promptly inform us of the actions your office plans to take regarding this violation. Thank you for your attention to this matter.

Sincerely yours,

/s/ Elissa Graves
Elissa Graves, Esq.

cc: Kevin Theriot, Esq., Senior Counsel, Alliance Defending Freedom
Clients



RECEIVED
SEP 12 2017
HHS/OCR HQ

September 11, 2017

Via E-Mail and U.S. Mail: OCRComplaint@hhs.gov

Centralized Case Management Operations
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 509F HHH Bldg.
Washington, DC 20201

Re: Complaint of Discrimination in Violation of Federal Statutes

Dear Sir or Madam:

Alliance Defending Freedom represents Anthony Caruso, MD and A Bella Baby OBGYN, Inc. (incorporated as Best Care for Women, Inc.), who have been subjected to unlawful discrimination by the Illinois Department of Financial & Professional Regulation, a state agency subject to the Church Amendments (42 U.S.C. § 300a-7), the Public Health Service (PHS) Act (§ 245 (42 U.S.C. § 238n)), and/or the Weldon Amendment (Continuing Appropriations Resolution, Pub. L. No. 113-164, Sec. 101(a) (Sept. 19, 2015)) by virtue of its status as a recipient of federal funding.

Dr. Caruso practices medicine in conformance with his religious convictions that prohibit him from performing, assisting in, referring for, or participating in any way with abortion or abortion-causing drugs. He does so at his private Ob/Gyn practice, A Bella Baby OBGYN, and also as a medical director for pro-life pregnancy centers. The rights of Dr. Caruso, A Bella Baby OBGYN and said pro-life pregnancy centers to offer medical assistance to women in need without compromising their religious convictions relating to abortion or abortion-causing drugs are protected by the First Amendment to the United States Constitution, the Constitution of the State of Illinois and the Illinois Healthcare Right of Conscience Act, 745 ILCS 70/1 *et seq.*, in addition to the federal conscience clauses named above.

Pursuant to Illinois Senate Bill 1564, signed into law by Governor Bruce Rauner on July 29, 2016, "healthcare entities" such as A Bella Baby and others similarly situated are required to "adopt written access to care and information protocols that are designed to ensure that conscience-based objections will be addressed in a timely manner to facilitate patient health care services." SB 1564, § 6.1. The safeguards of the state's Healthcare Right of Conscience Act, 745 ILCS 70/1, only apply if conscience-based refusals are asserted in accordance with these protocols. *Id.* The mandated protocols

Centralized Case Management Operations
U.S. Department of Health and Human Services
Complaint of Discrimination
September 11, 2017
Page 2

must, at a minimum, require health care facilities, physicians, and health care personnel to inform a patient of “legal treatment options” in a timely manner, § 6.1(1), and if such treatment is contrary to their conscientious beliefs, arrange for others in the entity to provide the service or refer or transfer the patient to other health care providers whom they know will do so. § 6.1(3).

Because SB 1564 violates their right to practice medicine according to their conscience and religious beliefs, Dr. Caruso, A Bella Baby and others brought suit in the Seventeenth Judicial Circuit in Winnebago County, Illinois. The attached First Amended Complaint, *The Pregnancy Care Center of Rockford, et al., v. Rauner*, Case No. 2016-MR-741, filed Aug. 17, 2016 (attached as Exhibit A), contains the factual and legal descriptions of this violation of our clients’ rights. On December 20, 2016, the court enjoined the application of SB 1564 to Dr. Caruso, A Bella Baby and the other plaintiffs in the lawsuit, holding the plaintiffs had raised a “fair question” whether their constitutional right to free speech had been infringed. See attached Order Granting Motion for Preliminary Injunction at 14 (attached as Exhibit B).

Please promptly inform us of the actions your office plans to take regarding this violation. Thank you for your attention to this matter.

Sincerely yours,

/s/ Elissa Graves
Elissa Graves, Esq.

cc: Kevin Theriot, Esq., Senior Counsel, Alliance Defending Freedom
Clients

THOMAS MORE SOCIETY

A National Public Interest Law Firm

January 4, 2018

Via US Mail & email: ocrmail@hhs.gov

U.S. Department of Health and Human Services
Office of Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201

Re: Violations of Federal Law arising from Illinois Public Act 99-690.

Dear members of the Office of Civil Rights for the Department:

We write on behalf of our clients, Dr. James Gallant and Hope Life Center, to request that the Office of Civil Rights investigate what we believe to be ongoing, serious violations of federal law by the State of Illinois. The basis for our request is Illinois' enactment and enforcement of Illinois Public Act 99-690, which became effective January 1, 2017, and which amends the 1977 Illinois Health Care Right of Conscience Act, 745 ILCS 70/1, *et seq.*, in ways that gut its protection of state and federal conscience rights. (P.A. 99-690 is attached as **Exhibit 1**.) As explained below, we believe that P.A. 99-690 violates existing federal laws that have been enacted to protect the conscience rights of healthcare providers. We respectfully request your office to investigate this claim and to take appropriate action to prevent the State's application of P.A. 99-690 to our clients, and similarly situated health care providers in Illinois, who cannot comply with the amendment because of their sincerely held religious beliefs.

The complainant, Dr. James Gallant, is a physician licensed to practice in Illinois. He serves, pro bono, as a medical director of Hope Life Center, a pregnancy resource center providing limited medical services (pregnancy testing, ultrasounds, and STD tests) to women facing unplanned pregnancies. Although abortion, sterilization, and abortifacient contraception are "legal treatment options" for these women under P.A. 99-690, Dr. Gallant cannot, in conscience, perform or promote these procedures, or refer women to, or provide identifying information about, providers of these procedures. Yet, P.A. 99-690 now requires him, and the officers, employees, and volunteers who work at Hope Life Center, to perform these very actions.

Dr. Gallant and Hope Life Center thus face an unacceptable dilemma under the new Illinois law. P.A. 99-690 requires them to discuss so-called "benefits" of the very abortion and sterilization procedures they, as a matter of conscience, vigorously oppose. See P.A. 99-690 at Sec. 6 and Sec. 6.1(1). And it requires them, if asked, to refer for, or provide information about, providers of the very abortion services they abhor. See P.A. 99-690 at Sec.

19 S. LaSalle | Suite 603 | Chicago, IL 60603 || P: 312.782.1680 | F: 312.782.1887
501 Scoular | 2027 Dodge | Omaha, NE 68102 || P: 402-346-5010 | F: 402 345 8853
www.thomasmoresociety.org

"Injustice anywhere is a threat to justice everywhere." – Rev. Dr. Martin Luther King

HHS, Office of Civil Rights
January 4, 2018
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6.1(3)(ii)&(iii). Failure to comply with the amendment subjects them to loss of conscience protection under the Health Care Right of Conscience Act, the possibility of professional discipline, liability for penalties and damages (including attorneys fees), and discrimination in funding and licensing under Illinois law. See 745 ILCS §70/6.1 (stripping protection of IHACA from those who do not comply with its conditions); see also, 745 ILCS §70/4 & §§70/9—70/11.4 (forms of protection stripped away by Section 6.1); see also, 745 ILCS §70/10 (private cause of action for violations of statute, including statutory minimum damage award and liability for attorney's fees and costs).

We believe that Illinois is using this amendment (P.A. 99-690) to target and discriminate against healthcare providers in violation of federal law. First, the Hyde-Weldon Amendment, 114 P.L. 116, Title V, §507(d), as incorporated in 114 P.L. 223, Title III, Division C, Section 101(a)(8), prohibits any state or local government receiving federal HHS funds from discriminating against any health care entity based on its refusal to “provide, pay for, provide coverage of, or refer for” abortions. Second, Coates-Snow, 42 U.S.C. §238n, prohibits a state or local government that receives federal financial assistance from discriminating against a healthcare entity because it refuses to “perform” induced abortions, “provide referrals for” abortions, or “make arrangements for” abortions. Third, the Church Amendment, 42 U.S.C. §300a-7 prohibits an entity receiving federal funds under a wide range of federal legislation from discriminating against physicians or healthcare personnel because they refuse “to perform or assist in the performance of any sterilization procedure or abortion. . . contrary to [the person’s] religious beliefs or moral convictions.” The State of Illinois and its political subdivisions are subject to these federal laws by virtue of federal funding of many social welfare programs including Medicare, Medicaid, Child’s Health Insurance Program, Head Start, Supplemental Nutrition Assistance Program, and Temporary Assistance for Needy Families. Yet P.A. 99-690 purports to nullify the protection Illinois physicians and health care providers enjoy under these federal laws.

P.A. 99-690 violates federal law in its purpose, practical operation, and effects. Section 6.1(1) compels physicians and other healthcare providers to inform patients about supposed “benefits” of abortions, abortifacient drugs, or sterilization, as legal treatment options. Provision of medical advice within the professional competence of a medical provider is an integral part of medical practice. Yet P.A. 99-690’s discussion requirement coerces physicians and other healthcare providers, against their consciences, to assist in the promotion and provision of abortion or sterilization. This result, we believe, is directly contrary to the federal laws cited. In addition, Section 6.1(3)(ii)&(iii) of P.A. 99-690 requires medical professionals, upon request, to refer for abortion or sterilization, or in the alternative, to supply patients with a list of abortion and/or sterilization providers. In this way, P.A. 99-690 coerces physicians and other healthcare providers to promote and participate in abortion and sterilization, contrary to the cited federal laws.

A review of the publicly available committee proceedings and floor debates of the Illinois General Assembly shows that the clear intent of this law was to force medical professionals and their medical facilities to cooperate with abortion in ways that violate the deeply held religious

HHS, Office of Civil Rights
January 4, 2018
Page 3 of 4

and moral beliefs of those professionals and facilities. The Illinois General Assembly knew well the risks of enacting P.A. 99-690, as even the fiscal note entered on the bill by the Illinois Department of Healthcare & Family Services recognized that:

It is unclear if the passage of SB 1564 would jeopardize federal funding for the Illinois Medical Assistance Program. The Church Amendment codified at 42 U.S.C. § 300a-7, stipulates that for healthcare services funded in whole or in part by a program administered by the U.S. Department of Health and Human Services (HHS), no person may be required to 'perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions.' *The requirement in SB 1564 that the provider refer individuals to other providers who perform the procedure, especially if abortion or sterilization, violates the Church amendment*; such referral could be interpreted as assistance with a morally objectionable procedure.

(emphasis added). See Bill Status of P.A. 99-690, at <http://www.ilga.gov/legislation/billstatus.asp?DocNum=1564&GAID=13&GA=99&DocTypeID=SB&LegID=88256&SessionID=88&SpecSess=> (accessed on December 19, 2017).

P.A. 99-690 also violates our clients' First Amendment rights to free speech and the free exercise of religion. The law is content-based, compelling speech, and viewpoint discriminatory, targeting only conscientious objectors. It is not religiously neutral because on its face it blatantly discriminates against the religious beliefs and practices of pro life physicians and health providers. The unconstitutionality of P.A. 99-690 was recognized earlier this year when its application against conscientious objectors was preliminarily enjoined on First Amendment grounds. See *NIFLA, et al., v. Rauner, et al.*, 16 C 51030, (N.D. Ill., July 19, 2017, Hon. Frederick J. Kapala, attached as **Exhibit 2**). The decision did not, however, find that the Plaintiffs had a private right of action under the Coates-Snowe Amendment, observing that "enforcement of § 238n is left up to the Department of Health and Human Services which may terminate funding in the event of non-compliance. See 45 C.F.R. § 88.2." *Id.* at p.4.

We are therefore requesting the Office of Civil Rights of the Department of Health and Human Services to investigate this complaint that alleges that P.A. 99-690 violates the federal laws cited, and to act to prohibit enforcement of P.A. 99-690 by the State of Illinois against our clients and all similarly situated health care providers in the State through all means at its disposal. We urge the Office to take prompt and effective action to prevent the State of Illinois from ever using P.A. 99-690 to punish physicians and healthcare providers who refrain, because of conscience, to counsel patients about so-called benefits of abortion or who refrain from assisting women desiring an abortion by referring them to (or providing information about) abortion providers.

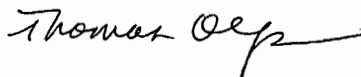
We also respectfully request, for the benefit of physicians and healthcare providers throughout the nation, that your office issue interpretive guidelines making it clear that the cited federal

HHS, Office of Civil Rights
January 4, 2018
Page 4 of 4

laws reach, and prohibit, any state law which, like P.A. 99-690, targets and punishes religious and conscience-based opposition to the practice of abortion. The cited federal laws were enacted precisely to protect conscience-based refusals to participate in abortion, and should be interpreted so as to be effective in prohibiting state laws like P.A. 99-690, which seek to force conscience objectors to participate in and promote abortion against their will. Without this office's interpretive guidance some states will continue to interpret these laws in ways contrary to their manifest purpose, and will continue to enact laws punishing conscience-based refusals to participate in abortion, as did Illinois through enactment of P.A. 99-690. Such state actions flouting the federal laws cited should not be countenanced. This office's regulatory guidance would facilitate that desired outcome.

Thank you for considering this complaint. Contact the undersigned in the event additional information is needed to bring your investigation to conclusion.

Respectfully,



Thomas Olp
Counsel, Thomas More Society
19 South LaSalle Street, Suite 603
Chicago, IL 60603
tolp@thomasmoresociety.org

Enclosures:

Exhibit 1 - Text of P.A.99-690

Exhibit 2 - Hon. Frederick J. Kapala's decision in *NIFLA, et al., v. Rauner*

Exhibit 17

Attachment C



OFFICE OF THE ATTORNEY GENERAL
STATE OF ILLINOIS

Kwame Raoul
ATTORNEY GENERAL

February 25, 2019

SENT VIA E-MAIL

Mandi Ancalle
Contractor
Office for Civil Rights
U.S. Department of Health & Human Services
Mandi.Ancalle@hhs.gov

Re: Response to December 14, 2018 Questionnaire Regarding the Illinois Health Care Right of Conscience Act and Federal Funding of State of Illinois Health Care Programs.

Dear Ms. Ancalle,

The State of Illinois ("State") submits the following response to Deputy Director Perez's December 14, 2018 letter and questionnaire regarding the Illinois Health Care Right of Conscience Act and federal funding of the State's health care programs. This response is provided on behalf of the Office of the Illinois Attorney General, the Illinois Governor, and the Illinois Department of Financial & Professional Regulation.

1. Has the State of Illinois, or any of its instrumentalities, implemented or enforced 745 Ill. Comp. Stat. Ann. 70/6-6.2 of the Illinois Health Care Right of Conscience Act?

Response: No.

2. Does the State of Illinois, or any of its instrumentalities, intend to implement or enforce 745 Ill. Comp. Stat. Ann. 70/6-6.2 of the Illinois Health Care Right of Conscience Act?

Response: No. On July 19, 2017, Judge Frederick Kapala granted a preliminary injunction in the United States District Court in the Northern District of Illinois enjoining the Secretary of the Illinois Department of Financial & Professional Regulation from enforcing the Illinois Health Care Right of Conscience Act. The July 19, 2017 order is attached as Exhibit 1. The State has no intention of enforcing the statute while the injunction remains effective.

3. Please indicate whether, and to what extent, the State of Illinois considers the U.S. Supreme Court's decision in *National Institute for Family and Life Advocates v. Becerra*, 585 U.S. ___, 138 S. Ct. 2361 (2018), to have impacted the constitutionality or enforceability of the

Illinois Health Care Right of Conscience Act.

Response: The U.S. Supreme Court's *Becerra* decision is not dispositive as to whether the Illinois Health Care Right of Conscience Act is constitutional or enforceable.

4. Please indicate whether the State of Illinois, or any of its instrumentalities, has been a recipient or sub-recipient of Federal financial assistance from HHS from July 29, 2016 to the present. If yes, please describe the awarding HHS component (or non-Federal organization receiving Federal financial assistance from HHS), dates the financial assistance was received and when it first began, the purpose of the assistance, and the dollar amount of the assistance.

Response: Yes. However, Question 4 is extremely broad, and the collection of responsive information involves every State agency that provides or may provide health care services to analyze all sources of funding for each of its numerous programs. This process is time-consuming and overly burdensome to the State. In light of the burdensome nature of this request, the State has provided funding information obtained from HHS's Tracking Accountability in Government Grants System database, which the State has exported to a spreadsheet and attached as Exhibit 2. Although the State is currently unable to verify the accuracy of all of the relevant data in the HHS database, the data the State has obtained to date from its agencies is consistent with the data in the database.

5. Please indicate whether the State of Illinois, or any of its instrumentalities, participate in Medicaid and/or CHIP programs, and if so, please provide an approximate amount of funding from the program from July 29, 2016, to the present.

Response: Yes. Since July 29, 2016, the State of Illinois received approximately \$28.5 billion from Medicaid and approximately \$780 million from CHIP.

6. Please indicate whether the State of Illinois, or any of its instrumentalities, received funding through any of the programs or mechanisms listed below from July 29, 2016, to the present, and if it has, please provide the amount received, the date received, the program under which the funding was received, and any grant, contract, loan, loan guarantee, interest subsidy, award or health plan numbers associated with the funding, as applicable.
 - The U.S. Department of Health and Human Services' appropriation within the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act.
 - Public Health Service Act (42 U.S.C. §§ 201 *et seq.*), whether by grant, contract, loan, or loan guarantee.
 - Patient Protection and Affordable Care Act (Pub. L. No. 111-148 (2010)), as amended, whether for federally-qualified health plans or otherwise.
 - Biomedical or Behavioral Research Grants or Contracts, under any program administered by the Secretary of the U.S. Department of Health & Human Services.
 - Health Service Program or Research Activity Funds, under a program administered by the Secretary of the U.S. Department of Health & Human Services.

Response: Yes. However, Question 6 is extremely broad, and the collection of responsive information involves every State agency that provides or may provide health care services to

analyze all sources of funding for each of its numerous programs. This process is time-consuming and overly burdensome to the State. Furthermore, the State's investigation to date has revealed that funding through the programs or mechanisms listed in Question 6 is not necessarily itemized when provided to the State. For example, some funding received through the Patient Protection and Affordable Care Act is included within the Medicaid entitlement funding mechanism and is not provided separately to the State. Although the State is currently unable to verify the accuracy of all of the relevant data in HHS's Tracking Accountability in Government Grants System database, the data provided in response to Question 4 includes any funding provided pursuant to the programs or mechanisms listed in Question 6.

