Exhibit 109

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Submitted VIA: https://www.regulations.gov

March 23, 2018

Roger Severino
Director, Office for Civil Rights
Department of Health and Human Services
Office for Civil Rights
200 Independence Ave. SW
Washington, DC 20201

RE: Department of Health and Human Services, Office for Civil Rights: RIN 0945-ZA03 (Proposed Rule – Protecting Statutory Conscience Rights in Health Care; Delegations of Authority)

Dear Director Severino:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on the proposed rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' nearly 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 152,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 20 countries. Please visit www.NACDS.org

We strongly urge the Department of Health and Human Services (Department) and the Office for Civil Rights (OCR) to rescind the proposed rule given the absence of any convincing evidence that it is necessary, and because the reach of the proposed rule is broader than permitted by the supporting statutes. For example, none of the laws referenced as the authority for the proposal include health care providers that are involved in settings other than hospitals, clinics, and the medical profession. The proposed rule attempts to incorporate health care settings such as retail community pharmacies that are far outside the reach of clinical medical practices. Absent a rescission of the proposed rule, we urge the Department to exempt pharmacies, including licensed pharmacists and non-licensed pharmacy employees, from the

1776 Wilson Blvd • Suite 200 • Arlington, VA 22209 • 703.549.3001 • Fax: 703.836.4869 • www.NACDS.org

proposal given the potential for negative impact on access to necessary prescribed medications and thus patients' health and pharmacy operations.

Federal Conscience Protections are Already in Place and are Effective

The Department fails to show that non-compliance with conscience protections has been a problem and that the current laws have not provided sufficient protection against discrimination in covered health care settings. The Department attempts to justify the need for the proposed rule by 1) citing examples of allegations and evidence that coercion and discrimination have occurred in the last ten years, and 2) stating there has been provider confusion about the scope and applicability of current conscience law protections. However, in providing example lawsuits intended to illustrate the problem, the Department notes that it has not "opined on or judged the legal merits or sufficiency of any of the above-cited lawsuits or challenged laws." This hardly rises to the level of justification needed to impose new rules on providers already burdened with overreaching regulations and administrative requirements.

The proposed rule also cites the recent increase in complaints received by OCR as an indication that further action is needed through a proposed rule. The vast majority of complaints, thirty-four (34) out of forty-four (44) in the last ten (10) years, have been received since the November 2016 election. However, the proposed rule notes that of the ten (10) complaints received before the November 2016 election, only two (2) remain open. The proposed rule details the actions taken by OCR on the other complaints and supports the fact that the OCR has been successful in investigating and enforcing its conscience rights obligations. This does not support the need for the proposed rule, but rather supports the idea that the proposed rule is unnecessary as the current protections are working and being properly enforced.

The proposed rule notes that recipients of federal funds already certify compliance with federal nondiscrimination laws.[1] Thus, there appears to be no need to require additional certification for notification of non-discrimination based on individuals' exercise of their conscience. If each federal agency were to require unique certifications for activities that fall within their jurisdiction, the single all-encompassing non-discrimination certification currently in use would be rendered meaningless. As the federal government already requires certification of compliance with this and other nondiscrimination laws, the current proposal is unnecessary.

While the agency may wish to raise awareness about federal conscience protections, exercise of agency rulemaking authority is improper for this purpose. Licensing boards and provider accreditation bodies should be left to guide provider communities about practices within their professions or trade. These bodies have the expertise and membership reach to ensure that pertinent information about these and other federal

[1] Conscience Clause Proposed Rule, 83 Federal Register 380 (proposed January 26, 2018); note 177 at 50276. 3920.

laws are widely known. In addition, state licensing boards are charged not only with licensure but also with protecting the public and are appropriate bodies to weigh the rights of the public to access care with the rights of licensed professionals to exercise their conscience. If the Department has reason to believe that providers are unaware of their rights, these and other avenues should be explored to raise awareness about federal and state protections instead of the current proposal.