7. Please indicate whether the State of Illinois, or any of its instrumentalities, received funding or other assistance as a recipient or sub-recipient through any of the grant programs listed below from July 29, 2016, to the present, and *if it has, please provide the amount received, the date received, and any grant, grantee, or provider numbers, as applicable.*

PROGRAM NAME	U.S.C	CFDA#
Preventive Health and Health Services Block Grant	42 U.S.C. 300w-7	93.991
Substance Abuse Prevention and Treatment Block Grants	42 U.S.C. 300x-57	93.959
Community Mental Health Services Block Grant	42 U.S.C. 300x-57	93.958
Maternal & Child Health Services Block Grant	42 U.S.C. 708	93.994

Response: Yes. The State's investigation continues, but the data the State has collected to date in response to this question is consistent with the relevant data in HHS's Tracking Accountability in Government Grants System database. Although the State is currently unable to verify the accuracy of all of the relevant data in the database, in the interest of providing a comprehensive response, the State provides the following data obtained from the Tracking Accountability in Government Grants System database:

Preventive Health and Health Services Block Grant

Issue Date Fiscal Year	OPDIV	Recipient Name	Award Number	Award Title	CFDA Number	CFDA Program Name	Sum of Actions
2019	CDC	IL ST DEPARTMENT OF PUBLIC HEALTH	NB010 T009229	Preventive Health and Health Services Block Grant 2018	93991	Preventive Health and Health Services Block Grant	\$0
2018	CDC	IL ST DEPARTMENT OF PUBLIC HEALTH	NB010 T009229	Preventive Health and Health Services Block Grant 2018	93991	Preventive Health and Health Services Block Grant	\$3,756,818

Substance Abuse Prevention and Treatment Block Grants

Issue Date Fiscal Year	OPDIV	Recipient Name	Award Number	Award Title	CFDA Number	CFDA Program Name	Sum of Actions
2019	HRSA	SOUTHERN ILLINOIS UNIVERSITY AT EDWARDSVILLE	UK131730	Nurse, Education, Practice, Quality and Retention - Registered Nurses in Primary Care	93959	Block Grants for Prevention and Treatment of Substance Abuse	\$0
2018	SAMHSA	ILLINOIS DEPT OF HUMAN SERVICES	B08TI010018	Substance Abuse Prevention & Treatment Block Grant	93959	Block Grants for Prevention and Treatment of Substance Abuse	\$67,917,901
2018	HRSA	ILLINOIS STATE UNIVERSITY	UK1HP31717	Nurse, Education, Practice, Quality and Retention - Registered Nurses in Primary Care	93959	Block Grants for Prevention and Treatment of Substance Abuse	\$675,020
2018	HRSA	SOUTHERN ILLINOIS UNIVERSITY AT EDWARDSVILLE	UK1HP31730	Nurse, Education, Practice, Quality and Retention - Registered Nurses in Primary Care	93959	Block Grants for Prevention and Treatment of Substance Abuse	\$612,349
2017	SAMHSA	ILLINOIS DEPT OF HUMAN SERVICES	TI010018-17	Substance Abuse Prevention & Treatment Block Grant	93959	Block Grants for Prevention and Treatment of Substance Abuse	\$67,646,569

2016	SAMH SA	ILLINOIS DEPT OF HUMAN SERVICES	TI01001 8-16	Substance Abuse Prevention & Treatment Block Grant	93959	Block Grants for Prevention and Treatment of Substance Abuse	\$67,645,777
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Community Mental Health Services Block Grant

Issue Date Fiscal Year	OPDIV	Recipient Name	Award Number	Award Title	CFDA Number	CFDA Program Name	Sum of Actions
2019	SAMH SA	ILLINOIS DEPT OF HUMAN SERVICES	B09SM 010018	Block Grants for Community Mental Health Services	93958	Block Grants for Communit y Mental Health Services	\$12,412,106
2018	SAMH SA	ILLINOIS DEPT OF HUMAN SERVICES	B09SM 010018	Block Grants for Community Mental Health Services	93958	Block Grants for Communit y Mental Health Services	\$26,215,382
2017	SAMH SA	ILLINOIS DEPT OF HUMAN SERVICES	SM0100 18-17	Block Grants for Community Mental Health Services	93958	Block Grants for Communit y Mental Health Services	\$20,529,098
2016	SAMH SA	ILLINOIS DEPT OF HUMAN SERVICES	SM0100 18-16	Block Grants for Community Mental Health Services	93958	Block Grants for Communit y Mental Health Services	\$19,839,321

Maternal & Child Health Services Block Grant

Issue Date Fiscal Year	OPDIV	Recipient Name	Award Number	Award Title	CFDA Number	CFDA Program Name	Sum of Actions
2019	HRSA	IL ST DEPT OF PUBLIC HEALTH	B0432538	Maternal and Child Health Services	93994	Maternal and Child Health Services Block Grant to the States	\$10,616,119
2018	HRSA	IL ST DEPT OF PUBLIC HEALTH	B04MC29341	Maternal and Child Health Services	93994	Maternal and Child Health Services Block Grant to the States	\$0
2018	HRSA	IL ST DEPT OF PUBLIC HEALTH	B04MC31484	Maternal and Child Health Services	93994	Maternal and Child Health Services Block Grant to the States	\$21,129,026
2017	HRSA	IL ST DEPT OF PUBLIC HEALTH	B04MC30610	Maternal and Child Health Services	93994	Maternal and Child Health Services Block Grant to the States	\$20,926,998
2016	HRSA	IL ST DEPT OF PUBLIC HEALTH	B04MC29341	Maternal and Child Health Services	93994	Maternal and Child Health Services Block Grant to the States	\$21,077,799

Sincerely,

s/ Harpreet K. Khera

Harpreet K. Khera
Deputy Bureau Chief
Special Litigation Bureau
Office of the Illinois Attorney General
100 W. Randolph St., 11th Floor
Chicago, IL 60601
(312) 814-3553
hkhera@atg.state.il.us

CC: Jessica Baer
Anna Crane
Sarah Gallo
Dina Masiello
Leigh Richie
Jeanne Witherspoon
Kristiana Yao

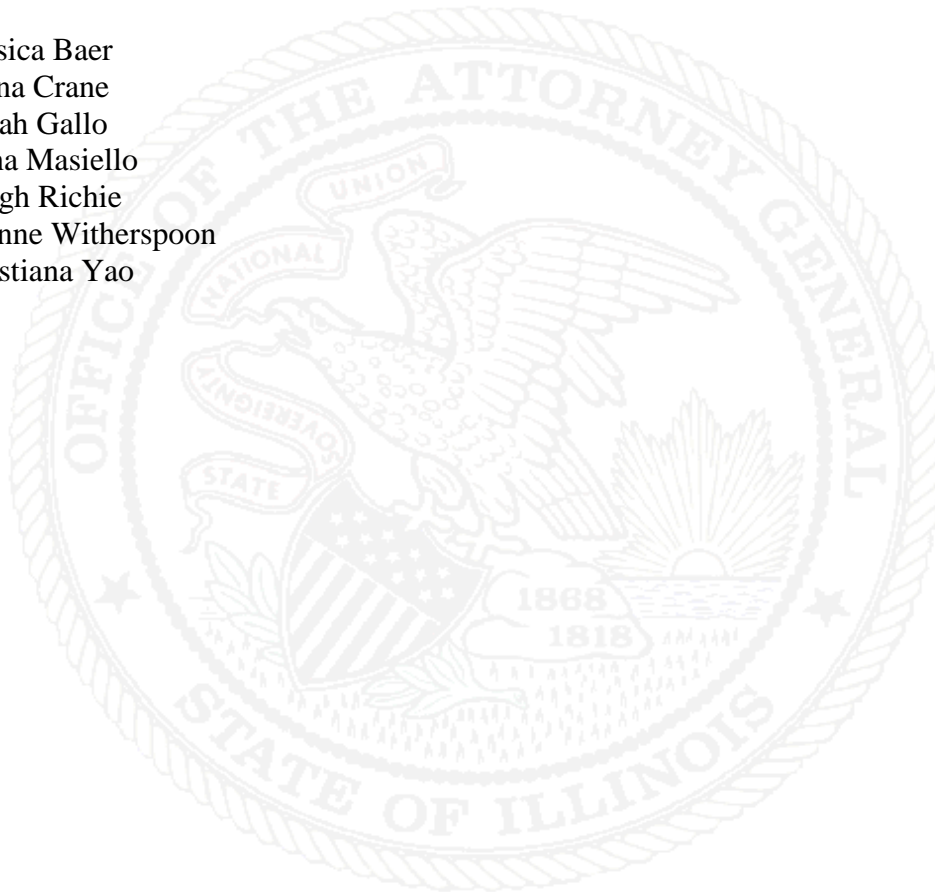


Exhibit 18

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. TERENCE R. FLOTTE

I, Terence R. Flotte, do hereby depose and state the following:

1. I am Dean, Provost and Executive Deputy Chancellor at the University of Massachusetts Medical School. As Chief Academic Officer and Chief Research Officer, I am responsible for all matters related to students and faculty of UMass Medical School, particularly as relates to their participation in any educational programs in medicine, biomedical sciences, nursing, and post-graduate medicine, as well as their participation in any research, including human subjects research.

2. I am familiar with the Final Rule entitled “Protecting Statutory Conscience Rights in Health Care; Delegation of Authority” (“Final Rule”).

3. 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 Dean, Provost and Executive Deputy Chancellor.

4. UMass Medical School is the Commonwealth’s only public academic health sciences center. In order to successfully fulfill this role, UMass Medical School must maintain compliance with educational accrediting bodies and with funding agencies, including the US Department of Health and Human Services.

5. In addition to UMass Medical School’s core mission of distinction in medical education, the school is also a nationally recognized center for biomedical and behavioral research.

6. UMass Medical School employs and enrolls 2,911 clinical full and part-time faculty-physicians and 165 nursing faculty, 557 post-graduate medical residents, and 1,185 students (including medical, nursing and biomedical sciences students).

7. UMass Medical School has a unique clinical partnership with UMass Memorial Health Care, one of the largest (private, non-profit) health care systems in Massachusetts. Under this partnership, students, residents, and faculty—who are employed by both UMass Medical School and UMass Memorial—provide all levels of health care, and conduct research activities, at UMass Memorial hospitals. UMass Memorial provides funding to UMass Medical School for several critical elements of UMass Medical School’s operations, including the teaching and research efforts of faculty and the entire salary of residents, who provide direct patient care as provisionally-licensed physicians. The two institutions are inter-dependent to an extent that a disruption to the operation of one will inevitably cause a disruption to the other.

8. Federal funding is critical to the operation of UMass Medical School. In fiscal year 2019, UMass Medical School received \$213,358,592 in direct federal funding exclusively for biomedical and behavioral research. Of this, \$168,086,949 was from the National Institutes of Health.

9. The Final Rule threatens UMass Medical School’s continuing eligibility for federal funding. For this reason, the Medical School has expended time and resources reviewing and determining how to comply with the Rule.

10. UMass Medical School recognizes the importance of conscience protections for health care providers. However, these protections must be balanced with other important—and sometimes competing—considerations, including overriding professional, ethical, and legal responsibilities for patient safety and care.

11. The Medical School’s policies regarding the professional conduct of medical students, residents and physician faculty strike a considered and appropriate balance between accommodating faculty members’, residents’, and students’ religious and moral beliefs, and other

critical factors, including the need to comply with applicable Massachusetts laws, regulations, and licensing requirements.

12. The professional standards of UMass Medical School to which faculty, residents, medical students and nursing students must adhere are built around the core ethical principles of the profession, namely to respect the autonomy of patients and to always act in the patient's best interest. Consistent with these standards and applicable Massachusetts laws and regulations, providers may tailor their choice of medical specialty or practice setting based upon their religious and moral beliefs. Further, reasonable staffing and scheduling accommodations may be made to avoid conflicts with providers' religious and moral beliefs if advance notice is given. However, providers' may not decline to provide care or services in circumstances that threaten the health or well-being of patients—particularly in situations in which a provider is responsible for the provision of urgent or emergent care. Furthermore, professional standards do not allow for providers to discriminate among patients they choose to treat based on the patient's race, ethnicity, gender, gender identity or sexual orientation among other factors.

13. The Final Rule is inconsistent with this balanced approach.

14. If the Rule were permitted to go into effect, it would place UMass Medical School in an unworkable position. The Medical School could not effectively comply with the Rule without harming important aspects of its educational, clinical, and research missions. However, failure to comply with the Rule would place critical federal funding at risk.

15. UMass Medical School has a fundamental responsibility to educate students about their professional and ethical obligations, including those owed to patients. The Rule is inconsistent with those obligations as I understand them. Implementing the Rule would undermine the Medical School's ability to fulfill this responsibility to its students.

16. The Rule would harm the efficient and effective operation of UMass Medical School and its clinical partner, UMass Memorial.

17. Among other factors, the Rule significantly restricts employers' ability to require advance notice of religious and moral objections, and to make hiring and staffing decisions necessary to ensure that personnel can perform critical clinical, educational, and research functions; are not placed in situations that conflict with their beliefs; and do not compromise patient care and safety.

18. If clinical personnel refuse to participate in procedures in emergent situations, or other circumstances where continuity of care is compromised, patients could be harmed. As a result, students, residents, and faculty could be forced to step-in to try and provide care without adequate preparation or qualification. In addition to creating an unacceptable risk to patient safety, this could expose UMass Medical School, UMass Memorial, and students, residents, and faculty to legal liability and other sanctions under Massachusetts laws and regulations.

19. To mitigate these unacceptable risks, double-staffing and other difficult and costly measures would be required.

20. The Rule would also subject UMass Medical School to conflicting legal and regulatory obligations and create conflicts with core policies based on professional and ethical standards.

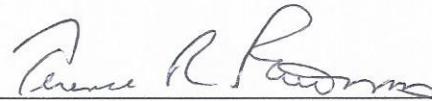
21. For example—and in addition to the discussion above—UMass Medical School faculty, students or residents engaged in clinical trials are required to adhere to ethical research standards and school policies, among them the principle that enrollment in clinical trials of investigational therapies must not be based upon factors including the subject's race, ethnicity, gender, gender identity or sexual orientation, unless medically or scientifically justified in the

clinical protocol approved by the UMass Medical School Institutional Review Board. The religious or moral beliefs of the clinical researcher are not recognized as appropriate reasons to deny access to, or otherwise interfere with, investigational therapies, some of which may represent the only available option for patients with cancer or other life-threatening conditions.

22. Similarly, UMass Medical School generally cannot accommodate religious or moral objections based upon factors including the race, ethnicity, gender, gender identity, or sexual orientation of patients under Massachusetts civil rights laws.

PURSUANT TO 28 U.S.C. § 1746, I DECLARE UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT.

Executed on this 8th day of June, 2019



Terence R. Flotte
Dean, Provost and Executive Deputy Chancellor
University of Massachusetts Medical School

Exhibit 19

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 HAWAII,
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 ANNE FOLEY

1. I, Anne Foley, 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 ("the State") 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 the Connecticut Office of Policy and Management ("OPM") personnel who have assisted me in gathering this information from our agency, or on the basis of documents, including the Final Rule, which have been provided to and/or reviewed by me.

3. I am Senior Policy Advisor to the Secretary of OPM and also serve as the Acting Undersecretary of the OPM Health and Human Services Policy and Planning Division ("HHSPP Division"). My educational background includes a B.A. in Social Work from Providence College in 1983, a M.S.W. in Policy and Planning from the University of Connecticut in 1987, and a M.A. in Social Policy from Brandeis University in 2000. I have been employed as Senior Policy Advisor to the Secretary since June 2018.

Background on OPM's Use of HHS Funds

4. OPM is the Connecticut state agency primarily responsible for planning and analyzing the State's budget. OPM also provides management, planning and program evaluation for the Executive Branch agencies of the State. The OPM's HHSPP Division staff work on policies and planning to improve the delivery of health care, long-term services and supports and human services in the State. The HHSPP Division manages grants, and monitors state and national activities that address quality, access and cost issues on a range of topics including health care.

5. As the Acting Undersecretary of the OPM HHSPP Division, I work to facilitate inter-agency coordination and collaboration between the State of Connecticut and the Federal government. My responsibilities include responding to federal legislation, regulation, and policy initiatives and implementing federal programs and mandates. I also work on coordinating federal block grants from HHS for Connecticut state agencies. HHS block grants support diverse programs administered by the State aimed at improving health outcomes for at-risk populations or those with specific medical conditions.

6. In 2018, Connecticut received approximately \$5.5 billion in total HHS funds, according to the HHS Tracking Accountability in Government Grants System. I anticipate the amount of HHS funds in 2019 will be comparable. These HHS funds are essential to maintaining public health in Connecticut.

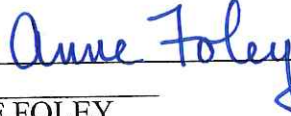
The Final Rule Could Result in Negative Health Outcomes for the Citizens of the State of Connecticut

7. My understanding of the Final Rule is that if the State, or any sub-recipients of HHS funds, fails to fully comply with the requirements in programs receiving HHS funds, HHS could, in its discretion, revoke some or all of the approximately \$5.5 billion in HHS funds awarded to Connecticut.

8. The loss of HHS funds for Connecticut due to non-compliance by a State agency or by a sub-recipient would result in negative health outcomes to the citizens of Connecticut because it would significantly reduce the ability of the State to provide healthcare to its citizens.

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

Executed on this 5th day of June, 2019

A handwritten signature in blue ink that reads "Anne Foley". The signature is written in a cursive style and is positioned above a horizontal line.

ANNE FOLEY

Senior Policy Advisor to the Connecticut Secretary of the
Office of Policy and Management
Acting Undersecretary of the Office of Policy and
Management Health and Human Services Policy and
Planning Division

Exhibit 20

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 ANDREW C. FORSAITH, J.D.

1. I, Andrew C. Forsaith, 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 Wisconsin's litigation against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as HHS Secretary, 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 through Department of Health Services personnel who have assisted me in gathering this information from our institution. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Department of Health Services.

3. I am the Director of the Office of Policy Initiatives and Budget of the State of Wisconsin Department of Health Services. I have been employed in this position since 2014 and with the Department of Health Services since 1995. I have a juris doctorate degree from the University of Wisconsin-Madison and a bachelor's degree in political science from the University of Chicago.

4. In my position, I am responsible for managing the biennial budget development process for the Department of Health Services, monitoring expenditures against budget during the fiscal year, managing the Department's federal application development process, and providing policy and fiscal analysis to the Department's leadership.

5. The Division of Public Health ("DPH") serves the State of Wisconsin by overseeing and administering a wide variety of programs and services that protect the health of its citizens. DPH staff work with local and tribal public health partners, and community groups statewide, on a wide variety of programs and services that protect the health of Wisconsin residents. A few of these programs are: communicable and chronic diseases; health promotion; environmental

health; occupational health; family and community health; emergency medical services (“EMS”); and injury prevention.

6. The Department of Health Services received over \$6.7 billion in federal health care funding from HHS in the 2018 fiscal year.

7. More specific funding figures are as follows. For fiscal year 2019, Wisconsin received \$10,906,650 from the Title V Maternal and Child Health block grant. For fiscal year 2019, Wisconsin received a total of \$30,318,400 in combined federal opioid grant awards. For fiscal year 2019, Wisconsin’s budgeted expenditures for federal Medicaid benefits is \$5,549,940,600.

8. These funds support a variety of important programs. For example, in 2018, Wisconsin received \$11,402,328 in funding from HHS through the Title V Maternal and Child Health Block Grant, along with \$10.3 million in matching State funds. Wisconsin used these funds to support and improve the health of over 463,933 women, infants, and children, including children and youth with special health care needs (“CYSHCN”). Wisconsin has five CYSHCN Regional Centers, which provide local information and referral services to parents and guardians of CYSHCN. In addition, the Maternal & Child Health Block Grant funds the Women’s Health Family Planning Program, which addresses women’s reproductive health and family planning, as well as Maternal, Child and Infant Death Reviews addressing maternal and infant mortality. These block grant funds also provide resources to the Child Psychiatry Consultation Program and Periscope Program addressing child and maternal mental health respectively, and the blood lead screening program, including case management and environmental assessments.

9. As another example, responding to Wisconsin’s opioid crisis is one of our top priorities. Through partnerships with State, tribal, county, and local agencies, our approach to this epidemic empowers communities to prevent misuse, expand access to quality treatment and

recovery services, and reduce death and harm. In Fiscal Year 2018, the Department of Health Services received over \$7 million in funding from HHS to combat the opioid epidemic. That funding helped to improve public health surveillance in the State and to strengthen prevention programming and data infrastructure regarding opioid use disorder (“OUD”) and substance use disorder (“SUD”). The funding also expanded access to evidence-based prevention and treatment for OUD and SUD. Previous funding from the Centers for Disease Control through the Prescription Drug Overdose Prevention for States Program, the Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality, and the Cooperative Agreement for Emergency Response: Public Health Crisis Response – Opioid Epidemic has been critical to establishing Wisconsin’s surveillance system. That system engages the Wisconsin State Coroners and Medical Examiners Association in providing information on violent deaths, enhances the quality and sharing of data among state agencies, strengthens our prescription drug monitoring program, facilitates overdose fatality review teams, links EMS first responders with treatment and recovery support, and promotes education around opioid prescribing in our health systems.

10. Finally, the Medicaid program provides acute, primary, and long-term care services to 1.1 million enrollees, or about 1 of 5 Wisconsin residents. The program serves roughly 776,000 low income children, parents, and childless adults, providing comprehensive primary and acute care services and prescription drug coverage to them through health maintenance organizations and fee-for-service providers. The program also serves approximately 230,000 elderly adults and adults and children with disabilities. The program enrolls thousands of individuals in targeted eligibility categories. Roughly 40% of Wisconsin Medicaid expenditures are for long-term care services in people’s homes, in assisted living facilities, or in nursing homes. The program also provides \$1.3 billion in prescription drug coverage per year.

11. The Final Rule imposes new conditions on the federal funding the Department of Health Services receives from HHS. The Department relies on these funds to ensure access to health programs and services to the citizens of the State of Wisconsin. These funds are essential to the functioning of the Department and all programs and services overseen or administered by the Department.

12. As I understand it, the Final Rule would allow the termination of all federal funding from HHS, if HHS determines that the Department of Health Services, one of its divisions, or one of its subrecipients violated—even once—any aspect of the Final Rule.