The Scope of the Proposed Rule Exceeds Statutory Authority and Should Not Apply to Community Retail Pharmacies

The federal statutes on which the proposal relies, focused primarily on clinical or research settings, neither expressly nor by implication apply to community retail pharmacies or their pharmacists. Further, the proposed rule fails to make any connection between the community retail pharmacy and the perceived problem described in the proposed rule. Nonetheless, the impact analysis section of the proposed rule states that over 44,000 pharmacies could be impacted by the proposed rule. Despite absence of any indication in the underlying federal laws that community retail pharmacies and the services they provide are meant to be covered, the proposed rule seeks to expand the reach of the statutes to the community retail pharmacy settings. In expanding the application of these laws, the Department exceeds its statutory authority. However, even if the underlying statutes were applicable, there are several other reasons why the proposed rule should not apply to community retail pharmacies.

The Proposed Rule Will Force Pharmacies to Violate State Dispensing Laws

The current proposal is at odds with many state laws that require pharmacists and pharmacies to fill prescriptions presented at the counter. These states have recognized the importance of access to lifesaving drugs and pharmacy services and have crafted their mandatory dispensing laws in a manner that ensures public health and safety. As proposed, the rule would not allow pharmacies to be certain of compliance with both their state law and the conscience rule.

State laws and regulations governing pharmacy practice are promulgated and implemented under the authority granted to the state boards of pharmacy, which are comprised of licensed pharmacists and consumers working together to ensure the health and safety of the states' citizens. If the current proposal is adopted, pharmacists and pharmacies could be in legal jeopardy in many states for their refusal to dispense prescriptions presented at the counter. Pharmacies have adjusted their practices according to the laws of their states and should not be forced to choose between compliance with state pharmacy practice laws or the requirements of the proposed rule. State boards of pharmacy have tremendous expertise on these issues and their judgment about pharmacy practice should not be replaced by the Secretary's.

Pharmacies Should be Exempt from Assurance and Certification of Compliance Requirements

The proposed rule contains several exemptions from the proposed requirements for written assurance and certification of compliance, including:

(1) Physicians, physician offices, and other health care practitioners participating in Part B of the Medicare program;

(2) Recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, whose purpose is unrelated to health care provision as specified;

(3) Recipients of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, whose purpose is unrelated to health care provision as specified; and

(4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self-Determination and Education Assistance Act.

In validating the need for the exemptions, the Department states:

> *"[r]equiring the large number of entities in these four categories to submit assurance and certification requirements would pose significant implementation hurdles for Departmental components, programs, and services. Furthermore, the Department believes that, due primarily to their generally smaller size, several of the excepted categories of recipients of Federal financial assistance or other Federal funds from the Department are less likely to encounter the types of issues sought to be addressed in this regulation."*

Retail pharmacies are the perfect examples of providers that should be exempt based on these criteria. Not only will the management of retail pharmacy certifications and re-certifications cause enormous challenges to the Department, but the amount of money received by pharmacies for services intended to be covered by the regulation are, at most, quite insignificant.

In addition to these criteria, the Secretary should also consider the amount of federal funds reimbursed for products for which there may be a conscience objection. A very small percentage of a typical pharmacy's reimbursement would be for products for which there may be a conscience objection (2.13% of all prescriptions for 2017[2]). It

[2] Source® PHAST Prescription Monthly, data drawn 3/2/2018 and includes contraceptives (including plan B) and Mifepristone.

would be inappropriate and unduly burdensome for the Secretary to place a pharmacy's total federal reimbursement at risk for the small percentage of prescriptions filled that are likely to be the subject of a conscience objection.

The Proposed Rule Forces Pharmacies to Interfere with the Decision of the Patient and his/her Physician to Use Appropriate, Legal Medications

The proposed rule requires pharmacies to interfere with the decision of the patient and his/her doctor to use a drug that has been approved for safe and effective use without requisite clinical basis for the interference. By refusing to fill prescriptions, pharmacies would effectively step between the patient and the prescriber without appropriate clinical reasons for the refusal. Pharmacists have a role in counseling patients on the proper use of medications and to make appropriate recommendations based on their professional knowledge. Where a refusal to fill a necessary prescription as determined by the licensed prescriber and the patient is based on considerations outside of professional, clinical opinion or knowledge of the pharmacist, the pharmacy's core role in health care delivery becomes undermined and the patient's clinical status is unnecessarily endangered.

While the proposal creates barriers to patients' access to care determined necessary by their licensed prescriber, the rule as proposed does not provide sufficient protections for patients to receive legal medications. In many cases, an appropriate window of opportunity to use a medication may have passed by the time a patient ultimately receives the medication if the patient is turned away to accommodate the pharmacist's objection, even though it is based on considerations other than his/her professional clinical judgment. In these cases, effective protections should be in place to ensure that a patient's life or health is not placed at unnecessary risk.

Proposed Rule Should Only Apply to Licensed Health Care Providers and Should Not Cover Pharmacy Support Staff

The proposed rule seeks to expand the statutory conscience protections beyond licensed health care providers to include support staff by broadly defining ''assist in the performance'' as:

> *''to participate in any activity with an articulable connection to a procedure, health service or health service program, or research activity, so long as the individual involved is a part of the workforce of a Department-funded entity. This includes counseling, referral, training, and other arrangements for the procedure, health service, or research activity.''*

Under this proposal, the federal conscience laws would be rendered meaningless as *any employee* within a company could make a discrimination claim regardless of whether their job functions are truly incompatible with their religious or moral beliefs. Despite

clear indication from current protections that non-discrimination protections apply to physicians or health care personnel, the proposed rule expands the scope of coverage to other members of the workforce through an improper definition of "assist."

Whereas "assist in the performance" could be appropriately interpreted broadly in some health care settings, its application in the retail pharmacy setting will severely debilitate pharmacies' abilities to serve their patients. In addition to over 150,000 pharmacists currently practicing in retail drug stores, supermarkets, and other general merchandising stores, this rule would expand federal conscience laws to millions of support staff and cashiers. Accordingly, an employee with even the most tangential involvement in the retail pharmacy's dispensing operations could refuse to carry out their job functions because of their moral beliefs. For example, from a technician to a cashier with no clinical training or expertise and no direct patient care role, one could refuse to stock the pharmacy shelf or execute a sale for any legal drug or pharmacy service under the proposal. As these pharmacy support staff are not directly involved in the provision of health care, expanding the scope of the proposed rule to them is tantamount to the agency's expansion of the federal laws to include any person employed by an entity. Similar analyses would apply to pharmacy support staff employed at non-retail pharmacy settings.

Moreover, there is a risk that the proposed rule could be read broadly enough that anyone in the drug supply chain could effectively stifle important pharmacy operations based on their moral belief, regardless of whether those beliefs are being threatened or compromised. Pharmacies rely on a predictable flow of medications in the supply chain, including wholesalers and their own warehouses, as well as the pharmacy staff to ensure that patients needing drugs get them in a timely manner. Refusal to carry out one's required responsibilities by a single person in the process could cause severe disruptions and jeopardize patients' health. For example, a pharmacy employee with moral objections to certain drugs or biologicals could refuse to order, stock, or maintain a shipment of these products, which could be rendered useless or deleterious if other employees are not available to promptly store and maintain the shipment according to Food and Drug Administration's protocols. Some may even read the proposed rule to permit the objecting employee to refuse to inform others of the shipment of highly sensitive products.