13. The termination of all HHS federal funding would be devastating to the mission of the Department of Health Services and DPH. If Wisconsin were to lose this funding, I anticipate that it would not be able to make up the \$6.7 billion shortfall. As a result, a vast number of vital services would need to be cut.

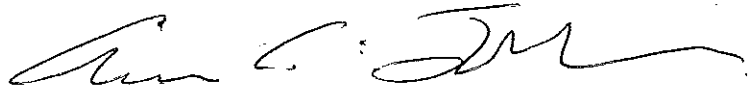
14. If Wisconsin were to lose Title V Maternal and Child Health Block Grant funding, I anticipate that the state would not be able to make up the more than \$11 million shortfall. Instead, services would need to be cut. For example, cuts to the CYSHCN program would likely result in the 245,000 children with special healthcare needs not having access to critical information about local resources and programs to support them and their families. In addition, primary care providers could lose access to child mental health experts that provided over 2,200 consultations in 2018. Wisconsin has the highest African American infant mortality rate in the country and is dedicating both State appropriations and Title V Maternal and Child Health Block Grant funding to this issue. If federal funding were removed, I anticipate this disparity would continue to worsen and more African American babies would die.

15. If Wisconsin were to lose federal opioid prevention funding, I anticipate that the State would not be able to make up the budget shortfall with State funds. As a result, Wisconsin's opioid surveillance and data infrastructure, initiatives to enhance linkages to care between EMS teams and local public health departments, efforts to enhance non-punitive neonatal abstinence screening, and substance use prevention efforts would all face severe cuts, which would negatively affect the health and welfare of Wisconsin residents, especially those suffering from substance-related disorders.

16. If funding were eliminated for Medicaid, I anticipate that the State would not be able to make up the budget shortfall with State funds. Medicaid members would experience a serious reduction, if not an elimination, in access to services, including critical acute care and long-term care services. Health care providers would see an extraordinary increase in uncompensated care for individuals without health coverage.

I hereby declare that the above statement is true to the best of my knowledge and belief, and that I understand it is made for use as evidence in court and is subject to penalty for perjury.

Executed on this 12 day of June, 2019



Andrew C. Forsaith, J.D.

Director, Office of Policy Initiatives and Budget
Wisconsin Department of Health Services

Exhibit 21

**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 HAWAII,
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. ADENA GREENBAUM, MD, MPH

1. I, Dr. Adena Greenbaum, MD, MPH 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 Maryland'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 Baltimore City Health Department personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the Baltimore City Health Department.

3. I am the Assistant Commissioner overseeing the Bureau of Clinical Services & HIV/STD Prevention Services within the Division of Population Health & Disease Prevention in the Baltimore City Health Department. I entered this position in August 2016.

4. The City Health Department is committed to public-health measures that reduce social inequalities and ensure the well-being of every Baltimorean. To accomplish this, the Department dedicates significant efforts and resources to building trust in communities that historically have been marginalized and disenfranchised. Baltimore is also home to a high number of people who have experienced trauma; it has high rates of poverty and violent crime, both of which tend to affect communities of color more than other groups.

5. As a result of historical marginalization and community trauma, some cross-sections of the Baltimore population have been distrustful of both medical providers and government. And when segments of a population don't trust government to provide healthcare in the population's best interest, it can harm public health as a whole.

6. To combat these forces and advance the health of every Baltimorean, the Health Department has adopted a public-health philosophy that prioritizes breaking down stigma associated with particular diseases, conditions, or groups of people, developing relationships with community-based organizations, building trust with individuals in targeted communities, and providing judgment-free and trauma-informed care. Our work is designed to effectuate this this public-health philosophy; for years we have painstakingly implemented it to build trust with formerly marginalized communities.

7. I am familiar with the new rule promulgated by the U.S. Department of Health and Human Services, entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("the Rule").

8. If the Rule allows City Health Department health professionals and staff broad and unqualified rights to refuse to provide or facilitate services, it will jeopardize all our work toward judgment-free and trauma-informed public health; contradict the City's public-health philosophy; and set the Health Department back years in its efforts to advance and defend the well-being of every person in Baltimore, with effects that will ripple beyond the city limits.

About Me

9. I am an infectious-disease physician, board certified in both Internal Medicine and Infectious Disease.

10. I attended Johns Hopkins School of Public Health, where I earned a Master's in Public Health degree in May 2007.

11. I also attended Johns Hopkins School of Medicine, completing my M.D. degree in May 2008.

12. I completed an Internal Medicine Residency in June 2011 at Johns Hopkins Hospital Internal Medicine Residency Program, and an Infectious Disease Fellowship at Johns Hopkins School of Medicine in June 2016.

13. Before entering my current position at the Baltimore City Health Department, I was an Epidemic Intelligence Service Officer in the Influenza Division at the Centers for Disease Control and Prevention.

14. My full curriculum vitae is attached to this declaration as Exhibit A.

15. In my role as Assistant Commissioner, I oversee the various clinics, services, and programs described below. I lead a staff of about 150 personnel and am responsible for an annual budget of about \$20 million.

16. I am responsible for hiring staff for the clinics, services and programs described below. Most city job openings are listed on a central website and describe the open positions in the most general of terms. An applicant learns of the specific job duties of the position and the services that he or she would be asked to provide only during the interview for the position. Thus it is possible that applicants who would object to providing certain services or treating some subpopulations would not know that the job required them to perform those services for those people until at least partway through the hiring process. A rule requiring the City nevertheless to hire persons to perform services they have no intention of performing would be completely

unworkable given the size of our clinic staff and the lack of redundancy (or the funding to create such redundancy).

The Field of Public Health

17. In order to grasp the value of the various clinics, programs, and initiatives at the Baltimore City Health Department—as well as the devastating harm that can result under broad exemptions from requirements to provide equal care—it is important to understand the field of public health, as distinguished from individual medicine.

18. Unlike the role of medical care in our health system, where professionals diagnose and treat individual health problems, public health deals with preventing disease and promoting health at the community or population level.

19. One way to measure the success or failure of a public-health program is by using statistics, of which some key ones include: disease incidence (the number of new cases of a particular disease within a population in a given time period), disease prevalence (the number of individuals within a population who have a particular disease at a given time), and mortality rates (the number of deaths due to a disease divided by the total population). Thus, where individual medicine concerns disease treatment and care for an individual patient, public health emphasizes the health and well-being of a community.

20. In public health we focus not only on how to diagnose and treat diseases, but also on how to prevent them in the first place. We aim to prevent the spread of infectious diseases throughout a community or population and prevent the development of medical conditions or illnesses like heart disease or obesity. Sometimes this means that the public is not aware of our public-health interventions—for example, ensuring that food is inspected so that the food supply is safe, or establishing regulations ensuring safe air and water quality.

21. Our former Commissioner of Health was fond of putting it this way: Public health saved your life today—you just didn't know it.

22. Thus, though the clinics, programs, and initiatives of the Baltimore City Health Department indeed provide individuals with medical services (testing, diagnosis, and treatment), those efforts also serve a broader public purpose of disease prevention and promotion of a healthy population generally. To bring about large-scale health improvements most effectively and efficiently, programs should be targeted to serve communities that are most at risk and might have challenges gaining access to other parts of the healthcare system. Public-health efforts thus tend to focus on populations of the homeless or those who otherwise lack secure housing; the impoverished; those without support systems in place; individuals who engage in risky behavior such as sex workers or those with substance addictions; and otherwise vulnerable communities. These populations can also be distrustful of government and the medical system. Improved population-health results can take years or even decades to obtain. Any disruption in these efforts, especially through interference that impedes public-health efforts in marginalized communities, can set programs back years, if not decades. And those setbacks could threaten the broader population with devastating harms, including increased prevalence of tuberculosis, HIV, sexually transmitted diseases, teen pregnancies, infant deaths, and opioid overdoses.

Clinical Services

23. The Bureau of Clinical Services & HIV/STD Prevention Services of the Baltimore City Health Department operates STD, HIV, Hepatitis C, Pre-Exposure Prophylaxis (PrEP), Buprenorphine, Dental, and Tuberculosis Clinics in two physical locations open during standard business hours. We also offer additional mobile-clinic services using two vans. It is my hope that

the Health Department will have enough resources to offer evening and weekend clinic hours in the future.

24. The clinics are funded in part by federal financial assistance administered through the U.S. Department of Health and Human Services either directly or as passed through the State of Maryland. This includes funds under the Public Health Services Act, the Ryan White HIV/AIDS Program, and grants from the Centers for Disease Control and Prevention.

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

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

27. All the nurse practitioners, nurses, doctors, and the two case managers who drive the mobile-clinic vans are contracted employees through Johns Hopkins University. In addition, the vans used for the mobile clinics are owned by Johns Hopkins. The contracted employees are, from the perspective of anybody visiting a clinic, indistinguishable from city employees. They are employed under annual contracts that, as a matter of course and historical practice, continue to be renewed each year. Johns Hopkins posts announcements for Health Department job openings separately from other openings, specifically noting that successful applicants will be contracted to the Baltimore City Health Department. The majority of contracted employees serve only in the Health Department clinics; they do not rotate or fill positions at Johns Hopkins's facilities. Two of the nurse practitioners spend 20 percent of their hours at a Johns Hopkins clinic. There are no signs in the city clinics to indicate that Johns Hopkins employees staff the clinics, and there is no

mention of Johns Hopkins on the clinics' websites. In my capacity as Assistant Commissioner, I supervise hiring decisions over these contract positions and I supervise and direct the contracted employees, managing their job duties and assignments. I am responsible for their day-to-day activities and for the standard procedures that govern the provision of medical services for which they are employed. I also have the ability to initiate personnel actions against them through Johns Hopkins's human-resources framework.

28. Clinical Services currently administers two subgrants of HHS funds: one Ryan White Part A subgrant, and one for TB elimination. Clinical Services does not presently have a staff member assigned to ensure compliance with the terms and conditions of these subgrants.

29. STD/HIV Prevention currently administers over 50 subgrants of federal funds from HHS. These subgrants support outreach, HIV and STD surveillance and prevention, behavioral health, and other programs.

STD Clinic

30. The STD Clinic offers walk-in services, similar to an urgent-care facility. The clinic offers testing and treatment—including follow-up visits—for chlamydia, gonorrhea, and syphilis. We also diagnose and treat trichomonas, bacterial vaginosis, and herpes. We offer referrals to key services in the community, including pregnancy testing, prenatal care, substance-abuse treatment, mental health, and immunizations.

HIV Clinic

31. The HIV Clinic is a continuity clinic for approximately 350 patients living with HIV. The clinic offers HIV-related care in addition to general medical care specifically for those living with HIV. For some patients, the HIV Clinic is their source of primary care. The clinic provides services to patients so long as they wish to continue coming back.

32. Although the Health Department is interested in dispensing medication at its HIV Clinic, it does so only in very limited capacity at this time. Instead, most patients are given prescriptions and referred to a local pharmacy of their choice. If a patient does not have insurance or pharmacy coverage for a medication or cannot afford a co-pay, the Health Department may cover the cost of the medication through Ryan White funding as the payor of last resort.

33. The Bureau of Clinical Services also runs the Directly Observed Therapy Program for residents who have been diagnosed with HIV but struggle with adhering to their medication regimens. Program staff visit patients to watch them take their medications. They can also provide reminder calls and help coordinate medication refills and travel to medical appointments.

Hepatitis C Clinic

34. The Hepatitis C Clinic treats patients diagnosed with Hepatitis C, using 8–12 week courses of medication. Clinic staff also ensure that patients stay up to date on their laboratory testing, and perform a blood test three months after the course of treatment is complete to ensure Hepatitis C cure. If these tests confirm that a patient has been cured of Hepatitis C—which occurs in 90 percent of cases—the clinic staff send a letter stating that the patient is cured to the patient and the patient’s primary-care provider, if applicable.

35. This course of treatment for Hepatitis C is relatively new, and at nearly \$100,000 for some therapies, it can be cost prohibitive. Many primary-care clinics do not offer Hepatitis C treatment. Thus, many patients come to the clinic for treatment that they cannot receive from their primary-care provider.

PrEP Clinic

36. The PrEP Clinic prescribes PrEP and Post-Exposure Prophylaxis (PEP) to patients who are referred to the clinic. PrEP and PEP are used to prevent contraction of HIV either before or after coming into contact with the virus.

37. PrEP is relatively new and not necessarily widely available throughout Baltimore. There may be limited options for some patients to obtain PrEP or PEP. Therefore the Health Department's PrEP Clinic is a last resort for some Baltimore residents and plays an important role in combatting the HIV/AIDS epidemic in the region.

38. The PrEP Clinic does not distribute medication, but either provides prescriptions for PrEP or links patients to the Gilead Advancing Access Program, which provides PrEP and PEP free of charge for some patients.

39. PrEP Clinic staff follow up with patients and monitor their health at least every three months while they are on PrEP medication.

Buprenorphine Clinic

40. The City's Buprenorphine Clinic offers medication-assisted treatment for drug addiction to combat the growing opioid crisis. The clinic prescribes buprenorphine in its sublingual form; patients place the medication under their tongues and wait 5–10 minutes for it to dissolve.

41. The Health Department established the Buprenorphine Clinic in May 2018 in response to the worsening opioid epidemic. Buprenorphine treatment is offered in the mobile clinics to serve areas most affected by the opioid crisis.

42. Special certification requirements to prescribe buprenorphine and regulatory limits on the number of patients for whom a provider can prescribe restrict the maximum number of patients that a facility can serve. This, combined with other barriers to care faced by many suffering

from opioid addiction, mean that the City Health Department's clinic is a healthcare resource of last resort for many Baltimoreans.

Tuberculosis Clinic

43. The Tuberculosis Clinic manages the complex task of containing and treating tuberculosis in Baltimore. The Health Department is the governmental entity responsible for coordinating TB response whenever a case is reported.

44. When a positive TB diagnosis is reported to the Health Department, the TB Clinic manages the 6–9 month treatment of the patient. Treatment might include a short quarantine following the initial diagnosis while the patient remains infectious. Typically patients are no longer infectious after two weeks on therapy. The logistics of this quarantine and the strictly scheduled course of treatment for TB raise particular complexities among Baltimore's transient, imprisoned, and homeless populations. It can also be difficult to provide treatment for and quarantine of people who lack robust support networks, are undocumented residents, or cannot get time off work or cannot afford to take the time off. Sometimes the Health Department has no choice but to pay for hotel rooms to provide the best protection for public health. Last year, for the first time in many years, the Health Department was forced to exercise its authority to have a patient with TB involuntarily committed because the patient refused to comply with the quarantine.

45. The TB Clinic also conducts investigations of each of the 20–30 cases of TB reported annually in Baltimore. Staff members attempt to contact anybody with whom the infected patient came into close contact while contagious.

46. The Baltimore City Health Department is responsible for controlling TB in the city and ensuring that all patients are treated to avoid TB outbreaks. TB is an airborne infection and has the potential to cause large outbreaks. Therefore, diagnoses and treatment of active cases and

investigation of TB transmission are key public-health activities undertaken by the Health Department.

Mobile Clinics

47. The mobile clinics offer STD, HIV, and Hepatitis C testing and treatment, as well as buprenorphine treatment, wound care, and naloxone distribution. The mobile clinic provides services to patients who use drugs and are often marginalized and may not have access to or seek out care elsewhere. These mobile task forces are an essential part of the City's public-health strategy because they allow the Health Department to reach historically marginalized and distrustful communities that are most affected by the various health challenges facing Baltimore.

Dental Clinic

48. The Dental Clinic provides dental care to certain subpopulations on the basis of available federal funding. The clinic provides pediatric dental services through Head Start, services to patients living with HIV through Ryan White funding, services to pregnant women through Medicaid reimbursement, and services to seniors through Medicare reimbursement. The clinic also offers emergency dental care.

Laboratory

49. Clinical Services also runs an STD-testing laboratory, which processes all STD testing for the Health Department, as well as some testing for outside partner organizations.

HIV/STD Prevention Services

50. The nonclinical programs that I oversee in HIV/STD Prevention Services complement the Clinical Services programs as part of the City Health Department's overall public-health philosophy. Staff in these programs conduct administrative, surveillance, field, outreach,

and educational functions that are essential to reducing stigma and other barriers to care, building community trust and relationships, and maintaining public health. Programs within HIV/STD Prevention Services receive federal financial assistance administered through the U.S. Department of Health and Human Services—including funds from the Centers for Disease Control and Prevention, and Ryan White funding. HIV/STD Prevention Services also receives funds from the State of Maryland.

51. Partner Services teams ensure that patients newly diagnosed with HIV or syphilis are connected to treatment and providers who specialize in HIV or syphilis healthcare. They ensure that patients with syphilis are adequately treated. The teams also identify and interview the sexual partners of patients who are diagnosed with HIV or syphilis to assess and control the spread of those diseases.

52. The Bureau's outreach teams operate in two vans (which are different from the clinical vans) to attend health fairs, community events, visit drug-treatment centers, and reach other targeted locations to provide education and STD testing.

53. The Bureau's Linkage to Care team connects people living with HIV who are not in care to healthcare providers for HIV treatment, and also connects people with chronic Hepatitis C to healthcare providers so that they may be assessed for treatment. The Linkage to Care team connects these people with providers in the area, either within the Health Department's system or at another facility.

54. The Social Innovations program uses outreach and social media to reduce stigma and build community engagement around HIV and STD prevention. For example, the Baltimore in Conversation campaign uses storytelling and community conversations to build a movement to reduce stigma about sexual health and sexual identity.

55. HIV/STD Prevention Services also provides testing kits to providers and facilities around Baltimore.

56. The Health Department subgrants HHS funds to various community partners through HIV/STD Prevention Services. These subgrants tend to fund educational efforts in Baltimore, including one campaign called Undetectable = Untransmittable, which educates the community about safe sex for people living with HIV, addresses the stigma associated with HIV, and involves the community in HIV-prevention messaging.

Baltimore's Philosophy, Successes, and Challenges

57. The Health Department has made significant progress in addressing public-health challenges in recent years. Though Baltimore still has relatively high rates of STDs, we've accomplished reductions in the number of new HIV infections, established model Linkage to Care programs, and integrated programs with our mobile clinics to reach new demographic groups.

58. The City has made great progress in stemming the spread of HIV and improving access to treatment. For example, in 2008 there were 794 new HIV diagnoses. In 2017 that number dropped to 231. Reported HIV diagnoses, AIDS diagnoses, and AIDS deaths are the lowest they have been since the 1980s, early in the AIDS crisis. Continuing on our current path would establish Baltimore as a success story in fighting the HIV epidemic.

59. This progress is at least in part because of the Department's philosophy of meeting people where they are; we reach out to previously marginalized and ignored communities and offer judgment-free care. This philosophy is borne out in various techniques such as our flexibility, trauma-informed approach, and status-neutral programs—each explained more fully below. Through these strategies, we develop community relationships built on trust and begin to break

down the social barriers that can prevent certain subpopulations from seeking out or accepting healthcare services from the City.

60. Trauma-informed care starts with understanding the various types of trauma that many Baltimoreans have experienced. In part because of Baltimore's relatively high rates of poverty and crime, individuals who often have the greatest need and the most to gain from the Health Department's services have a high likelihood of having experienced some physical, psychological, or emotional trauma. Without informed sensitivity to those experiences and their lasting effects, Health Department providers and personnel might inadvertently cause those in need of care to relive their trauma, might trigger sensitivities based on past trauma events, or might fail to build trusting provider-client relationships that are so crucial to our success. Trauma-informed care allows providers and others to empower patients and encourages communities and individuals that have suffered trauma (and who tend to face the greatest public-health challenges) to seek out and accept care.

61. Staff in the Bureau of Clinical Services & HIV/STD Prevention Services have undergone training in trauma-informed care, and more training is planned. Trauma-informed care manifests throughout the provision of services, starting with something as simple as providing more than two checkboxes for gender on intake forms, to showing understanding when paperwork might be out of order, to considering how a physician conducts a physical exam for a person who exhibits psychological or emotional effects from past sexual or violent trauma.

62. We also try to make it as easy as possible for a person to visit the City's clinics. Because the clinics provide care at no cost to patients, they are safety-net services for people who have nowhere else to turn. And the clinics do not impose any rules on the patients that might deter them from seeking care. For example, the clinics do not cancel appointments when a patient shows

up late, like many private providers might. Through the lens of the Health Department's overall philosophy, this lets patients know that the City is there for them, for whatever they need, even when others might turn them away. This establishes trust and keeps patients coming back and recommending the Health Department's services to their communities.