Further, the broad definition of "assist in the performance" would seem to permit the objecting employee to refuse to refer. This means that a licensed pharmacist would have the right to refuse to leave the legitimate prescription for the necessary drug for the next pharmacist on duty to dispense to the patient as an exercise of their conscience right. In this situation, the patient placed at risk by this refusal to "assist" (the placement of a simple piece of paper on the counter to be dispensed the next shift or next day by another licensed professional) most likely has no relation to federal funds received by the pharmacy. It cannot be ignored that, as written, the proposal when implemented at the pharmacy level will have the most negative effect on privately insured and cash

paying patients who will be denied necessary prescriptions under the guise of federal funding being used as a stick to prevent discrimination. Such refusals by pharmacy personnel to carry out their job functions could have far reaching consequences and place the public in grave danger.

The underlying laws are very clear that the conscience protections apply to certain licensed health care providers and only those who have *direct* assisting duties. The laws did not intend to cover someone simply because they are employed by a pharmacy or have a duty that may support the core function of a pharmacy. Nor do the laws indicate that the simple accepting, processing, and dispensing of a prescription is an activity that can be considered morally objectionable. Therefore, the Department should specifically exclude non-pharmacist pharmacy or retail staff from the reach of the proposed rule.

In addition, the definition of "assist in the performance" should not include referral of the prescription to another pharmacist (e.g. next shift or another staff pharmacist) or another pharmacy if the pharmacist present at the counter has a religious or moral objection to dispensing the prescription. In these cases, the pharmacist would neither be "assisting" nor involved in the dispensing of the drug to which he/she objects. Nonetheless, under the current proposal, an objecting pharmacist would not be required to fill or refer the prescription. When the patient returns to the pharmacy for pick-up, they may find that the pharmacist simply refused to fill the prescription without providing any notification to the patient of his/her objection or providing appropriate referral. In many cases, by the time the situation can be remedied, the optimal window of time for using the medication may have passed, placing the patient's health at risk. Thus, even if the Secretary feels that a pharmacist may refuse to dispense based on his/her moral conviction, the Secretary should not regard the patient's right to legal medications as any less important. Therefore, if the Secretary applies the rule to pharmacists, referral of the prescription to another pharmacist or pharmacy should not be considered "assisting."

Notice Requirement is Overreaching and Burdensome

The proposed rule requires covered entities to notify the public, patients, and employees of their protections under the Federal health care conscience and associated anti-discrimination statutes and the proposed regulation. It is proposed that this requirement be accomplished by posting on a covered entity's website and the entity's establishment(s) where notices to the public and their workforce are customarily posted.

These requirements impose significant burdens on retail pharmacies. With over 40,000 chain pharmacy locations, the cost and time required to post materials for both the public and employees would be considerable. This is especially troublesome as it seems the intended audience for the posting is beyond the healthcare providers covered under the proposed rule. As an alternative, the requirement to notify covered licensed health care providers of conscience laws should only apply at the time of initial hiring. There

appears to be no reason to craft a new, unique system of notification that could be operationally difficult to implement.

Conclusion

The proposed rule fails to provide any evidence that federal conscience laws have not had their intended effect or that discrimination towards health care employees' exercise of conscience is a problem. Thus, we urge the Secretary to rescind the proposed rule and instead rely on appropriate licensing boards to raise awareness of anti-discrimination laws.

Further, the proposal's application to community retail pharmacy is an inappropriate expansion of federal laws. Alternatively, we strongly urge the Secretary to exempt community retail pharmacies from the proposed requirements and ensure that the proposal is limited to licensed health care providers and not support staff.

In its current form, the proposal would cause major disruptions in the practice of pharmacy without any safety-valves to protect the patients' health. Pharmacies already abide by federal conscience laws just as they do with all other federal and state non-discrimination laws. Accordingly, we do not believe that special assurances and certifications and notice to the public and workforce should be required as proposed in this rule. Where appropriate, notification of federal conscience rights should only be required at the time of initial hiring of the licensed health care provider.

Thank you for the opportunity to comment.

Exhibit 115

NHeLP Draft as of March 22, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM
RIN 0945-ZA03
Hubert H. Humphrey Building, Room 209F
200 Independence Avenue SW
Washington, DC 20201

Introduction

On behalf of National Association of Councils on Developmental Disabilities, we submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."[1]

The regulations as proposed would introduce broad and poorly defined language to the existing law that already provides ample protection for the ability of health care providers to refuse to participate in a health care service to which they have moral or religious objections. While the proposed regulations purport to provide clarity and guidance in implementing existing federal religious exemptions, in reality they are vague and confusing. The proposed rule creates the potential for exposing patients to medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, and undermines the ability of health facilities to provide care in an orderly and efficient manner.

Most important, the regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) individuals. These communities already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, possibly ending in in poorer health outcomes. By issuing the proposed rule along with the newly created "Conscience and Religious Freedom Division," the Department seeks to use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, the National Health Law Program calls on the Department and OCR to withdraw the proposed rule in its entirety.

I. Under the guise of civil rights, the proposed rule seeks to deny medically necessary care

Civil rights laws and Constitutional guarantees, such as due process and equal protection, are designed to ensure full participation in civil society. The proposed rule,

[1] U.S. Dept. of Health and Human Serv., Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880-3931 (Jan. 26, 2018) (hereinafter "proposed rule").

while cloaked in the language of non-discrimination, is designed to deny care and exclude disadvantaged and vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for § 1557,

> "[e]qual access for all individuals without discrimination is essential to achieving" the ACA's aim to expand access to health care and health coverage for all, as "discrimination in the health care context can often…exacerbate existing health disparities in underserved communities."[2]

The Department and OCR have an important role to play in ensuring equal health opportunity and ending discriminatory practices that contribute to health disparities. Yet, this proposed rule represents a dramatic, harmful, and unwarranted departure from OCR's historic and key mission. The proposed rule appropriates language from civil rights statutes and regulations that were designed to improve access to health care and applies that language to deny medically necessary care.

The federal government argues that robust religious refusals, as implemented by this proposed rule, will facilitate open and honest conversations between patients and physicians.[3] As an outcome of this rule, the government believes that patients, particularly those who are "minorities", including those who identify as people of faith, will face fewer obstacles in accessing care.[4] The proposed rule will not achieve these outcomes. Instead, the proposed rule will increase barriers to care, harm patients by allowing health care professionals to ignore established medical guidelines, and undermine open communication between providers and patients. The harm caused by this proposed rule will fall hardest on those most in need of care.

II. The expansion of religious refusals under the proposed rule will disproportionately harm communities who already lack access to care

Women, individuals living with disabilities, LGBTQ persons, people living in rural communities, and people of color face severe health and health care disparities, and these disparities are compounded for individuals who hold these multiple identities. For example, among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[5] Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[6]

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[2] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[3] 83 Fed. Reg. 3917.
[4] *Id.*
[5] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.
[6] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.;At the end of 2014, of the total

Meanwhile, people of color in rural America are more likely to live in an area with a shortage of health professionals, with 83% of majority-Black counties and 81% of majority-Latino/a counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

The expansion of refusals as proposed under this rule will exacerbate these disparities and undermine the ability of these individuals to access comprehensive and unbiased health care, including sexual and reproductive health information and services. Any efforts by providers or other health care personnel to limit the information and access that patients are entitled to receive, even when the organization may not provide those services itself, is incompatible with true consumer choice and individual decision making.

a. *The proposed rule will block access to care for low-income women, including immigrant women and African American women*

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but can particularly harm low-income women. The burdens on low-income women can be insurmountable when women and families are uninsured,[7] underinsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services nor travel to another location. This is especially true for immigrant women. In comparison to their U.S. born peers, immigrant women are more likely to be uninsured.[8] Notably, immigrant, Latina women have far higher rates of uninsurance than Latina women born in the United States (48 percent versus 21 percent, respectively).[9]

According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery possibly due to stereotypes about Black women's sexuality and reproduction.[10] Young Black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.[11]

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number of women diagnosed with HIV, 60 percent were Black. *HIV Among Women,* CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.