63. In addition, the Health Department's clinics display notices to patients that they will receive care without discrimination on the basis of their race, color, national origin, age, gender, sexual orientation, gender identity or expression, physical or mental disability, religion, ethnicity, language, or inability to pay.

64. The clinics also pride themselves on the philosophy of providing judgement-free care, helping patients feel comfortable to be themselves and unashamed of any behaviors or life experiences that might be stigmatized in other settings. It is only then that we are able to truly assess patients' needs and help provide them with the resources that they need to stay healthy.

65. Another emerging line of thinking that pairs with the City's judgment-free-care philosophy is the notion of a status-neutral health approach. Traditionally, public-health agencies and organizations have offered a range of wraparound social services to people diagnosed with HIV, often through Ryan White funding. Those services may include housing assistance, transportation, and referral to other medical services such as mental-health services or substance-abuse treatment, in addition to the necessary medical care. Access to these services certainly affects an individual's health and well-being. It also affects the overall public health. For example, people living with HIV who do not have stable housing might struggle to take their medication on schedule, and as a result their HIV will be difficult to control. They are thus more likely to pass HIV to others, affecting the public health of the community. But if they are provided with housing, which was their main barrier to taking their medication, and can now control their HIV infection

and have an undetectable HIV viral load, they are much less likely to transmit HIV to others and the public health of the community is more protected.

66. Though effective at containing existing infections, this traditional approach of providing services only to those who are HIV-positive ignores those who are at risk for HIV. For example, these individuals may be experiencing housing insecurity, food insecurity, substance abuse, or mental-health issues. And it's these issues that might place them at higher risk for contracting HIV. But because they have been historically neglected by governmental programs, they might not trust the services that government does offer to them, compounding their risk factors. Even worse, I have heard of people so desperate to obtain wraparound support services that they actually want to contract HIV so that they are no longer excluded from those programs.

67. If we can address these socioeconomic issues or other health issues, we may prevent more people from becoming infected with HIV. Therefore, a status-neutral health approach calls for providing support services to members of high-risk communities before they are diagnosed with HIV or an STD. These communities include those without housing or support networks, sex workers, and people with drug addictions. Providing wraparound services to these communities is, in some cases, just as important and effective as providing PrEP. Building trust and providing stigma-free care are essential in order to move forward with a status-neutral approach to HIV prevention. The Department is currently working on building its status-neutral approach toward HIV prevention.

68. By continuing to advance these philosophies, we will continue to make improvements to public health in Baltimore. But there remain significant crises for us to combat.

69. Baltimore is at a tipping point in fighting the HIV epidemic: much of our progress could be undone if we do not keep up our current pace. And while numbers of new HIV infections

are declining in Baltimore, other STDs are on the rise. In 2017, there were 7,636 cases of chlamydia in Baltimore. Chlamydia is the disease most commonly reported to the CDC. In 2017, Baltimore also had the highest number of gonorrhea cases than it has had in any of the previous nine years. In 2017, there were over 4,231 cases of gonorrhea in Baltimore, compared with 3,198 in 2008. Nationally, the number of gonorrhea cases increased 67% between 2013 and 2017.

70. Gonorrhea is of particular public-health concern: it is increasingly resistant to drug treatment. The STD Clinic currently follows treatment guidelines in treating gonorrhea, which include two-drug therapy: ceftriaxone, an injection, and azithromycin, a pill. It is the last known effective outpatient treatment. Should this therapy become ineffective, gonorrhea infection might require inpatient hospital therapy for treatment. If that comes to pass, the cost to the Health Department, the medical system, and public-health entities everywhere would be exorbitant, and it would be difficult, if not impossible, for the City to stem the spread of the infection. It is crucial that the City prevent a new drug-resistant strain of gonorrhea from developing within Baltimore, and we must prepare to contain any strain that develops elsewhere and makes its way to our region.

71. In 2017, Baltimore had 210 primary and secondary syphilis cases—a rate of 34.3 per 100,000 population. This is substantially higher than national rates of 5-8 per 100,000 population.

72. Congenital syphilis is also a significant concern. Congenital syphilis occurs when a woman is infected with syphilis while she is pregnant and she passes it to the fetus or later to the newborn child. Congenital syphilis can lead to premature birth, miscarriage, stillbirth, and long-term health consequences in infants, including birth defects, blindness, deafness or meningitis. There were 10 cases of congenital syphilis in Baltimore City in 2017. Each instance of congenital

syphilis is considered a seminal event, meaning that it medically should not have occurred, and formal investigations are triggered in each case.

73. According to analysis by the Centers for Disease Control and Prevention, racial and ethnic minority groups and LGBTQ people are affected by social disparities in access to healthcare that lead to higher rates of STDs. In the United States, the reported rate of chlamydia in black women, for example, is 5 times the rate of white women, and the rate in black men is 6.6 times the rate in white men. Or take syphilis: Nationally, the majority of syphilis cases occur among men who have sex with men, a trend that is also seen in Baltimore.

74. In Baltimore, the HIV epidemic further highlights social disparities in our public-health system. Roughly 83 percent of Baltimore residents living with HIV are black, but only about 61 percent of the total Baltimore population is black. And over half of those living with HIV in Baltimore are gay men, bisexual men, or other men who have sex with men. The City Health Department will not be able to continue making progress in the fight against HIV and other STDs without the meet-them-where-they-are philosophy that allows us to reach these historically stigmatized and marginalized communities.

Harms Created by the New Rule

75. The new Rule will be costly and difficult, and in some respects even impossible, for the Bureau of Clinical Services & HIV/STD Prevention Services to implement. Because the Bureau's work is highly targeted and because it renders the same types of services every day, a provider or staff member objecting to assisting provision of a service or to helping a particular patient demographic would necessarily refuse to perform a significant portion of his or her job duties. Without being able to fill that position with someone willing to perform critical job duties, the Health Department's only alternative would be to double-staff the clinics. That, however, is

essentially impossible. New positions can be challenging to create. We do receive some city funds and private grant funds, but they are not enough to cover the cost of additional staffing. The bulk of funding is through the U.S. Department of Health and Human Services.

76. Staffing burdens would be made even worse because of the specialized training requirements in some of our clinics. To prescribe buprenorphine, for example, medical professionals are legally required to undergo specialized training. And once certified, providers may treat only up to a maximum number of patients depending on the level of certification. Similarly, TB treatment is highly specialized and new nurses must train for up to six months before they can provide the full spectrum of care for TB patients. Accommodating staff refusals in either the Buprenorphine Clinic or the TB Clinic would thus create a gap in services before new staff could be put in place—assuming that funding could even be secured for new staff. And in the interim, patients could suffer, overdoses might increase, or TB cases could increase in Baltimore, potentially leading to a TB outbreak.

77. The subgrantee-compliance certification that the Rule appears to require would also create unmanageable administrative burdens. Most of the programs with subgrants have staff who are assigned to ensure compliance with terms and conditions of the subgrants. These terms, consistent with existing federal law, ensure that federal funds are being used appropriately. But were federal law to require that the Health Department review the internal personnel policies and procedures of all subgrantees, it would subject our staff to an enormous burden. Such a rule would require our staff to investigate not only the uses of federal funds as is common practice, but also the way in which each subgrantee organization interacts with its employees—a subject beyond the expertise of the Health Department staff who currently oversee subgrantee compliance. The Health Department's workload would increase significantly, and it may be impossible in some instances

to obtain assurances that an organization handles its internal human-resources matters in compliance with the Rule.

78. Though many of the Health Department's subgrants are awarded to large, sophisticated organizations such as Johns Hopkins University that may be more likely to be able to provide assurances of internal policies, it is the Department's growing strategy to work with small, community-based subgrantees.

79. These smaller organizations tend to be new and have very few, if any, paid staff members. The small subgrantee organizations allow the Health Department to use a more nuanced, flexible approach in protecting and improving public health. The nature of these organizations complements the Health Department's philosophy by allowing those who implement the Department's programs to become familiar with and trusted by the community.

80. But because of their inexperience and lack of resources, these small organizations sometimes lack processes that would allow the Health Department to ensure that their internal personnel policies comply with the Rule.

81. Aside from the administrative challenges of implementing the Rule, if patients were turned away from Baltimore City Health Department services under the Rule, the individual harms would be drastic. And if the Rule requires clinics to display notices that staff may refuse service, it would undermine the Department's efforts to build trust and create a safe, judgment-free environment.

82. Because the Health Department's clinics are often facilities of last resort for Baltimore's most at-need residents, those turned away or scared away from its services would go without necessary medical care. And even those who have access to healthcare elsewhere sometimes choose to come to the Health Department for some services because they are too

embarrassed to seek those services from their primary-care providers. That fear of stigma is precisely why the City offers judgment-free care, and the experience of being denied treatment could make that fear worse.

83. Baltimoreans' health and very lives are at stake. Without treatment, syphilis and gonorrhea may lead to infertility. Syphilis also causes blindness, pelvic inflammatory disease (causing extreme pain in women), miscarriages, stillbirths, and disabilities in infants. And HIV and Hepatitis C, if left untreated, can be deadly.

84. In addition, denials of care create psychological harms, particularly in those patient populations that are vulnerable because of past traumas.

85. These harms become more pronounced on a broader scale. If a provider or staff member at the Health Department were to turn an individual away because of a religious or moral objection to either the services sought or the individual's identity, it would inherently communicate a sense of judgment to the individual. Refusing to serve certain people would thus lead them to lose trust in the City and be reluctant to seek care in the future, and would give the Health Department a poor reputation in hard-to-reach communities.


86. The progress that the Health Department has made in preventing and treating HIV and STDs could be undone by a rule allowing refusals to provide care, setting our public-health efforts back by 20 or 30 years.

87. What is more, if the Baltimore City Health Department were to lose federal financial assistance through an enforcement action under the Rule, it would cripple our ability to provide all but the most minimal of services. Nearly all the funding for programs that I oversee comes from the U.S. Department of Health and Human Services.

88. Baltimore has seen firsthand the effects of service interruptions in underserved communities. In the early 1990s, federal funding to the City's STD clinics was reduced, decreasing the number of medical professionals and outreach personnel on staff. This, combined with the rise of crack-cocaine use and housing displacement of many poor residents, led to a 500 percent increase in syphilis infections across Baltimore.

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, in the State of Maryland.



Adena Greenbaum, M.D., M.P.H.

Exhibit 22

**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 JERRIS R. HEDGES

1. I, Jerris R. Hedges, MD, MS, MMM, 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 Hawaii'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 the University of Hawai'i at Mānoa John A. Burns School of Medicine personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the University of Hawai'i at Mānoa John A. Burns School of Medicine.

3. I am the Dean at the University of Hawai'i at Mānoa John A. Burns School of Medicine located in the State of Hawai'i. My educational background includes a Doctorate of Medicine, Master of Science, and Master of Medical Management degrees and advanced training as an emergency physician. I have been employed as Dean since 2008.

4. The University of Hawai'i is the only state university in Hawai'i and has 10 campuses across the Hawaiian Islands which include three universities and seven community colleges. The University of Hawai'i at Mānoa John A. Burns School of Medicine has students, residents and fellows undergoing clinical education and/or training at health care facilities in Hawai'i.

5. The clinical education and/or training of students, residents and fellows in some instances includes education and/or training in providing health care services related to vaccinations, HIV/STD prevention and contraception, and abortion.

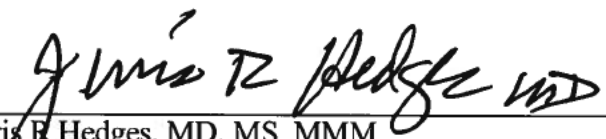
6. The University of Hawai'i received \$56,358,106 in contracts and grants from the HHS from July 1, 2017 to June 30, 2018.

7. If the University of Hawai'i is deemed to be in non-compliance with the Final Rule, this financial assistance from HHS is threatened and could be terminated.

8. In addition, University of Hawai'i at Mānoa John A. Burns School of Medicine will need to expend time and effort in training staff regarding which behaviors are now permissible from objectors and how to work around objections not previously of material impact.

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.



Jerris R. Hedges, MD, MS, MMM
Dean, University of Hawaii John A. Burns School of
Medicine

Exhibit 23

**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 HAWAII,
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 SUSAN HERBST

I, Susan Herbst, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct based on my personal knowledge and belief:

1. I am over the age of eighteen and believe in the obligations of an oath.

2. I am the President of the University of Connecticut (“UConn” or “the University”).

3. I have been employed at the University in my present capacity since 2011. Previously I served as executive vice chancellor and chief academic officer of the University System of Georgia, where I led 15 university presidents and oversaw the academic missions for all 35 public universities in Georgia. Before arriving in Georgia, I was provost and executive vice president at the University at Albany (SUNY), and also served as officer in charge of the university, effectively the acting president, from 2006 to 2007. I also previously served as the dean of the College of Liberal Arts at Temple University. I initially spent 14 years at Northwestern University, joining the faculty in 1989 and serving until my departure to Temple University. At Northwestern I held a variety of positions including professor of political science and chair of the department. I earned my doctorate in communication theory and research from the University of Southern California’s Annenberg School for Communication in Los Angeles in 1989 and a Bachelor of Arts from Duke University in 1984.

4. As President, I am the chief executive officer of UConn, its schools and colleges, and its other divisions and units, including the UConn Health Center located in Farmington, Connecticut (“UConn Health”).

5. 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 by the University administrative and professional staff, all of whom report to me.

6. 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”).

I. UConn Health Is A Leading Provider Of Healthcare, Medical Training And Research In The State Of Connecticut.

7. UConn Health is Connecticut’s flagship public academic medical center, with an integrated 3-part mission focused around education, research and patient care.

8. UConn Health includes UConn School of Medicine (“SOM”); UConn School of Dental Medicine (“SODM”); the Graduate School; UConn John Dempsey Hospital; UConn Medical Group (“UMG”); University Dentists; and UConn Health Pharmacy Services, Inc.

9. UConn Health is a critical source of the State of Connecticut’s future health care professionals, with 37% of medicine and 44% of dental graduates practicing in the State.

10. UConn Health is also an essential provider of healthcare and dental services to underserved populations.

11. In 2017, UConn Health had a total operating budget of more than \$1 billion, including approximately \$235 million in state appropriations annually and employed nearly 5,000 full- and part-time individuals across the clinical, research, and academic missions, with over 2,300 devoted to the clinical work.

12. In 2017, UConn Health discharged approximately 10,000 inpatients, and had 1.1 million outpatient encounters and over 35,000 ER visits. It also received over \$87 million in federal and non-federal research grants and contracts that year.

13. UConn Health received an average of \$53 million in each of the last five full fiscal years in grant funding from HHS for biomedical research and health-related research

education and training initiatives. In addition to this direct funding from HHS, UConn Health also received about \$10 million per fiscal year of HHS grant funding passed through to it from other institutions that received HHS funding, for purposes similar to those for which UConn Health received direct HHS funding. A portion of the \$53 million per year received by UConn Health, about \$9 million per year, is passed through from UConn Health to other institutions for similar purposes.

14. These HHS funds are essential to functioning of UConn Health and to maintaining public health within the State of Connecticut and training its next generation of medical professionals.

II. UConn Health Protects The Rights of Employees To Decline To Participate In Activities To Which They Have Religious, Moral or Ethical Objections.

15. UConn Health seeks to accommodate the religious, moral and ethical concerns of its employees who may wish to decline to participate in certain medical care. Our policies are consistent with both federal and Connecticut state laws regarding religious and moral objection accommodation. We train our employees about the importance of valuing and respecting individual diversity and differences, including religious and ethical differences. Our administrators and staff are trained that differences can enhance interactions and organizational productivity.

16. At UConn John Dempsey Hospital (“JDH”), the State’s only public acute care hospital, there is a written conscience objection policy. JDH balances a respect for individual employee diversity (including cultural values, ethics, and religious beliefs) with its mission of providing high quality patient care.

17. JDH employees may request to not participate in procedures, including but not limited to: blood product administration; termination of pregnancy; initiation and/or cessation of

life support; end of life decisions; administration of pharmacological agents to terminally ill; harvesting of human organs; and sterilization and reproductive technologies. These are the areas that JDH has concluded are most likely to lead to an employee request for an accommodation.

18. In order to accommodate an employee request, while also protecting our patients, JDH requires that a requesting employee make a request in advance, where feasible, and in all circumstances continue to provide appropriate patient care until arrangements for a transfer of care to another provider can be made. JDH does not permit patient care to be compromised under any circumstances.

19. An employee who knows that he or she does not wish to participate in these or other patient care services is required to put the request in writing as soon as he or she first becomes aware of the possible conflict. JDH does not permit an employee to refuse to provide care at the time a patient is in need of immediate care or treatment.

20. An employee's written request must detail the tasks expected to be performed by the employee and the reason for the request not to participate. JDH policy requires the institution to address employee requests in a reasonable time frame and inform the employee of its decision.

21. If the employee request is granted, the supervisor or manager must document the accommodation(s) made for adequate delivery of patient care services.

22. If the request is denied, the employee is expected to perform all duties of his/her position.

III. The Final Rule Will Impact Operations At UConn Health When It Becomes Effective.

23. My understanding of the Final Rule suggests that its implementation could seriously jeopardize UConn Health's ability to deliver on its core mission of serving the health needs of the people of Connecticut.

24. Of particular concern are the expanded definitions of key terms such as: "assist in the performance," "discrimination," "health care entity," and "referral or refer for." Expanded definitions of these terms, or any ambiguity regarding the scope of those terms, will affect how UConn Health functions.

25. This new uncertainty generated by expanded definitions in the Final Rule seriously undermines UConn Health's ability to provide health care safely, effectively and reliably. I am concerned that allowing employees to opt out of providing care without prior notice will create unsafe and unethical situations with potentially awful results for our patients and staff.

26. If the Final Rule definitions are as expansive as they appear to be, UConn Health seemingly could no longer inquire of prospective candidates whether they can perform the essential functions of a particular position. This could have serious consequences on our ability to provide care to the citizens of Connecticut.

27. As just one example, if UConn Health was staffing for a nurse position in the midst of a communicable disease epidemic, the Rule would prohibit UConn Health from asking if the candidate had a religious objection to administering vaccinations. The Final Rule also seems to permit a broader range of employees – some of whom may have no direct role in providing actual health care, such as receptionists, to refuse to perform the functions of their job, and without any advance notice, no matter the risk to others.

28. UConn Health will now have to expend staff time and resources to plan for the contingencies caused by the Final Rule. This will be extremely costly. For example, UConn Health will be forced to examine whether it must double-staff emergency functions in light of limits the Final Rule places on requiring advance notice of objections. Our existing budget simply does not permit us to double-staff our emergency departments or other departments, which may necessitate scaling back and/or eliminating certain types of services and care to avoid violating the Final Rule.

29. The Final Rule will require UConn Health to retrain staff for compliance with the Rule. However, the ambiguity surrounding the meaning of the Final Rule would make training to comply with it very difficult.

IV. The Final Rule Subjects UConn Health To Potentially Conflicting Legal Obligations.

30. The Final Rule is not the only law or regulation with which UConn Health must comply. I am concerned that the Final Rule will place UConn Health in the untenable position of having to choose whether to comply with our obligations under other laws and regulations, agreements, and grant terms or the Final Rule.

31. For example, JDH, as a public hospital, has obligations under federal law to provide care to **all** patients who present at the emergency department for emergency treatment, regardless of their ability to pay. This federal law, the Emergency Medical Treatment & Labor Act (EMTALA), imposes specific obligations on Medicare-participating hospitals, like UConn Health's JDH to medically screen every patient who seeks emergency care and to stabilize or transfer those with an emergency medical condition (including active labor). If a UConn Health employee is allowed by law to simply refuse to provide the required medical screening or

stabilizing care (or transfer) without any advance notice or planning, UConn Health risks violating EMTALA (not to mention placing the patient's health at significant risk). Such action could expose UConn Health to EMTALA penalties and possibly other regulatory enforcement action.

32. I am also concerned about the impact of the Final Rule on particular groups of individuals served by UConn Health. UConn Health serves many vulnerable populations, and the Final Rule may impede our ability to provide the highest level of care to those populations.