[7] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. KAISER FAMILY FOUND., *Women's Health Insurance Coverage* 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[8] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf.

[9] *Id.* at 8, 16.

[10] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at* https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[11] *Reproductive Injustice*, *supra* note 10, at 16-17.

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals, subjecting them to treatment that does not comply with the standards of care.[12] In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[13] In New Jersey, for example, women of color make up 50 percent of women of reproductive age in the state, yet have twice the number of births at Catholic hospitals compared to their white counterparts.[14] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.[15] The proposed rule will give health care providers a license, such as Catholic hospitals, to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

b. The proposed rule will negatively impact rural communities

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[16] with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[17] Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[18] Among the many geographic and spatial barriers that exist, individuals in rural areas often must have a driver's license and own a private car to access care, as they must travel further distances for regular checkups, often on poorer

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[12] Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[13] *Id* at 12.
[14] *Id* at 9.
[15] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.
[16] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).
[17] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.
[18] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations*, ECON. RESEARCH SERV. (2009), *available at* https://www.ers.usda.gov/publications/pub-details/?pubid=44427.

quality roads, and have less access to reliable public transportation.[19] This scarcity of accessible services leaves survivors of intimate partner violence (IPV) in rural areas with fewer shelter beds close to their homes, with an average of just 3.3 IPV shelter beds per rural county as compared to 13.8 in urban counties.[20] Among respondents of one survey, more than 25 percent of survivors of IPV in rural areas have to travel over 40 miles to the nearest support service, compared to less than one percent of women in urban areas.[21]

Other individuals in rural areas, such as people with disabilities, people with Hepatitis C, and people of color, have intersecting identities that further exacerbate existing barriers to care in rural areas. Racial and ethnic minority communities often live in concentrated parts of rural America, in communities experiencing rural poverty, lack of insurance, and health professional shortage areas.[22] People with disabilities experience difficulties finding competent physicians in rural areas who can provide experienced and specialized care for their specific needs, in buildings that are barrier free.[23] Individuals with Hepatitis C infection find few providers in rural areas with the specialized knowledge to manage the emerging treatment options, drug toxicities and side effects.[24] All of these barriers will worsen if providers are allowed to refuse care to particular patients.

Meanwhile, immigrant, Latina women and their families often face cultural and linguistic barriers to care, especially in rural areas.[25] These women often lack access to transportation and may have to travel great distances to get the care they need.[26] In rural areas there may simply be no other sources of health and life preserving medical care. When these women encounter health care refusals, they have nowhere else to go.

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[19] Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region*, 40 HEALTH SERV. RESEARCH (2005) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130/.

[20] Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources*, 20 J. OF WOMEN'S HEALTH (Nov. 2011) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064/.

[21] *Id.*

[22] Janice C. Probst et al., *Person and Place: The Compounding Effects of Race/Ethnicity and Rurality on Health*, AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1695.

[23] Lisa I. Iezzoni et al., *Rural Residents with Disabilities Confront Substantial Barriers to Obtaining Primary Care*, 41 HEALTH SERV. RESEARCH (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1797079/.

[24] Sanjeev Arora et al., *Expanding access to hepatitis C virus treatment – Extension for Community Healthcare Outcomes (ECHO) Project: Disruptive Innovation in Specialty Care*, 52 HEPATOLOGY (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1002/hep.23802/full.

[25] Michelle M. Casey et al., *Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest*, AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709.

[26] NAT'L LATINA INST. FOR REPROD. HEALTH & CTR. FOR REPROD. RIGHTS, NUESTRA VOZ, NUESTRA SALUD, NUESTRO TEXAS: THE FIGHT FOR WOMEN'S REPRODUCTIVE HEALTH IN THE RIO GRANDE VALLEY, 7 (2013), *available at* http://www.nuestrotexas.org/pdf/NT-spread.pdf.

c. *The proposed rule would harm LGBTQ Communities who continue to face rampant discrimination and health disparities*

The proposed rule will compound the barriers to care that LGBTQ individuals face, particularly the effects of ongoing and pervasive discrimination by potentially allowing providers to refuse to provide services and information vital to LGBTQ health.