33. For example, UConn Health serves many deaf and hearing impaired patients perhaps due in part to our proximity to the American School for the Deaf, located in an adjacent town. As part of caring for this unique population, UConn Health is required to provide auxiliary aids and translator services. In fact, in 2016, the United States Department of Justice ("US DOJ") investigated UConn Health for an alleged failure to provide adequate translator services in a timely manner to a hearing impaired patient. Thereafter, in December 2016, the US DOJ and UConn Health entered into an agreement whereby UConn Health was required to satisfy certain specific requirements for serving this population in a timely manner.

34. If an American Sign Language ("ASL") translator is empowered under this Final Rule to refuse to provide services to a hearing-impaired patient, for whatever reason, UConn Health could risk falling short of our mission to our patients, which in turn could invite another investigation or enforcement action by the US DOJ. ASL translators, and other language translators for that matter, are not always able to be replaced quickly or easily.

35. UConn Health physicians and staff also serve patients with HIV/AIDS, and UConn Health conducts clinical trials on new therapies for HIV/AIDS.

36. UConn Health is a Ryan White service provider that offers HIV primary medical care, essential support services, and medications for low-income people living with HIV who are uninsured and underserved. Under the terms of the Ryan White Program grant, UConn Health must provide care to this population without discrimination. If the Final Rule permits an employee to refuse to provide care to a person with HIV/AIDS, without prior notice and for any reason, UConn Health could be in violation of its obligations under this valuable grant program.

37. I am also concerned about UConn Health's ability to continue to comply with both Connecticut law and the Final Rule. To highlight just one potential conflict caused by the Final Rule, UConn Health could be forced to violate a state law requirement to provide emergency contraception. Connecticut law provides that emergency treatment to a victim of sexual assault includes the provision of emergency contraception to the victim of sexual assault at the facility upon the request of such victim. Conn. Gen. Stat. § 19a-112e(b)(3). The Final Rule seems to empower a pharmacist or treating physician or nurse at UConn Health to simply refuse to provide this care without notice. This would clearly violate state law, which as an arm of the State, would be especially problematic for UConn Health.

V. **The Final Rule Could Have Lasting Effects on UConn Health's Next Generation of Health Care Providers.**

38. Lastly, UConn Health is proud of its role in training the next generation of Connecticut's and the nation's physicians and medical personnel. The Final Rule could tarnish the ability of UConn Health to provide medical students with the breadth and depth of training and knowledge required to be the best-trained health care providers possible. If a physician, nurse or other medical personnel who is employed to train students refuses to provide care in an emergent or non-emergent situation based on the Final Rule, students will be deprived of the

invaluable learning opportunity that this practical on-the-job training provides. The loss of this educational opportunity could have serious repercussions in the future if health care providers lack the training required to address the full range of medical needs of our citizens.

39. In addition to the grave financial impact the Final Rule could have on UConn Health, the Final Rule may erode UConn Health's ability to deliver care in a manner consistent with our values and mission for many years to come.

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

Executed on this 11th day of June, 2019



SUSAN HERBST
PRESIDENT OF THE UNIVERSITY
OF CONNECTICUT

Exhibit 24

**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. HEATHER HIRATA APRN

1. I, Dr. Heather Hirata APRN, 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 Hawaii'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 the University of Hawai'i at Hilo personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me. I have also familiarized myself with the Final Rule in order to understand its immediate impact upon the University of Hawai'i Student Health Center at my campus.

3. I am the Director of Medical Services at the University of Hawai'i at Hilo located in the State of Hawai'i. My educational background includes Doctorate of Nurse Practice, Masters of Nursing and a Bachelors of Nursing. I have been employed as Director of Medical Services since September 2010.

4. The University of Hawai'i is the only state university in Hawai'i and has 10 campuses across the Hawaiian Islands which include three universities and seven community colleges. The University of Hawai'i at Mānoa and the University of Hawai'i at Hilo both have student health centers which provides health related services to approximately 20,000 students; 16,806 for the University of Hawai'i at Mānoa and 3,204 for the University of Hawai'i at Hilo.

5. The Student Health Center at the University of Hawai'i at Hilo provides health services including vaccinations, HIV/STD prevention and contraception, and abortion referrals.

6. The University of Hawai'i received \$56,358,106 in contracts and grants from the HHS from July 1, 2017 to June 30, 2018. The University of Hawai'i at Hilo Student Health Center receives approximately \$90,000.00 per year directly from HHS.

7. If the University of Hawai'i is deemed to be in non-compliance with the Final Rule, this financial assistance from HHS is threatened and could be terminated.

8. In addition, the Student Health Center will need to expend time and effort in training staff on what behavior is now permissible from objectors and how to work around objections not planned for in advance.

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

Executed on this 29th day of May, 2019.

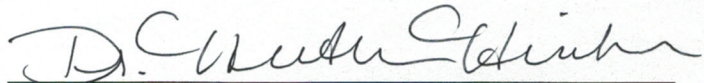

Dr. Heather Hirata APRN, DNP, MSN, BSN, FNP-BC
Director of Medical Services

Exhibit 25

**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 JOHN G. HUNTER, MD

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

2. I am Executive Vice President and Chief Executive Officer of the OHSU health system at Oregon Health & Science University (“OHSU”) located in Portland, Oregon. My educational background includes a Bachelor of Arts Degree from Harvard University and an MD from the University of Pennsylvania. I am a Fellow of the American College of Surgeons. I have been employed as Chief Executive Officer of the OHSU health system since 2017. Prior to that date I served as Chief Clinical Officer, Interim Dean of the School of Medicine, and as Chair of the Department of Surgery at OHSU.

3. I submit this Declaration in support of the State of Oregon’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”).

4. I have compiled the information in the statements set forth below either through personal knowledge, through OHSU personnel who have assisted me in gathering this information from our institution, or on the basis of documents that have been provided to and/or reviewed by me.

Oregon Health & Science University

5. OHSU is Oregon's public academic medical center. It is comprised of the degree-granting schools of dentistry, medicine, nursing, public health and pharmacy; multiple scientific research institutes; the OHSU Hospital and Doernbecher Children's Hospital; and several pediatric

HUNTER DECLARATION

and adult ambulatory care clinics in the Portland, Oregon metropolitan area. As part of its statutory state-wide mission, as set by the legislature and governed by a board appointed by the Governor of the State of Oregon, OHSU also provides patient care services and educational and training programs for its students throughout Oregon.

6. OHSU has 16,400 employees engaged in fulfilling its mission to: (a) educate tomorrow's health professionals, scientists, engineers and managers in top-tier programs that prepare them for a lifetime of learning, leadership and contribution; (b) explore new basic, clinical and applied research frontiers in health and biomedical sciences, environmental and biomedical engineering and information sciences and translate these discoveries, wherever possible, into applications in the health and commercial sector; (c) deliver excellence in healthcare, emphasizing the creation and implementation of new knowledge and cutting-edge technologies; and (d) lead and advocate for programs that improve health for all Oregonians, and extend OHSU's education, research and healthcare missions through community service, partnership and outreach. As Oregon's only academic health center, OHSU through its hospitals and clinics is proud to offer the broadest level of care to patients in Oregon and southwest Washington.

7. OHSU receives reimbursement for services provided to Medicaid and Medicare patients and other pass-through payments from HHS. For the period July 1, 2018 through June 30, 2019, OHSU estimates it will have net revenue of approximately \$799,000,000 with respect to such payments.

8. These funds are essential to functioning of OHSU, including delivering direct patient care to patients throughout the State of Oregon and the wider region and educating health care professionals.

HUNTER DECLARATION

9. OHSU faculty and students, as well as OHSU institutional divisions and units receive approximately \$1.08 billion in HHS grants for research, education, and policy development in biomedical science, patient care, and public health.

10. Disruption of some or all of these funds could adversely affect medical education and training, impair the health of patients in clinical studies, and delay or permanently disrupt development of life-saving treatments, pharmaceuticals, and medical devices.

Existing OHSU policies to address religious objections

11. OHSU has in place, and complies with, policies and procedures consistent with existing requirements of Federal and Oregon law on religious accommodation, which require that we honor requests for alternative work arrangements in response to conscientious objections to direct involvement in the following interventions: providing care according to the provisions of the Oregon Death with Dignity Act; withholding or withdrawing of life sustaining treatments, including artificial nutrition and hydration; termination of a viable pregnancy; or, writing or filling certain prescriptions for the specific interventions listed above.

12. OHSU is committed to providing outstanding patient care and medical education, while recognizing and accommodating the religious beliefs of those who work and train at our institution. Patients may request legally available, medically recognized interventions and treatments, and OHSU informed consent standards prohibit intentionally preventing patients from obtaining information related to interventions that may benefit them. OHSU's ethics principles require employees to be respectful of patient decisions regarding their own care and to refrain from imposing their beliefs on their patients.

13. OHSU is committed to creating an environment that permits healthcare staff to provide patient care according to their belief system without adverse actions, compromising patient

HUNTER DECLARATION

care, or compromising OHSU's public responsibility to provide medically recognized care to all patients in an unbiased manner.

14. OHSU policy provides that when a healthcare workforce member's beliefs prevent him or her from having direct involvement in an intervention, the member is not required to be directly involved in such intervention so long as he or she notifies a supervisor or department chair in writing of conscientious objection and the desire to withdraw from direct involvement in the intervention.

15. OHSU's requires written notice in advance of a healthcare workforce member's objection for several reasons. First, it assists healthcare management at OHSU in having reasoned discussions with a healthcare workforce member concerning the nature and scope of her religious objection, in order properly to accommodate the individual before a patient in need of care becomes involved. For example, advance notice allows healthcare management to consider whether an employee with a written objection to assisting in the performance of abortions should be staffed in the hospital's OBGYN department, as opposed to another department where the employee is less likely to be confronted with procedures she finds objectionable. Similarly, advance discussion of an employee's religious objection permits OHSU to understand the complete range of procedures that an employee finds objectionable. For example, some individuals do not consider medical treatment to address an ectopic pregnancy to constitute an "abortion," while others do. A written objection and subsequent discussion with OHSU personnel, which allows us to fully understand the scope of an individual's religious objection, allows our institution to meaningfully accommodate an employee's beliefs.

16. Second, advance notice of an employee's conscientious objection allows OHSU to make appropriate staffing decisions that take into account any necessary accommodation and the

HUNTER DECLARATION

manner in which it could affect patient care. This is particularly important in settings like emergency room overnight shifts, where patient care could be compromised by the unexpected unavailability of a single employee. In such settings, OHSU has a duty to the communities we serve to ensure that there is no sudden disruption to the provision of medical care that could endanger the lives or safety of patients. Avoiding disruptions in patient care is also a fundamental duty of our institution as a matter of medical ethics.

Immediate impact of the Final Rule upon OHSU.

17. OHSU understands the Final Rule to expand definitions of terms in ways that affect how we function. In particular, the Final Rule's overly broad definition of "assist in the performance," which requires only an articulable connection to a procedure, will capture acts with only a remote connection to a given medical procedure. The definition likely implicates involvement in the delivery of care that is deemed "indirect involvement" under OHSU policy and would therefore require OHSU to prepare alternative work arrangements (without the benefit of advance notice) with respect to a larger group of functions.

18. OHSU places a priority on continuity and effectiveness of patient care and does not permit the healthcare work force to refuse indirect care, including basic admission procedures, follow-up care, discharge, assistance with pain control, or providing information or educational materials, or referring a patient to other persons that will provide the intervention or facilitate an appropriate referral.

19. Expanding the definition of "assist in the performance" will have financial implications for OHSU in connection with staffing, scheduling, and supervision. Such costs would likely impact the speed and efficiency at which OHSU can provide the care needed by our patients.

HUNTER DECLARATION

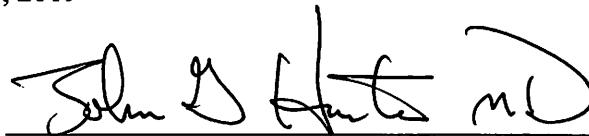
20. In addition, the Final Rule expands the protections of the underlying statutes beyond healthcare professionals to “healthcare personnel.” Including “healthcare personnel” with the broad definition of “assist in the performance” would force OHSU to plan its employee schedules around not only its healthcare workforce members delivering care, such as nurses and doctors, but also schedulers and others who have only tangential or no involvement in the delivery of patient care.

21. If the Final Rule goes into effect as written, OHSU must expend resources to double-staff in light of limits the Final Rule places on requiring advance notice of objections. Lack of advance notice reduces OHSU’s ability to work around objections not planned for in advance of a procedure. The need to double staff would apply to a large number of functions across our institution in light of the expansion of objector rights beyond those healthcare workforce members engaged in direct patient care.

22. Lack of advance notice requirement, plus greatly expanding the categories of workers who may decline to provide care, increases the risk of disrupting patient care, with corresponding adverse health outcomes.

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

Executed on this 16th day of June, 2019



John G. Hunter, MD

Executive Vice President and CEO
Oregon Health & Science University

HUNTER DECLARATION

Exhibit 26

**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
KATHYLEEN KUNKEL

DECLARATION of KATHYLEEN KUNKEL,
SECRETARY, NM DEPARTMENT OF HEALTH

1. I, Kathyleen Kunkel, 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 health impact upon the people of New Mexico.

3. I was named Secretary of the Department of Health (DOH) for the State of New Mexico on February 4, 2019.

4. Prior to being named as Secretary, I worked seven years at DOH, most recently as deputy director. I have overseen the DOH Bureau of Behavioral Supports, its regional offices and supported employment programs and have served as the department's general counsel. I created the position of "community inclusion manager" to develop and supervise the work of DOH coordinators statewide.

5. I also worked eight years at the University of New Mexico's Health Sciences Center, first as a pediatric social worker and ultimately as assistant director of care management services.

6. DOH, which has offices in Santa Fe and Albuquerque and clinics in 32 of New Mexico's 33 counties, is committed improving health outcomes for all New Mexicans.

7. Because of my extensive experience with health care policy and health services management throughout New Mexico, I am acutely aware of the challenges for training staff and ensuring compliance with federal regulatory and statutory requirements.

8. Because DOH is a provider of clinical medical services throughout the state I am also very aware of the risk to New Mexico patients that misapplication of regulations could shortchange our ability to provide services to our patients statewide, many of whom live below the poverty level.

9. DOH is a provider of community public health clinics in New Mexico. It is the primary recipient of HHS funds directed to New Mexico health programs.

10. On average over the past five years, DOH has received \$125 million per year in federal dollars.

11. DOH serves all ages of persons throughout New Mexico and serves all parts of the state through providing services for family, child and teen health.

12. DOH services include accrediting and licensing health facilities, nursing homes and emergency transportation providers.

13. DOH also works to improve the public health overall including preventing the spread of infectious diseases, encouraging compliance with immunization regulations, and educating persons of all ages to prevent chronic health conditions, unintended pregnancy and addiction. Our clinics treat addiction as well as contributing to healthy health practices and providing well-baby care.

14. In the course of its regulatory duties, DOH receives federal grants and, in some instances, passes along grant funds from HHS to other agencies, among them the New Mexico Aging and Long Term Services Department.

15. DOH policies are tailored to comply with existing requirements of our state laws on religious accommodation which, for instance, prohibit requiring a health facility or health clinic to admit anyone for the purpose of being sterilized. N. M. Stat. Ann. 1978, Sec. 24-8-6 (1973).

16. DOH's understanding is that the Final Rule expands definitions of terms in ways that affect how we can function: Among these are addressing expanded definitions governing the terms "assist in the performance" that would allow clerical and janitorial staff to refuse to participate in activities such as notifying a woman of her appointment time for a family planning consultation.

17. DOH will be forced to expend time, resources and efforts if the Final Rule stands. It will have to modify its hiring practices and train or retrain clinic staff on accommodating religious and moral objections. The stakes are inordinately high for DOH, New Mexico patients and others who serve them, and potentially involve the loss of critical federal funds.

18. In New Mexico, there is a great need for publicly funded family planning services because of the high poverty rate, medically underserved areas and the high rate of unintended pregnancies and teen births. While we never use federal funds for abortion services, we use federal funds for much needed family planning. Accommodating "conscience" objections of a broad spectrum of clinic staff will pose a challenge as we ensure that women and teenage girls who need clinical services and information on avoiding an unplanned pregnancy get the services they need.

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

Executed on this 10th day of June, 2019.



Kathyleen Kunkel
Secretary

New Mexico Department of Health

Exhibit 27

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 LINDA A. LACEWELL

1. I, Linda A. Lacewell, pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:
2. I am the Acting Superintendent of the New York State Department of Financial Services (“DFS”). 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”) 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 DFS 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 Rule in order to understand its immediate impact upon DFS.
3. I began serving as Acting Superintendent on February 4, 2019. Prior to this role, I served in various positions including as Chief of Staff, Chief Risk Officer, and Counselor to New York Governor Andrew Cuomo, and as an Assistant United States Attorney for the Eastern District of New York, including two years on the Enron Task Force. I received my B.A. from New College of the University of South Florida and my J.D. with honors from the University of Miami School of Law. I also serve as an adjunct professor at New York University School of Law, teaching ethics in government, and previously served as an adjunct professor of law at Fordham University School of Law, teaching international criminal law.
4. As Superintendent of DFS, I am charged with protecting the viability of the health insurance markets in New York State. I am also responsible for ensuring that residents

of the State of New York have continued access to comprehensive and affordable health insurance, and that such insurance covers all procedures and treatments required by New York State law.

New York Laws and Regulations Concerning Coverage for Abortion and Contraception

5. Among the laws DFS is tasked with enforcing is the New York Insurance Law (“Insurance Law”), which requires that group health insurance companies provide contraceptive coverage to their enrollees, unless the entity that an enrollee is insured in coverage through (*i.e.*, the enrollee’s employer) requests an exemption and that entity fits a limited statutory definition of a “religious employer.” *See* New York Insurance Law §§ 3221(1)(8) & (1)(16) and §§ 4303(j) & (cc). This mandate includes coverage for emergency contraception (*i.e.*, birth control designed to prevent pregnancy subsequent to sexual intercourse). In addition, New York’s recently enacted Comprehensive Contraception Coverage Act, which will go into effect in January 2020, will require group health insurance companies to cover contraceptive drugs and devices approved by the Food and Drug Administration, as well as voluntary sterilization procedures for women, with no patient cost-sharing. *See id.*, §§ 3221(1)(16) & 4303(cc).
6. DFS is also tasked with enforcing New York State regulations, which require all fully insured policies that provide hospital, surgical, or medical expense coverage to cover medically necessary abortions without copayments, coinsurance, or annual deductibles. *See* 11 N.Y.C.R.R. 52.16(o).
7. A shared purpose of these provisions is to ensure that all New York residents enrolled in group health insurance plans have access to and can afford available, legal methods of

birth control. It is the view of New York State, as reflected in our laws, that our residents are healthier and the state's public health is promoted through such access.

Religious Objections and DFS's Past Enforcement Work on Contraceptive Coverage

8. Through the agency's enforcement of the laws described above, DFS is familiar with the concept of objection to coverage for particular health services based on religious beliefs. One subject of DFS's enforcement work is the review of exemptions that group health insurance companies provide to employers who seek to avoid providing contraception coverage to their employees on the ground that the employer is "religious," as that term is defined in Insurance Law §§ 3221(1)(16)(A)(1) & 4303(cc)(1)(A).
9. Last month, in May 2019, DFS announced the results of investigations and settlements with group health insurance companies that improperly provided exemptions to contraception coverage for employers that were not "religious employers." Together, the insurers covered by the settlements improperly granted exemptions to thirty-three different employers in a broad range of non-religious industries: the employers included a chimney cleaner, a real estate firm, a wood floor refinisher, construction companies, tax consultants, and a publisher. As a result of the improper exemptions, a significant number of New York residents were not provided the mandated coverage for contraception in accordance with the Insurance Law during the two-year period reviewed by DFS. The number of enrollees receiving coverage through these employers, and affected by the exemptions, totaled over 2,400 individuals.
10. These enforcement actions confirmed for DFS that employers who are not "religious" under the Insurance Law – *i.e.*, the inculcation of religious values is not the purpose of the entity, nor does the entity primarily employ or serve persons who share the religious

tenets of the entity – would and did lodge objections, on religious grounds, to New York’s requirement that health insurance cover contraception for enrollees.

The Final Rule and Its Immediate Effect Upon New York State and Its Residents

11. The Final Rule defines “health care entity” to include a “plan sponsor,” for purposes of the Weldon Amendment and Section 1553 of the Patient Protection and Affordable Care Act. *See* 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2). The effect of this inclusion, as our agency understands it, is that any employer who merely purchases or sponsors a group health insurance plan for employees may now object to providing coverage for services – including contraception and medically necessary abortion – on the basis of a religious, moral, or other view. It is DFS’s understanding that the Final Rule permits any plan sponsor in any industry to object and refuse to provide employee coverage on such a ground, whether or not the employer is religious in nature – in conflict with the narrow definition of religious employer under New York law.¹
12. DFS believes it is likely that, upon the effective date of the Final Rule, a significant number of plan sponsors will immediately object to providing coverage for both contraception and medically necessary abortions on religious or moral grounds. This belief is based in part on the investigations and settlements announced last month concerning non-religious plan sponsors’ objections to contraception coverage. Furthermore, in our agency’s experience, objections to contraception coverage are accurate proxies for objections to coverage for abortion, in that plan sponsors objecting to one are likely to object to the other. Indeed, based upon our experience regulating

¹ Throughout this declaration, I use “plan sponsor” interchangeably with an “employer” that purchase a group health insurance policy to cover its employees.

health insurance plans, it is DFS's understanding that some individuals view emergency contraception (*i.e.*, birth control designed to prevent pregnancy subsequent to sexual intercourse) as a form of abortion or equivalent to abortion.

13. As a practical matter, group policies purchased by plan sponsors are not like individual insurance policies – *i.e.*, that run with a calendar year – and instead group policies are renewed fairly evenly at the beginning of each month throughout the year. This means that the Final Rule's effective date will inevitably fall in the middle of some plan sponsors' plan year and before their annual plan year renewal date. In such cases, an employer objecting to existing coverage in its policy would have to seek from its insurer a rider to change the insurer's policy language immediately. Once submitted by the insurer, DFS is obligated to review all riders. *See* Insurance Law § 3201. Such review will place a burden on DFS's already thin staff and require the dedication of limited agency time and resources.
14. Historically, DFS has not approved mid-year contract changes that remove a benefit, as this would amount to an impairment of contract. However, our agency is uncertain as to whether its refusal of a rider sought by a plan sponsor – for example, to eliminate coverage for abortion or contraception, mid-plan year – would run afoul of the Final Rule. The expansive language of the Final Rule's definitions, including "health care entity" and "discriminate," make it difficult to understand its precise application. However, it is DFS's understanding that to refuse a rider sought by a plan sponsor to eliminate such coverage on religious grounds, could qualify as discrimination by DFS and subject New York State to serious consequences, including the potential loss of federal HHS funds.

15. With such a risk in mind, DFS would have to alter its historic policy and permit the approval of riders to eliminate coverage, mid-plan year, if a plan sponsor seeks the removal of the coverage described above on religious grounds. This presents an imminent risk to New York residents. Abortion is a time-sensitive procedure. If DFS is compelled to approve riders eliminating coverage for medically necessary abortions or contraception, because plan sponsors object to such coverage – which DFS believes the Final Rule requires – New York enrollees of those sponsors may be unable to afford a medical procedure that has a limited window of time in which it can be performed or, in the case of emergency contraception, in which it can be effective.
16. As described above, DFS is responsible for enforcing a New York State regulation that requires all fully insured policies that provide hospital, surgical, or medical expense coverage to cover medically necessary abortions. In the likely event that plan sponsors object to providing coverage for abortion, following the effective date of the Final Rule, DFS will be compelled to locate insurers willing to provide coverage for these services for affected employees to purchase. In our agency's experience, this will be difficult if not impossible to achieve. Because the persons likely to purchase such reproductive health coverage in a rider would be those likely to use the benefit, it will be adversely selected and insurers are likely to be unwilling to sell such a rider. Or if an insurer did choose to do so, the rider would be prohibitively expensive for the affected employee.

In this manner, the Final Rule inhibits DFS's ability to enforce the New York State regulation requiring insurance coverage for medically necessary abortions.

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

Executed on this 13 day of June, 2019



Linda A. Lacewell

Acting Superintendent
New York State Department of Financial Services

Exhibit 28

**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 THE PENNSYLVANIA DEPARTMENT OF HEALTH IN
SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION**

Pursuant to 28 U.S.C. § 1746(2), I, Rachel L. Levine, M.D., declare that the following is
true and correct:

1. I am currently the Secretary of Health for the Commonwealth of Pennsylvania in Harrisburg, Pennsylvania, and Professor of Pediatrics and Psychiatry at the Penn State College of Medicine.

2. I am a Fellow of the American Academy of Pediatrics, a Fellow of the Society for Adolescent Health and Medicine and a Fellow of the Academy for Eating Disorders.

3. I joined the Wolf administration in January 2015 as the Physician General of the Commonwealth of Pennsylvania and served from 2015-2017.

4. My previous posts have included: Vice-Chair for Clinical Affairs for the Department of Pediatrics and Chief of the Division of Adolescent Medicine and Eating Disorders at the Penn State Hershey Medical Center.

5. I graduated from Harvard College and the Tulane University School of Medicine. I completed my training in Pediatrics and Adolescent Medicine at the Mt. Sinai Medical Center in New York City.

6. As the Secretary of Health for the Commonwealth, I oversee the Pennsylvania Department of Health (“PADOH”).

7. I submit this Declaration in support of the Commonwealth of Pennsylvania’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,” 84 Fed. Reg. 23,170 (May 21, 2019) (“Final Rule”). I have instructed PADOH personnel to gather the information used in compiling the statements set forth below from our institution. I have also

familiarized myself with the Final Rule in order to understand its immediate impact upon PADOH.

The Pennsylvania Department of Health

8. PADOH works to “promote healthy lifestyles, prevent injury and disease, and to assure the safe delivery of quality health care for all Commonwealth citizens.”¹

9. Among other work, PADOH provides funding through contracts and grants to providers and community-based organizations in order to help Pennsylvania citizens live healthier lives.

10. Some PADOH grantees and contractors further subgrant and subcontract to health care providers and community-based organizations to help PADOH further its purpose.

11. PADOH relies on federal funding to administer its programs and carry out its mission, to educate the citizens of the Commonwealth about healthier lifestyles, to prevent and control the spread of disease, and to monitor health care facilities within the Commonwealth. On average, 60% percent of the money PADOH disperses in contracts and grants comes from HHS.

12. Specifically, PADOH received the following amounts in federal funding from HHS for the following fiscal years:

- (i) \$175,322,003. in federal funding (federal fiscal year 2015)
- (ii) \$174,318,327.08 in federal funding (FFY 2016),
- (iii) \$217, 674,582.42 in federal funding (FFY 2017), and
- (iv) \$147,184,583.00 in federal funding (FFY 2018).

¹ Pa. Dep’t of Health, *About the Department of Health*, <https://www.health.pa.gov/About/Pages/About.aspx> (2019).

13. These funds come from a variety of federal grants issued by HHS and its subcomponents. See attached chart.

14. PADOH distributes the funds outlined in Paragraph 12 to its grantees and contractors to preserve and improve the quality of life for Pennsylvanians. These grantees and contractors include, for example:

- (i) Physicians and physician practices to provide immunizations to eligible children.
- (ii) Hospitals to prepare for disaster emergencies.
- (iii) Community-based organizations to provide a variety of services, including HIV/AIDs and STD counseling and testing, prevention and education relating to chronic diseases, prevention and education relating to cancer, and lead poisoning prevention.
- (iv) Health care providers to provide STD testing and treatment, HIV testing and counseling, and TB diagnosis and treatment.

15. These millions of dollars in federal funds have improved the health outcomes for tens of thousands of individuals and families in Pennsylvania, addressing everything from childhood obesity to HIV treatment, cancer screenings and emergency preparedness to the opioid epidemic.

16. For example, in fiscal year 2017-2018, childhood obesity prevention interventions supported by these federal funds reached over 15,300 children and adolescents across the Commonwealth, increasing their access to nutritional education, physical activity and healthy eating.

17. Additionally, through this federal funding, an average of 10,000 women receive breast and cervical cancer screenings every year, allowing for critical diagnostics and referrals to treatment, and over 75 percent of the 40,000 Pennsylvanians living with diagnosed HIV infection receive lifesaving treatment and care.

18. These dollars also fund essential public health preparedness planning and programming, including enhanced public health surveillance, operational support for public health emergencies such as measles outbreaks or impacts from natural disasters, and the ability to ensure Pennsylvania's healthcare community is prepared to address large scale public health or medical emergencies.

19. Pennsylvania residents who benefit from this funding would be adversely affected, and in many cases face immediate health risks, in the absence of these federally funded programs.

20. PADOH also licenses facilities in Pennsylvania that provide health-related services. These facilities include ambulatory surgical facilities, hospitals, long term care facilities, home health agencies, home care agencies, hospice care, and tanning facilities.

21. Licensed health care facilities are required to comply with federal laws, such as the Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd.

22. Licensed health care facilities are likewise required to comply with Pennsylvania laws and regulations. For example, Pennsylvania law prohibits abandonment of patients. 35 Pa. Cons. Stat. § 8121(a)(4) (emergency medical services providers); 28 Pa. Code § 21.18(b)(7) (registered nurses); 49 Pa. Code § 16.61(a)(17) (physicians); 49 Pa. Code § 21.148(b)(7) (licensed practical nurses), 49 Pa. Code § 27.103(a) (pharmacists). Pennsylvania law also mandates informed consent for certain procedures. 40 Pa. Stat. and Cons. Stat. § 1303.504. In

addition, Pennsylvania regulations require any accommodation of religious and moral beliefs to be balanced against “undue hardship to the conduct of the employer’s business.” 16 Pa. Code § 51.44(b), (c). Pennsylvania regulations further allow hospitals and health care professionals to decline to provide or assist in the provision of abortions and sterilizations—as long as notice is provided in advance and the health and safety of the patient is not endangered. *E.g.*, 43 Pa. Stat. Ann. § 955.2 (hospitals); 16 Pa. Code §§ 51.31–51.33 (hospitals); 43 Pa. Stat. Ann. § 955.2 (individuals); 16 Pa. Code §§ 51.41–51.44 (individuals).

23. PADOH cites facilities for failing to be in substantial compliance with Commonwealth licensing requirements, and, as the certifying agency for the federal Medicare Program, cites facilities that fail to meet federal laws and regulations, including EMTALA.

Impact of the Final Rule on PADOH

24. PADOH understands that the Final Rule expands the definitions of “assist in the performance,” “discrimination,” “health care entity,” and “referral or refer for.” 84 Fed. Reg. at 23,263–64 (45 C.F.R. § 88.2). Although there is a lack of clarity about who and what falls under these terms, PADOH and its grantees, contractors, subgrantees, and subcontractors must prepare to comply with them.

25. PADOH further understands that HHS as asserted the authority to terminate all federal funding from states that are found to be noncompliant with the Final Rule. 84 Fed. Reg. at 23,272 (45 C.F.R. § 88.7(i)(3)). For example, if any of PADOH’s licensed health care facilities complies with the Final Rule in a way that causes a violation of EMTALA or Pennsylvania law, PADOH would issue a citation against that facility. As a result, HHS could attempt to terminate all grant monies provided by HHS to PADOH.

26. Likewise if any of PADOH's grantees, contractors, subgrantees, or subcontractors fails to comply with the Final Rule, HHS could attempt to terminate all grant monies provided HHS to PADOH. 84 Fed. Reg. at 23,270 (45 C.F.R. § 88.6(a)).

27. The termination of millions of dollars in federal funds from PADOH would significantly impact the Pennsylvanians PADOH serves through those funds, which includes its most vulnerable populations.

28. If PADOH were to lose federal funding:

- (i) Funds provided to ensure the Commonwealth's health care facilities meet appropriate licensing standards and remain safe for its citizens would be lost.
- (ii) Funds provided to ensure that diseases such as Ebola, influenza, Lyme Disease, Zika, and other emerging diseases threatening the Commonwealth, tuberculosis, sexually transmitted diseases and Hepatitis A, B and C, and HIV and AIDSs are prevented and appropriately treated would be lost. Dangerous diseases would be permitted to spread and sicken Pennsylvanians.
- (iii) Immunizations provided to those children who cannot easily afford childhood immunizations would be lost, and diseases like measles, polio, pertussis, varicella, meningitis, would spread more easily and potentially harm children and adults throughout the Commonwealth.
- (iv) Funds provided to ensure that the Commonwealth is prepared to face terroristic threats and natural disasters would be lost, and the Commonwealth would be more vulnerable to disasters and emergencies, such as the opioid epidemic.

- (v) Valuable research into education, prevention, screening and intervention activities regarding cancer, tobacco use prevention and cessation, and lead hazards would be ended, harming all age groups of vulnerable Pennsylvanians.
- (vi) The Prescription Drug Monitoring Program—which plays an important role in educating health care practitioners and in helping PADOH and other authorized users monitor the prescribing habits of physicians and the use of controlled substance prescription drugs by the public in order to prevent the improper prescribing and use of opioids and other drugs—would lose significant support, and the opioid crisis could potentially escalate.

29. Even if the populations served by PADOH's grantees, subgrantees, and contractors still receive some medical care, screening prevention and education activities under its programs, the quality of, and access to, that healthcare would be negatively impacted due to decreased information patients receive about their health care options, in addition to delayed access if their current medical provider objects to treating them under the Final Rule.

30. In addition, patients who are LGBTQ, women, or members of other vulnerable groups living in areas with already limited access to health care providers—such as rural areas currently experiencing health professional shortages—are already experiencing challenges from delayed care or no care at all. This will worsen if the medical professional initially treating them objects to treating them under the Final Rule.

31. In a recent study published by the Center for American Progress, nearly one in five LGBTQ people, including 31% of transgender people, said that it would be very difficult or impossible to get the health care they need at another hospital if they were turned away from

settings where they currently receive care.² That rate was substantially higher for LGBTQ people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.

32. For these patients, being turned away by a medical provider is not just an inconvenience; it often means being denied care entirely with nowhere else to go. The following scenarios have occurred and will continue to occur with little or no consequence to the provider but with serious and potentially fatal consequences to the patient:

- (i) Doctors refusing to see transgender patients, even for general medical concerns;
- (ii) Health professionals refusing care to someone living with HIV/AIDS, or refusing prescriptions for pre-exposure prophylaxis;
- (iii) Pediatricians refusing to treat the children of same-gender couples;

² American College of Obstetrics and Gynecologists, Health Disparities in Rural Women (2014), <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Disparities-in-Rural-Women#17>

Institute of Medicine, The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding (2011), <http://www.iom.edu/Reports/2011/The-Health-of-Lesbian-Gay-Bisexual-and-Transgender-People.aspx>

Sandy E. James et al., The Report of the U.S. Transgender Survey 93–126 (2016), www.ustranssurvey.org/report;

Lambda Legal, When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV (2010), <http://www.lambdalegal.org/publications/when-health-care-isnt-caring>;

Shabab Ahmed Mirza & Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care (2016), <https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care>.

- (iv) Emergency Department/Emergency Medical Services workers refusing to transport or provide emergency care to minority patients;
- (v) Medical professionals refusing to acknowledge homophobic rape (i.e., rape perpetrated due to perceived sexual or gender identity);
- (vi) Medical professionals denying care to individuals who have had abortions at any point for any reason, or denying pre- or post- care for terminated pregnancies; and
- (vii) Behavioral health professionals refusing to provide information or counseling.

Conclusion

33. The Final Rule may result in direct financial harm to PADOH, and thus direct financial, physical and mental harm to the Pennsylvanians it serves.

34. The Final Rule will allow for unprecedented discrimination and refusal of services, which undermines the intent and integrity of health and human services programs, and even runs contrary to HHS' own mission. It is unclear how doctors and nurses can adhere to their professional standards and ethics codes while also claiming a religious belief or moral conviction as a basis to not provide health care services. A shift in this direction by HHS will increase mistreatment. It will invite health and human services professionals to ignore existing law and medical standards, and it will go against person-centered approaches and evidence-based practices that have been at the core of social service and public health delivery for decades.

35. For these reasons, I believe that an injunction of the Final Rule is necessary to prevent immediate and irreparable harm in Pennsylvania and around the country.

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

Date: 6/7/19



Rachel L. Levine, M.D.
Secretary of Health
Pennsylvania Department of Health

SAP Grant #	App #	Grant Title	Grantor	Budget Bef	Budget End	Total Award Amt
52951	70-295	CLINICAL LAB IMPROVEMENT AMENDMENT (CLIA)	DHHS-CMS	10/1/2014	9/30/2015	\$ 597,424.00
53101	70-310	MEDICARE SURVEY & CERTIFICATION TITLE XVIII	DHHS-CMS	10/1/2014	9/30/2015	\$ 10,098,460.00
53103	70-310	MEDICARE - TITLE 18 (IMPACT)	DHHS-CMS	10/1/2014	9/30/2015	\$ 702,047.00
53151	70-315	MEDICARE CERTIFICATION TITLE XIX	DHHS-CMS	10/1/2014	9/30/2015	\$ 7,754,464.00
53201	70-317; 70-320	MATERIAL AND CHILD HEALTH SERVICES BLOCK GRANT	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	10/1/2014	9/30/2016	\$ 23,527,801.00
53351	70-335	ABSTINENCE EDUCATION GRANT PROGRAM	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2014	9/30/2016	\$ 1,552,455.00
53531	87-538	MEDICAL ELECTRONIC HEALTH RECORDS INITIATIVE PROG	DHHS-CMS	10/1/2014	9/30/2015	\$ 267,092.00
57761	70-776	PERSONAL RESPONSIBILITY EDUCATION PROGRAM	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2014	9/30/2017	\$ 1,978,932.00
53078	70-307	VIRAL HEPATITIS PREVENTION & SURVEILLANCE	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	11/1/2014	10/31/2015	\$ 180,396.00
53244	70-324	MCHE STATE SYSTEMS DEVELOPMENT INITIATIVE	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	12/1/2014	11/30/2015	\$ 95,374.00
51539	82-155	PHEP SUPPLEMENTAL FOR EBOLA VIRUS DISEASE	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	12/22/2014	6/30/2015	\$ 231,592.00
52941	70-294; 70-298	TB Elimination and Laboratory	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 962,252.00
52991	70-316; 71-015	COMPREHENSIVE HIV PREVENTION PROJECT FOR HLTH DEPT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 6,066,437.00
53041	70-304	IMMUNIZATION AND VACCINES FOR CHILDREN GRANTS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 6,682,221.00
53042	70-304	IMMUNIZATIONS AND VFC GRANTS (PHF)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 641,923.00
53051	70-305	STD AAPPS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 2,133,844.00
53059	70-305	STD AAPPS SUPPLEMENTAL FUNDING	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 82,954.00
53311	70-331	NATIONAL HIV SURVEILLANCE SYSTEM (NHSS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2015	\$ 922,639.00
56851	70-685	PA SEXUAL VIOLENCE PREVENTION AND EDUCATION	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2015	12/31/2016	\$ 1,248,357.00
59861	70-986	STATE INNOVATION MODELS: ROUND TWO OF FUNDING FOR	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	2/1/2015	1/31/2016	\$ 3,000,000.00
53291	70-329	EMSC PARTNERSHIP GRANTS	DHHS-CMS	2/1/2015	5/31/2016	\$ 478,352.00
59521	70-952	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM (BRFS)	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	3/1/2015	2/29/2016	\$ 244,349.00
59522	70-952	BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM (BRFS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/28/2015	3/28/2016	\$ 139,100.00
59532	70-953	TOBACCO CONTROL PROGRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2015	3/28/2016	\$ 133,073.00
53077	70-307	ELC GRANT BUILDING - EBOLA SUPPLEMENTAL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2015	3/28/2016	\$ 106,374.00
51555	82-155	SUPPLEMENTAL FOR EBOLA PREPAREDNESS AND RESPONSE	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/31/2015	3/30/2019	\$ 1,291,458.00
52961	70-296	APPLTREE	DHHS/TOXIC SUBSTANCES AND DISEASE REGISTRY	4/1/2015	4/30/2016	\$ 2,420,962.00
52971	70-297	STATE PRIMARY CARE OFFICES	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2015	3/31/2016	\$ 5,204,900.00
53021	70-323; 71-016	RYAN WHITE CARE ACT TITLE II	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2015	3/31/2016	\$ 478,352.00
53381	70-338	UNIVERSAL NEWBORN HEARING SCREENING & INTERVENTION	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2015	3/31/2016	\$ 39,015,039.00
53243	70-324	PREGNANCY RISK ASSESSMENT MONITORING SYSTEM PRAMS	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2015	3/31/2016	\$ 312,880.00
51556	82-155	HPP EBOLA PREPAREDNESS & RESPONSE ACTIVITIES	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	5/1/2015	4/30/2016	\$ 134,828.00
53312	70-331	MEDICAL MONITORING PROJECT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	5/18/2015	5/17/2020	\$ 10,417,536.00
53341	70-334	TRAUMATIC BRAIN INJURY IMPLEMENTATION	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/1/2015	5/31/2016	\$ 396,625.00
50362	71-086	LIVE HEALTHY PA	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	6/1/2015	5/31/2017	\$ 331,000.00
50365	71-086	LIVE HEALTHY PA	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2015	6/29/2017	\$ 1,288,777.00
55290	70-529	NATIONAL CANCER PREVENTION AND CONTROL PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2015	6/29/2016	\$ 1,623,873.00
55292	70-529	NATIONAL CANCER PREVENTION AND CONTROL PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2015	6/29/2017	\$ 2,547,613.00
51551	82-155	HOSPITAL PREPAREDNESS PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2015	6/29/2016	\$ 1,533,609.00
51552	82-155	PUBLIC HEALTH EMERGENCY PREPAREDNESS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2015	6/30/2016	\$ 8419,895.00
53392	70-339	STATE PBLC HLTH APPROXS TO IMP ARTHRITIS OUTCOMES	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2015	6/30/2016	\$ 19,830,937.00
55293	70-529	WISEWOMAN	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2015	6/30/2016	\$ 367,650.00
53075	70-307	EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2015	6/30/2016	\$ 1,434,255.00
53076	70-307	EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2015	7/31/2016	\$ 797,887.00
53396	70-339	CORE VIOLENCE AND INJURY PREVENTION PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2015	7/31/2016	\$ 1,213,973.00
55281	70-528	NATIONAL ENVIRONMENTAL PUBLIC HEALTH TRACKING PRGM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2015	7/31/2016	\$ 250,000.00
59535	70-953	STATE PUBLIC HLTH APPROXS TO ENS QUILINE CAPACITY	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2015	7/31/2016	\$ 1,061,002.00
50371	71-037	PRESCRIPTION DRUG MONITORING	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2015	10/31/2016	\$ 781,767.00
53245	70-324	SUDDEN UNEXPECTED INFANT DEATH CASE REGISTRY SUID	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2015	8/31/2016	\$ 940,000.00
53393	70-339	COMPREHENSIVE ASTHMA CONTROL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2015	8/31/2016	\$ 113,520.00
53394	70-339	NATIONAL VIOLENT DEATH REPORTING SYSTEM (NVDRS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2015	8/31/2016	\$ 677,327.00
53395	70-339	ORAL HEALTH WORKFORCE	DHHS/Health Resources and Services Administration	9/1/2015	8/31/2016	\$ 337,158.00
57741	70-774	FERN MICROBIOLOGICAL COOPERATIVE AGREEMENT	DHHS/FOOD AND DRUG ADMINISTRATION	9/1/2015	8/31/2016	\$ 488,680.00