LGBTQ people continue to face discrimination in many areas of their lives, including health care, on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[27] LGBTQ people still face discrimination in a wide variety of services affecting access to health care, including reproductive services, adoption and foster care services, child care, homeless shelters, and transportation services – as well as physical and mental health care services.[28] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[29] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[30]

i. Discrimination against the transgender community

Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[31] Numerous federal courts have found that federal sex discrimination

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[27] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).

[28] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[29] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[30] *Id.*

[31] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018); *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal Protection Clause); Doddsv. U.S. Dep't of Educ., 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *A.H. ex rel. Handling v. Minersville Area School District*, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); *Stone v. Trump*, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL 4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, ---F.Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); *E.E.O.C. v. Rent-a-Center East, Inc.*, ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); *Brown v. Dept. of Health and Hum. Serv.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); *Smith v. Avanti*, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); *Students & Parents for Privacy v. U.S. Dep't of Educ.*, No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill.

statutes reach these forms of gender-based discrimination.[32] In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[33]

Twenty-nine percent of transgender individuals were refused to be seen by a health care provider on the basis of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[34] Additionally, the 2015 U.S. Transgender Survey found that 23 percent respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[35] Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under Section 1557 of the ACA from 2012 through 2016.

- "In approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."
- "Approximately 20% of the claims were for misgendering or other derogatory language."

Oct. 18, 2016) (Title IX); *Mickens v. Gen. Elec. Co.* No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); *Fabian v. Hosp. of Cent. Conn.*, 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); *Doe v. State of Ariz.*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); *Rumble v. Fairview Health Serv.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); *Finkle v. Howard Cty.*, 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Lopez v. River Oaks Imaging & Diagnostic Grp.*, Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); *Mitchell v. Axcan Scandipharm*, Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); *Tronettiv. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).

[32] *See, e.g.*, *Smith v. City of Salem*, 378 F.3d 566, 572-75 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). *See also* Statement of Interest of the United States at 14, *Jamal v. Saks*, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

[33] *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

[34] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[35] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf [hereinafter *2015 U.S. Transgender Survey*].

- "Patients denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[36]

As proposed, the rule could allow religiously affiliated hospitals to not only refuse to provide transition related treatment for transgender people, but to also deny surgeons who otherwise have admitting privileges to provide transition related surgery in the hospital. Transition-related care is not only medically necessary, but for many transgender people it is lifesaving.

ii. Discrimination Based Upon Sexual Orientation

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[37] LGBTQ people still face discrimination. According to one survey, 8 percent of lesbian, gay, bisexual, and queer individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[38]

Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, LGB people are frequently not treated with the respect that all patients deserve. The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[39] Almost ten percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[40] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population. These disparities include:

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[36] Sharita Gruberg & Frank J. Bewkes, Center for American Progress, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (March 7, 2018), *available at* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.

[37] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.

[38] Mirza, *supra* note 34.

[39] LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* .http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

[40] *Id.*

- LGB individuals are more likely than heterosexuals to rate their health as poor, have more chronic conditions, and have higher prevalence and earlier onset of disabilities.[41]
- Lesbian and bisexual women report poorer overall physical health than heterosexual women.[42]
- Gay and bisexual men report more cancer diagnoses and lower survival rates, higher rates of cardiovascular disease and risk factors, as well as higher total numbers of acute and chronic health conditions.[43]
- Gay and bisexual men and other men who have sex with men (MSM) accounted for more than half (56 percent) of all people living with HIV in the United States, and more than two-thirds (70 percent) of new HIV infections.[44]
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.[45]

This discrimination affects not only the mental health and physical health of LGBTQ people, but that of their families as well. One pediatrician in Alabama reported that "we often see kids who haven't seen a pediatrician in 5, 6, 7 years, because of fear of being judged, on the part of either their immediate family or them [identifying as LGBTQ]".[46] It is therefore crucial that LGBTQ individuals who have found unbiased and affirming providers, be allowed to remain with them. If turned away by a health care provider, 17 percent of all LGBTQ people, and 31 percent of LGBTQ people living outside of a metropolitan area, reported that it would be "very difficult" or "not possible" to find the same quality of service at a different community health center or clinic.[47]

The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBT persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[48] The World Professional

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[41] David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), *available at* http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/.