Total PPTIS DHHS Funding Awarded to PA Health \$ 175,322,003.00

SAP Grant #	App #	Grant Title	Grantor	Budget Beg	Budget End	Total Award Amt
62951	70-295	CLINICAL LAB IMPROVEMENT AMENDMENT (CLIA)	DHHS-CMS	10/1/2015	9/30/2016	\$ 551,422.00
63101	70-310	MEDICARE - HOSPICE SURVEYS	DHHS-CMS	10/1/2015	9/30/2016	\$ 237,587.00
63101	70-310	MEDICARE SURVEY & CERTIFICATION TITLE 18	DHHS-CMS	10/1/2015	9/30/2016	\$ 12,952,476.00
63151	70-315	MEDICARE CERTIFICATION TITLE XX	DHHS-CMS	10/1/2015	9/30/2016	\$ 8,919,987.00
63181	70-300; 70-318	PREVENTIVE HEALTH & HEALTH SERVICES BLOCK GRANT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	10/1/2015	9/30/2017	\$ 7,390,984.00
63201	70-317; 70-320	MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	10/1/2015	9/30/2017	\$ 23,491,258.00
63351	70-335	ABSTINENCE EDUCATION GRANT PROGRAM	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2015	9/30/2017	\$ 2,316,829.00
67761	70-776	PERSONAL RESPONSIBILITY EDUCATION PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	10/1/2015	9/30/2018	\$ 1,983,697.00
68073	70-807	VIRAL HEPATITIS PREVENTION & SURVEILLANCE	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	11/1/2015	10/31/2016	\$ 225,941.00
69244	70-324	MICH STATE SYSTEMS DEVELOPMENT INITIATIVE	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	12/1/2015	11/30/2016	\$ 98,305.00
60151	70-316; 71-015	COMPREHENSIVE HIV PREVENTION PROJECT FOR HLTH DEPT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2016	12/31/2017	\$ 10,275,158.00
62941	70-294; 70-298	To Eliminate end Laboratory	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2016	12/31/2016	\$ 1,132,297.00
63041	70-304	IMMUNIZATION AND VACCINES FOR CHILDREN GRANTS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2016	3/31/2017	\$ 5,967,290.00
63051	70-305	STD APPS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2016	12/31/2016	\$ 2,195,388.00
63311	70-331	NATIONAL HIV SURVEILLANCE SYSTEM (NHSS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2016	12/31/2016	\$ 999,299.00
66851	70-685	PA SEXUAL VIOLENCE PREVENTION AND EDUCATION	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	2/1/2016	1/31/2017	\$ 1,982,886.00
63291	70-329	EMSC PARTNERSHIP GRANTS	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	3/1/2016	2/28/2017	\$ 140,264.00
69521	70-952	BRFS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2016	3/28/2017	\$ 299,686.00
69592	70-953	TOBACCO CONTROL PROGRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2016	3/28/2017	\$ 1,178,614.00
60161	70-323; 71-016	RWAN WHITE CARE ACT TITLE II	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2016	3/31/2017	\$ 34,066,309.08
62961	70-296	APPLETREE	DHHS/TOXIC SUBSTANCES AND DISEASE REGISTRY	4/1/2016	3/31/2017	\$ 526,794.00
62971	70-297	STATE PRIMARY CARE OFFICES	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2016	3/31/2017	\$ 232,260.00
63381	70-338	UNIVERSAL NEWBORN HEARING SCREENING & INTERVENTION	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2016	3/31/2017	\$ 254,576.00
63243	70-324	PREGNANCY RISK ASSESSMENT MONITORING SYSTEM PRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	5/1/2016	4/30/2017	\$ 175,000.00
63342	70-331	MEDICAL MONITORING PROJECT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/1/2016	5/31/2017	\$ 489,039.00
63341	70-334	TRAUMATIC BRAIN INJURY IMPLEMENTATION	DHHS-ACL	6/1/2016	5/31/2017	\$ 250,000.00
60863	71-036	LIVE HEALTHY PA	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2016	6/29/2017	\$ 932,370.00
60365	71-036	LIVE HEALTHY PA	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2016	6/29/2017	\$ 1,983,281.00
65292	70-529	NATIONAL CANCER PREVENTION AND CONTROL PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2016	6/29/2017	\$ 4,103,979.00
61551	82-155	HOSPITAL PREPAREDNESS PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2016	6/30/2018	\$ 8,193,982.00
61552	82-155	PUBLIC HEALTH EMERGENCY PREPAREDNESS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2016	6/30/2018	\$ 500,572.00
61557	82-155	PHPR ALL-HAZARDS PH EMERGENCIES - ZIKA 2016	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2016	6/30/2018	\$ 1,716,179.00
61558	82-155	PHEP - REPLENISHMENT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2016	6/30/2018	\$ 716,856.00
63392	70-339	STATE PBLG HLTH APPROCHS TO IMP ARTHRITIS OUTCOMES	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2016	9/29/2018	\$ 2,919,381.00
65293	70-529	WISEWOMAN	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2016	9/29/2018	\$ 840,000.00
63072	70-307	BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES-PREV	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2016	7/31/2019	\$ 525,402.00
63075	70-307	EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2016	7/31/2018	\$ 893,588.00
63076	70-307	EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2016	7/31/2018	\$ 751,668.00
65281	70-528	NATIONAL ENVIRONMENTAL PUBLIC HEALTH TRACKING PRGM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2016	7/31/2017	\$ 2,522,112.00
69535	70-953	STATE PUBLIC HLTH APPROCHS TO ENS QUITLINE CAPACITY	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2016	10/31/2017	\$ 490,000.00
60371	71-037	PRESCRIPTION DRUG MONITORING	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2016	8/31/2017	\$ 147,755.00
60373	71-037	SURVEILLANCE OF OPIOID-INVOLVED MORBIDITY-MORTALIT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2016	8/31/2017	\$ 677,327.00
63245	70-324	SUDDEN UNEXPECTED INFANT DEATH CASE REGISTRY SUID	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2016	8/31/2017	\$ 355,100.00
63393	70-339	COMPREHENSIVE ASTHMA CONTROL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2016	8/31/2017	\$ 721,092.00
63394	70-339	NATIONAL VIOLENT DEATH REPORTING SYSTEM (NVDRS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2016	8/31/2017	\$ 175,036.00
63395	70-339	ORAL HEALTH WORKFORCE	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	9/1/2016	8/31/2018	\$ 175,036.00
67741	70-774	FERN MICROBIOLOGICAL COOPERATIVE AGREEMENT	DHHS/FOOD AND DRUG ADMINISTRATION	9/30/2016	8/31/2017	\$ 174,318,327.08

Total FFY16 DHHS Funding Awarded to PA Health \$ 174,318,327.08

Grant Title	Grantor	Budget Beg	Budget End	Total Award Amt
CLINICAL LAB IMPROVEMENT AMENDMENT (CLIA)	DHHS-CMS	10/1/2016	9/30/2017	\$ 625,222.00
MEDICARE SURVEY & CERTIFICATION TITLE 18	DHHS-CMS	10/1/2016	9/30/2017	\$ 11,056,124.00
MEDICARE - HOSPICE SURVEYS	DHHS-CMS	10/1/2016	9/30/2017	\$ 145,814.00
MEDICAID CERTIFICATION TITLE XIX	DHHS-CMS	10/1/2016	9/30/2017	\$ 8,954,089.00
PREVENTIVE HEALTH & HEALTH SERVICES BLOCK GRANT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	10/1/2016	9/30/2018	\$ 7,433,418.00
MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	10/1/2016	9/30/2018	\$ 23,480,555.00
ABSTINENCE EDUCATION GRANT PROGRAM	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2016	9/30/2018	\$ 2,215,568.00
PERSONAL RESPONSIBILITY EDUCATION PROGRAM	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2016	9/30/2019	\$ 1,819,324.00
IMPROVING HEPATITIS B AND C CARE CASCADES	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	11/1/2016	10/31/2017	\$ 132,838.00
MCHB STATE SYSTEMS DEVELOPMENT INITIATIVE	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	12/1/2016	11/30/2017	\$ 111,127.00
PREGNANCY RISK ASSESSMENT MONITORING SYSTEM PRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	12/30/2016	4/30/2017	\$ 6,392.00
TB Elimination and Laboratory	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2017	12/31/2017	\$ 1,162,205.00
STD AAPPs	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2017	12/31/2017	\$ 2,209,521.00
ELC GRANT BUILDING - ZIKA SUPPLEMENTAL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2017	7/31/2019	\$ 980,801.00
NATIONAL HIV SURVEILLANCE SYSTEM (NHSS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2017	12/31/2017	\$ 909,645.00
PA SEXUAL VIOLENCE PREVENTION AND EDUCATION	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	2/1/2017	1/31/2018	\$ 1,160,477.00
EMSC PARTNERSHIP GRANTS	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	3/1/2017	3/31/2018	\$ 183,323.00
BRESS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2017	3/28/2018	\$ 197,166.00
BRESS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2017	3/28/2018	\$ 92,445.00
TORABACCO CONTROL PROGRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2017	3/28/2018	\$ 1,354,913.00
RYAN WHITE CARE ACT TITLE II	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2017	3/31/2018	\$ 58,341,857.00
APPLETREE	DHHS/TOXIC SUBSTANCES AND DISEASE REGISTRY	4/1/2017	3/31/2018	\$ 480,284.00
STATE PRIMARY CARE OFFICES	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2017	3/31/2018	\$ 336,596.00
IMMUNIZATIONS AND VACCINE FOR CHILDREN GRANTS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	4/1/2017	6/30/2019	\$ 20,322,935.00
IMMUNIZATIONS AND VFC GRANTS (PPHF)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	4/1/2017	6/30/2018	\$ 11,653,091.00
UNIVERSAL NEWBORN HEARING SCREENING & INTERVENTION	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2017	3/31/2018	\$ 250,000.00
NATIONAL DEATH INDEX	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	4/16/2017	4/15/2018	\$ 1,184,533.00
PENNSYLVANIA'S RURAL HEALTH MODEL	DHHS-CMS	4/21/2017	4/20/2019	\$ 10,000,000.00
PREGNANCY RISK ASSESSMENT MONITORING SYSTEM PRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	5/1/2017	4/30/2018	\$ 331,510.00
PREGNANCY RISK ASSESSMENT MONITORING SYSTEM PRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	5/1/2017	4/30/2018	\$ 29,830.00
MEDICAL MONITORING PROJECT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/1/2017	5/31/2018	\$ 412,980.00
TRAUMATIC BRAIN INJURY STATE IMPLEMENTATION	DHHS-ACL	6/1/2017	5/31/2018	\$ 250,000.00
LIVE HEALTHY PA (PPHF)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2017	9/29/2018	\$ 2,106,077.00
NATIONAL CANCER PREVENTION AND CONTROL PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2017	6/29/2018	\$ 1,363,228.00
HOSPITAL PREPAREDNESS PROGRAM (HPP)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2017	6/29/2018	\$ 3,700,763.00
PUBLIC HEALTH EMERGENCY PREPAREDNESS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2017	6/30/2019	\$ 8,093,898.00
SUPPORT, EMPOWER, LEARN, PARENTING HEALTH (SELPHI)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2017	6/30/2019	\$ 18,929,172.00
Early Hearing Detection & Intervention-IS	DHHS/PUBLIC HEALTH SERVICE	7/1/2017	6/30/2018	\$ 811,152.42
EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	7/1/2017	6/30/2018	\$ 150,000.00
EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2017	7/31/2018	\$ 718,027.00
STATE PUBLIC HLTH APPROCHS TO ENS QUITLINE CAPACITY	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2017	7/31/2018	\$ 3,641,865.00
PRESCRIPTION DRUG MONITORING	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2017	7/31/2019	\$ 1,503,398.00
SURVEILLANCE OF OPIOID-INVOLVED MORBIDITY-MORTALIT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2017	8/31/2018	\$ 4,107,622.00
PA RETAIL MEAT PRGM - COLLABORATION WITH FDA NARMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2017	8/31/2018	\$ 942,651.00
SUDDEN UNEXPECTED INFANT DEATH CASE REGISTRY SUID	DHHS/FOOD AND DRUG ADMINISTRATION	9/1/2017	8/31/2018	\$ 130,000.00
COMPREHENSIVE ASTHMA CONTROL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2017	8/31/2019	\$ 113,520.00
NATIONAL VIOLENT DEATH REPORTING SYSTEM (NVDRS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2017	8/31/2018	\$ 677,327.00
FERN MICROBIOLOGICAL COOPERATIVE AGREEMENT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2017	8/31/2018	\$ 355,100.00
Childhood Lead Poisoning Prevention Program	DHHS/FOOD AND DRUG ADMINISTRATION	9/1/2017	8/31/2018	\$ 214,000.00
FDA - TOBACCO RETAIL INSPECTIONS CONTRACT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2017	9/29/2018	\$ 316,429.00
	DHHS/FOOD AND DRUG ADMINISTRATION	9/30/2017	9/29/2018	\$ 1,975,860.00

Total FFY17 DHHS Funding Awarded to PA Health \$ 217,674,582.42

SAP Grant #	App #	Grant Title	Grantor	Budget Beg	Budget End	Total Award Amt
82951	70-295	CLINICAL LAB IMPROVEMENT AMENDMENT (CLIA)	DHHS-CMS	10/1/2017	9/30/2018	\$ 630,241.00
85101	70-310	MEDICARE SURVEY & CERTIFICATION TITLE 18	DHHS-CMS	10/1/2017	9/30/2018	\$ 10,601,209.00
83103	70-310	MEDICARE - HOSPICE SURVEYS	DHHS-CMS	10/1/2017	9/30/2018	\$ 162,143.00
83104	70-310	MEDICARE - HOSPICE SURVEYS	DHHS-CMS	10/1/2017	9/30/2018	\$ 104,595.00
83109	70-310	MEDICARE SURVEY & CERTIFICATION TITLE 18	DHHS-CMS	10/1/2017	9/30/2018	\$ 103,901.00
83151	70-315	MEDICAID CERTIFICATION TITLE XIX	DHHS-CMS	10/1/2017	9/30/2018	\$ 8,359,742.00
83181	70-300; 70-318	PREVENTIVE HEALTH & HEALTH SERVICES BLOCK GRANT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	10/1/2017	9/30/2019	\$ 8,028,754.00
83201	70-317; 70-320	MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2017	9/30/2019	\$ 23,748,778.00
83351	70-335	STATE SEXUAL RISK AVOIDANCE EDUCATION	DHHS/ADMINISTRATION FOR CHILDREN AND FAMILIES	10/1/2017	9/30/2019	\$ 2,047,439.00
87761	70-776	PERSONAL RESPONSIBILITY EDUCATION PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	11/1/2017	10/31/2018	\$ 1,952,047.00
83073	70-323, 71-016	IMPROVING HEPATITIS B AND C CARE CASCADES	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	11/1/2017	10/31/2018	\$ 182,599.00
83244	70-324	MCBR STATE SYSTEMS DEVELOPMENT INITIATIVE (SSDI)	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	12/1/2017	11/30/2018	\$ 100,000.00
79331	70-313	VITAL STATISTICS COOPERATIVE PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2018	12/31/2018	\$ 1,510,368.00
80151	70-316; 71-015	HIV SURVEILLANCE AND HIV PREVENTION PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2018	12/31/2018	\$ 6,929,484.00
82941	70-294; 70-298	TB Elimination and Laboratory	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2018	12/31/2018	\$ 1,079,316.00
83051	70-305	STD AAPS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	1/1/2018	12/31/2018	\$ 2,241,496.00
86851	70-685	PA SEXUAL VIOLENCE PREVENTION AND EDUCATION	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	2/1/2018	1/31/2019	\$ 1,393,715.00
18151	70-952	BRSS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2018	3/28/2019	\$ 456,500.00
89532	70-953	TOBACCO CONTROL PROGRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	3/29/2018	3/28/2019	\$ 1,290,286.00
80161	70-323, 71-016	RYAN WHITE CARE ACT TITLE II	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2018	3/31/2019	\$ 49,720,356.00
82961	70-296	APPLETREE	DHHS/TOXIC SUBSTANCES AND DISEASE REGISTRY	4/1/2018	3/31/2019	\$ 480,284.00
82971	70-297	STATE PRIMARY CARE OFFICES	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2018	3/31/2019	\$ 424,236.00
83291	70-329	EMSC PARTNERSHIP GRANTS	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2018	3/31/2019	\$ 252,687.00
83381	70-338	UNIVERSAL NEWBORN HEARING SCREENING & INTERVENTION	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	4/1/2018	3/31/2019	\$ 265,000.00
83134	70-313	NATIONAL DEATH INDEX	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	4/16/2018	4/15/2019	\$ 236,655.00
83243	70-324	PREGNANCY RISK ASSESSMENT MONITORING SYSTEM PRAMS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	5/1/2018	4/30/2019	\$ 157,500.00
83312	70-331	MEDICAL MONITORING PROJECT	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/1/2018	5/31/2019	\$ 402,892.00
83341	70-334	TBI STATE PARTNERSHIP PROGRAM MENTOR STATE FUNDING	DHHS/Administration for Community Living	6/1/2018	5/31/2019	\$ 300,000.00
83135	70-313	40 YRS DEATH RECORDS	DHHS/SOCIAL SECURITY ADMINISTRATION	6/19/2018	12/31/2018	\$ 14,100.00
83132	70-313	SSA DEATH RECORDS	DHHS/SOCIAL SECURITY ADMINISTRATION	6/29/2018	6/28/2023	\$ 304,000.00
85292	70-529	NATIONAL CANCER PREVENTION AND CONTROL PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	6/30/2018	6/29/2019	\$ 3,954,923.00
83247	70-324	SUPPORT, EMPOWER, LEARN, PARENTING HEALTH (SELPHI)	DHHS/PUBLIC HEALTH SERVICE	7/1/2018	6/30/2019	\$ 766,806.00
83076	70-307	EPIDEMIOLOGY, LABORATORY CAPACITY (ELC) GRANT BUIL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	8/1/2018	7/31/2019	\$ 3,878,432.00
80871	71-037	PRESCRIPTION DRUG MONITORING	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 1,940,000.00
80373	71-037	SURVEILLANCE OF OPIOID-INVOLVED MORBIDITY-MORTALITY	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 686,000.00
80851	71-085	GRANTS TO STATES FOR LOAN REPAYMENT	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	9/1/2018	8/31/2019	\$ 500,000.00
81555	82-155	PUBLIC HEALTH CRISIS RESPONSE - NCIPC	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 4,808,530.00
81556	82-155	PUBLIC HEALTH CRISIS RESPONSE - CEELS	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 197,857.00
81557	82-155	PUBLIC HEALTH CRISIS RESPONSE - NCHHSTP	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 129,099.00
83309	70-339	PA RETAIL MEAT PRGM - COLLABORATION WITH FDA NARMS	DHHS/FOOD AND DRUG ADMINISTRATION	9/1/2018	8/31/2019	\$ 344,793.00
83383	70-339	COMPREHENSIVE ASTHMA CONTROL	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 710,686.00
83394	70-339	NATIONAL VIOLENT DEATH REPORTING SYSTEM (NVDRS)	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 468,690.00
83395	70-339	ORAL HEALTH WORKFORCE	DHHS/HEALTH RESOURCES AND SERVICES ADMINISTRATION	9/1/2018	8/31/2019	\$ 400,000.00
83396	70-339	STATE ACTIONS TO IMPROVE ORAL HEALTH OUTCOMES	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/1/2018	8/31/2019	\$ 370,000.00
87741	70-774	FERN MICROBIOLOGICAL COOPERATIVE AGREEMENT	DHHS/FOOD AND DRUG ADMINISTRATION	9/1/2018	8/31/2019	\$ 214,000.00
18130	71-036	DIABETES AND HEART DISEASE PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2018	6/29/2019	\$ 1,917,642.00
18135	71-036	PA STATE PHYSICAL ACTIVITY AND NUTRITION PROGRAM	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2018	9/29/2019	\$ 923,000.00
82931	70-293; 70-314	Childhood Lead Poisoning Prevention Program	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2018	9/29/2019	\$ 600,735.00
83245	70-324	Sudden Unexpected Infant Death (SUID) and Sudden	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2018	9/29/2019	\$ 207,000.00
83246	70-324	PRAMS Supplemental Opioid and Disability Research	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2018	4/30/2019	\$ 36,177.00
85293	70-529	WISEWOMAN	DHHS/CENTERS FOR DISEASE CONTROL AND PREVENTION	9/30/2018	9/29/2019	\$ 870,000.00

Total FFY18 DHHS Funding Awarded to PA Health \$ 147,184,583.00

Exhibit 29

**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 HAWAII,
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 MICHAEL LUCCHESI, M.D.

1. I, Michael Lucchesi, M.D., pursuant to 28 U.S.C. § 1746, hereby declare that the following is true and correct:

2. I am the Interim Dean of the College of Medicine and Chairman of Emergency Medicine at the Downstate Medical Center of the State University of New York (“SUNY Downstate” or “Downstate”) located in Brooklyn, New York. 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”) 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 Downstate personnel who have assisted me in gathering this information from our institution, 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 SUNY Downstate.

3. I was named Officer-in-Charge of SUNY Downstate Medical Center on July 15, 2016, after nearly three decades of service at SUNY Downstate. I was appointed Chair of the Department of Emergency Medicine in 1998, after previously serving as Acting Chair, and am also the Chief Medical Officer of Downstate’s University Hospital of Brooklyn. I graduated *magna cum laude* from Boston College with a B.S. in 1979 and earned my medical degree in 1983 from the Universidad del Noreste (Northeastern University) in Tampico, Mexico, and my Fifth Pathway certificate from New York Medical College. I pursued my internship and residency in Internal Medicine at SUNY Downstate and its affiliated Kings County Hospital Center from 1985 to 1988, after which I completed a second residency in Emergency Medicine at Lincoln Hospital in the Bronx. I worked for several years as an attending physician in the Emergency Department of Robert Wood

Johnson University Hospital in New Jersey and then returned to Kings County as an attending physician in 1994. I served as the first Residency Program Director in the Department of Emergency Medicine at SUNY Downstate until I was appointed Chair of the Department in 1997. I am board certified in both Internal Medicine and Emergency Medicine and a fellow of the American College of Emergency Physicians.

4. SUNY is the largest comprehensive university system in the United States, comprised of 64 institutions, including research universities and academic medical centers. SUNY educates approximately 550,000 students in more than 7,500 credit bearing programs and another 850,000 through continuing education and community outreach programs. SUNY employs more than 90,000 faculty and staff and has over 3 million alumni worldwide. Each year SUNY students and faculty across the state make significant contributions to research in the field of medicine, among others.

5. SUNY Downstate, which is part of the SUNY system, is comprised of a University Hospital, College of Medicine, a School of Graduate Studies, a College of Health -Related Professions, a College of Nursing and a School of Public Health. The University Hospital and College of Medicine have a staff of over 800 physicians, representing 53 specialties and subspecialties. The full-service hospital consists of numerous departments, including emergency medicine, surgery, infectious diseases, nephrology, radiology, ophthalmology, pediatrics, and organ transplants. Among the many medical treatments provided to the public, the hospital offers vaccinations, induced abortions, and end-of-life care in the hospital's intensive care unit, including at times, the removal of life support to terminally ill patients. For calendar year 2018, the hospital served our patient communities by providing nearly 12,000 inpatient visits and over 240,000 outpatient visits in addition to over 62,000 patient visits to Downstate's emergency room.

6. The Downstate Medical College, founded 150 years ago, was the first medical school in the country located within a hospital. Today Downstate's medical college is a critical source of doctors for New York State and the New York metropolitan area. Indeed, more physicians practicing in New York City graduate from Downstate than from any other medical school in America.

7. Each year, Downstate receives approximately \$100 million in Medicare funds and \$50 million in research funds from multiple sources, including approximately \$26 million from HHS. The research funds support salaries and equipment for researchers engaged in various research projects in a wide range of medical areas and topics, such as alcoholism, HIV/AIDS, health disparities, genomics, diabetes, and cancer.

Existing Downstate policy to address religious objections

8. The SUNY Downstate community reflects a very diverse population. Its patients, staff, employees and students are comprised of individuals of many racial and ethnic backgrounds who come from a wide range of national origins; they represent all genders, from gender conforming men and women to the full spectrum of the Lesbian, Gay, Bisexual, Transgender and Queer ("LGBTQ") community, and, as individuals, they hold diverse religious, moral, and ethical beliefs. SUNY Downstate is committed to providing outstanding patient care and medical education, while recognizing and accommodating the religious, moral, and ethical beliefs of those who work and train at our institution.

9. Downstate maintains a policy expressly stating that employees have the right not to participate in the treatment of a patient where that treatment presents a conflict with sincerely held cultural values or ethical or religious beliefs. In order to achieve an appropriate balance between the provision of patient care and the beliefs of those who provide such care, Downstate's policy requires an employee to notify Downstate in writing of such objection, in advance of the actual needed

provision of such patient care. Pursuant to the policy, it is an employee's responsibility to notify the institution of any conflict between the specific job duties/assignment and his/her cultural values, ethical, or religious beliefs. If an employee determines that aspects of his/her job responsibilities "conflict with cultural values, ethical holdings or religious beliefs, the employee must submit those concerns in writing to the immediate supervisor." This written notification must include the "specific aspect of care at issue, the basis for the cultural, ethical or religious concern, and the date and time of the original conflict."

10. Downstate's requirement of advance notice of an employee's objection exists for several reasons. First, it assists management at Downstate in having reasoned discussions with an employee concerning the nature and scope of his/her religious objection, in order to properly accommodate the individual before a patient in need of care becomes involved. For example, advance notice allows management personnel to consider whether an employee with an objection to assisting in the performance of abortions should be staffed in the hospital's Obstetrics and Gynecology department, as opposed to another department where the employee is less likely to be confronted with procedures (s)he finds objectionable. Similarly, advance discussion of an employee's religious objection permits Downstate to understand the complete range of procedures that an employee finds objectionable. For example, while the prevailing medical understanding is that medical treatment to address an ectopic pregnancy does not constitute an "abortion" – and is necessary to protect the health or save the life of a woman – some individuals disagree with this prevailing understanding and believe such treatment amounts to the termination of a pregnancy. The scope of an individual's religious objection, fully developed through advance notice and subsequent discussion with Downstate personnel, allows our institution meaningfully to accommodate an employee's religious beliefs.

11. Second, advance notice of an employee's religious objection allows Downstate to make appropriate staffing decisions that take into account such accommodation and the manner in which it could affect patient care. This is particularly important in settings, like emergency room overnight shifts, where the hospital's staffing relies on a team effort, under exigent circumstances, in which patient care could be compromised by the unexpected unavailability of a single employee. In such settings, Downstate has a duty to the communities we serve to ensure that there is no sudden disruption to the provision of medical care that could endanger the lives or safety of patients who come through our doors. Avoiding disruptions in patient care is also a fundamental duty of our institution as a matter of medical ethics.

12. Third, Downstate's policy requiring advance notice of a religious objection is consistent, and seeks to comply, with existing New York State law. For example, New York Civil Rights Law 79-I prohibits discrimination against a person who refuses to perform or assist in performing an abortion, where such person has filed a prior written refusal setting forth the reasons for the refusal. Downstate's policy also seeks to comply with New York State Education Law § 6530(30), which defines professional misconduct to include "abandoning a professional employment by a . . . hospital . . . without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients."

Immediate impact of the Final Rule upon SUNY Downstate and New York

13. The Final Rule has an immediate and damaging impact upon Downstate and the health of the communities it serves in Brooklyn. The management of Downstate – including veteran doctors, ethicists, and hospital lawyers – has struggled to interpret a Final Rule that appears vague and conflicting in parts. Nevertheless, because Downstate is required to comply with the Final Rule, our management has grappled with and reached an understanding that the Final Rule

limits the type of advance notice an employer can seek concerning the religious or moral objections of employees.

14. Specifically, it is Downstate's understanding that it may not inquire, prior to hiring an applicant, if a religious or moral objection would prevent the applicant from performing core duties or responsibilities of the position sought. Once an employee is hired, it is Downstate's understanding that the Final Rule permits an employer to inquire about employees' religious objections no more frequently than once per calendar year—despite the possibility that an employee's religious or moral views could change within a year and affect their willingness to perform certain procedures.

15. It is our management's further understanding that, consistent with the Final Rule, an employee is now free to refuse to provide care to a patient based on a religious or moral objection—even if the employee provides no advance notice of objection and instead objects at the moment care is being sought by a patient, possibly in distress. In such a situation, it is Downstate's understanding that the Final Rule does not permit our hospital to discipline, terminate, or take any adverse action against that employee.

16. It is also Downstate's understanding that any steps we take to use alternate staff to provide any objected-to medical services are impermissible if those steps exclude the objecting employee from a "field of practice" or require "any" additional action by that person. It is our further understanding that any accommodation offered to an objecting employee must be voluntarily accepted by the employee. And in the event an objecting employee rejects an offered accommodation, it is Downstate's understanding that the Final Rule does not permit the hospital to move the employee or replace him/her with another qualified employee no matter how reasonable the offered accommodation. These provisions of the Final Rule wreak havoc upon

Downstate's ability to plan and staff to provide patient care – which in turn harms the public health of communities we serve – in several scenarios.

17. *Emergency care.* As a result of the Final Rule, and the risk that any employee may now refuse to provide patient care without advance notice to the hospital, Downstate must create contingency staffing plans to ensure that more than one of each necessary professional is available at all times in its emergency room. The scenario set forth below, a common occurrence in Downstate's emergency room, illustrates the costs and difficulty of ensuring uninterrupted emergency care for patients when any employee can refuse to participate in care without notice.

18. SUNY Downstate is located in an underserved community in which many of our patients use our emergency room in lieu of a primary care physician. Downstate's patient population presents with such a high rate of obstetrical emergencies, including ectopic pregnancies, that a second Obstetrics/Gynecology attending physician is assigned for overnight shifts. Staff in our emergency room regularly encounter women complaining of lower abdominal pain and vaginal bleeding, who are then diagnosed with an ectopic pregnancy. Downstate's emergency room has a high incidence of such ectopic pregnancies – a significantly higher incidence, in my experience, than hospitals serving other communities – and it is a common occurrence for an attending physician to conduct surgery on a woman who enters our emergency room with an ectopic pregnancy.

19. Given budgetary constraints, Downstate does not have extra staff to perform essential functions required for emergency patient care in the event of an ectopic pregnancy. On a given day or night, there is typically one of each type of staff member needed to provide patient care in our emergency room. A woman who arrives at our emergency room with an ectopic pregnancy will encounter between twelve to sixteen staff members in her course of treatment.

20. These staffers include: (i) a triage nurse to make initial patient inquiries and take vital signs; (ii) a clerk to check ID, insurance, and existing hospital records for the patient; (iii) a physician's assistant, nurse practitioner, or medical resident; (iv) an attending physician for the emergency room, who simultaneously covers the pediatric emergency room; (v) a nurse's aide or transport aide who transports the patient; (vi) a circulating nurse who inserts IVs (intravenous therapy access lines), administers medication, and takes blood and urine samples for pregnancy and other tests; (vii) an ultrasound technician to conduct an ultrasound, if a pregnancy test is positive; (viii) a radiologist to interpret the results of an ultrasound; (ix) a lab technician to interpret results of blood tests; and, in the event surgery is required, an operating room team consisting of the attending physician, circulating nurse, and (x) an anesthesiologist; (xi) a scrub nurse in sterilized gear; (xii) operating room supervisor; and (xiii) an operating room technician. Following surgery a patient receives care from a (xiv) recovery room nurse, (xv) mid-level providers and a physician in the recovery room, and (xvi) clerks and other ancillary recovery room staff (*e.g.*, housekeeping/food services staff). Furthermore, in the extremis situation of a ruptured ectopic pregnancy, at least seven different Downstate medical staff members will be providing care to a patient simultaneously.

21. Each of the staffers listed above plays a critical role in an emergency situation, and as we understand the Final Rule's definitions, would have "assisted in the performance" of the emergency medical treatment necessary to address the ectopic pregnancy. Following issuance of the Final Rule, Downstate must prepare for the possibility that any one of these critical staffers could object on religious or moral grounds – without advance notice to Downstate – to assisting in the provision of care to a woman with an ectopic pregnancy. It is the understanding of Downstate's management that, despite whatever notice provisions we seek to impose upon

religious objections by our employees consistent with the Final Rule, our employees still retain the right under the Final Rule to make objection in real time, without sanction or subsequent discipline from Downstate.

22. Given the literally life-or-death nature of providing emergency care, Downstate is actively in discussions about how to staff the emergency room (*e.g.*, double-staffing each essential function) to avoid any staffer abruptly objecting, refusing to provide care, and risking patient care at Downstate. These discussions must now also address the scenario, discussed above, of an emergency room staffer who does provide advance notice of an objection but refuses to accept a reasonable accommodation to be moved from our emergency room, because the functional result is the same: the hospital has one less essential employee to perform a core function required daily in our ER. Such additional staffing is costly, and it is not clear Downstate can feasibly achieve this goal and realistically avoid harm to patient care without jeopardizing or compromising other areas of its operations. In the absence of additional funds from HHS or other sources, Downstate must now evaluate what other essential functions at the hospital could be cut in order to fund additional emergency room staffing.

23. ***End of life care.*** Downstate must also prepare for the possibility that hospital staff may voice religious or moral objections to providing care – without notice – in end of life care settings. Religious or moral objections already occur within Downstate’s intensive care unit and emergency room concerning the removal of life-sustaining treatments, such as extubating a terminally ill patient. For example, prior to the Final Rule’s issuance, and under the notice regime Downstate has had in place for years, some attending physicians within the hospital’s intensive care unit and emergency room provided advance notice to the hospital that they objected to the removal of life-sustaining treatment for religious reasons. Downstate has successfully planned

and staffed its intensive care unit and emergency room to accommodate these doctors and their religious beliefs, while ensuring patient care and avoiding collateral harms to the patient's representatives and loved ones who are present for the removal of life support.

24. Following issuance of the Final Rule, it is the understanding of Downstate's management that, despite whatever notice provisions we seek to impose upon religious objections by our employees consistent with the Final Rule, our employees still retain the right under the Final Rule to make objection in real time, without sanction or subsequent discipline from Downstate. Again, Downstate faces an untenable choice. The hospital must either incur the expense of double-staffing functions within its intensive care unit and emergency room to avoid interruptions to end of life care, or else risk harm to a patient or his/her loved ones if an employee objects to assisting in the removal of life support close to or at the time the procedure is set to occur. An attending physician, nurse, or resident who objects to the removal of life support – when Downstate lacks notice and has not staffed for a replacement – risks extending the life of a patient whose representatives have made the arduous decision to remove life-sustaining treatment. Such an objection also risks inflicting irreparable emotional and dignitary harms upon loved ones who may be present for a scheduled end of life procedure and forced to witness a hospital employee objecting to and, either explicitly or implicitly, sharing his/her views on a monumental and deeply personal decision.

25. The end of life care scenario also demonstrates the harm the Final Rule causes to the medical training Downstate provides through its medical, nursing and health relate professional colleges. If an attending physician or nurse objects to the removal of life support, without advance notice, responsibility for that procedure may fall to another member of the care team in order to avoid delay or needlessly extend the life of the patient beyond the wishes of the patient and his/her

family. Inasmuch as the hospital teams do not have redundancy or duplication of roles, any health team member who suddenly withdraws from participation due to unknown religious or ethical reasons may disrupt medical care for a patient. Essentially, such a person would be following the Final Rule but not the ethical and legal requirement of placing the needs of the patient first. This would be the type of behavior that medical, nursing, and other health professional students would observe. Downstate's medical and nursing education programs are only as good as the professionals our students and residents are present to watch and learn from; in the absence of notice of possible religious objections from medical staff, the quality of Downstate's medical education may not reflect the high standards of patient care which it wishes to exemplify.

26. *Vaccination programs.* In numerous contexts of care, Downstate employees provide vaccinations, including pediatric vaccinations, to members of the public. Such vaccinations play a crucial public health role in New York City—a fact made clear with the recent outbreak of measles in our city. The responsibility of Downstate staff to vaccinate is so routine that I estimate some of our nursing staff vaccinate dozens of individuals a day during certain times of the year. In light of the frequency of vaccinations needed by our patient population, and the central role this duty plays in the employment of the hospital's nursing staff, accommodating a job applicant's refusal to provide pediatric vaccinations would, in almost every case, pose an undue hardship on Downstate. However, it is Downstate's understanding of the Final Rule that the refusal to hire a prospective employee who stated such an objection – regardless of the centrality of the task to the job – could expose Downstate to devastating consequences. Indeed, it is our management's understanding of the Final Rule that Downstate cannot even inquire, pre-hire, if a religious or moral objection would prevent the applicant from performing core duties or responsibilities of the position sought. These consequences, as I understand them, include the loss

of federal health-related funds, including the approximately \$100 million in Medicare funds and \$26 million in research funds Downstate receives annually from HHS.

27. ***Downstate's community reputation.*** Having served at Downstate for nearly three decades, I am keenly aware of the need for health institutions to build trust with the communities they serve. Trust and cultural competency are essential to delivering care to populations, particularly underserved and marginalized populations like some of the ones that Downstate serves. The harms described previously, to emergency or end of life care, are catastrophic ones: it would take only one death in our emergency room, or one employee objecting in front of family in the end of life context, to permanently damage a patient and his/her family, injure the mental health of other participating Downstate staff, and strike a serious blow to the trust our hospital has worked for decades to build among the Brooklyn communities we serve. Once such trust is damaged, it is very difficult to rebuild.

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

Executed on this 7 day of June, 2019



Michael Lucchesi, M.D.

Interim Dean of the College of Medicine
& Chairman of Emergency Medicine
Downstate Medical Center of the
State University of New York