[42] *Id.*

[43] *Id.*

[44] CTRS FOR DISEASE CONTROL & PREVENTION, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* 1(Feb. 2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

[45] HUMAN RIGHTS CAMPAIGN ET AL., *Health Disparities Among Bisexual People* (2015) *available at* http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

[46] HUMAN RIGHTS WATCH, *supra* note 28.

[47] Mirza, *supra* note 34.

[48] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).

Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[49] The American College of Obstetricians and Gynecologists warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[50] LGBTQ individuals already experience significant health disparities, and denying medically necessary care on the basis of sexual orientation or gender identity exacerbates these disparities.

In addition, LGBTQ individuals face disparities in medical conditions that may implicate the need for reproductive health services. For example, lesbian and bisexual women report heightened risk for and diagnosis of some cancers and higher rates of cardiovascular disease.[51] The LGBTQ community is significantly at risk for sexual violence.[52] Eighteen percent of lesbian, gay, bisexual students have reported being forced to have sex.[53] Transgender women, particularly women of color, face high rates of HIV.[54]

Refusals to treat individuals according to medical standards of care put patients' health at risk, particularly for women and LGBTQ individuals. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many. Given the broadly-written and unclear language of the proposed rule, if implemented, some providers may misuse this rule to deny services to LGBTQ individuals on the basis of perceived or actual sexual orientation and gender identity. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of patients to make a health decision that expresses their self-determination.

Finally, the proposed rule threatens to turn back the clock to the darkest days of the AIDS pandemic when same-sex partners were routinely denied hospital visitation and health care providers scorned sick and dying patients.

d. The proposed rule will hurt people living with disabilities

Many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically,

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[49] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, WORLD PROF. ASS'N FOR TRANSGENDER HEALTH (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.

[50] *Committee Opinion 512: Health Care for Transgender Individuals*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

[51] Kates, *supra* note 37, at 4.

[52] Forty-six percent of bisexual women have been raped and 47 percent of transgender people are sexually assaulted at some point in their lifetime. This rate is particularly higher for transgender people of color. Kates, *supra* note 37, at 8.; *2015 U.S. Transgender Survey*, *supra* note 35, at 5.

[53] *Health Risks Among Sexual Minority Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/healthyyouth/disparities/smy.htm (last updated May 24, 2017).

[54] More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 37, at 6.

people with disabilities who rely on these services have sometimes faced discrimination, exclusion, and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[55] Individuals with HIV – a recognized disability under the ADA – have repeatedly encountered providers who deny services, necessary medications, and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[56] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy, and well-being of people with disabilities.

Many people with disabilities live or spend much of their day in provider-controlled settings where they often receive supports and services. They may rely on a case manager to coordinate necessary services, a transportation provider to get them to community appointments, or a personal care attendant to help them take medications and manage their daily activities. Under this broad new proposed language, any of these providers could believe they are entitled to object to providing a service covered under the regulation and not even tell the individual where they could obtain that service, how to find an alternative provider, or even whether the service is available to them. A case manager might refuse to set up a routine appointment with a gynecologist because contraceptives might be discussed. A personal home health aide could refuse to help someone take a contraceptive. An interpreter for a deaf individual could refuse to mediate a conversation with a doctor about abortion. In these cases, a denial based on someone's personal moral objection can potentially impact every facet of life for a person with disabilities – including visitation rights, autonomy, and access to the community.

Finally, due to limited provider networks in some areas and to the important role that case managers and personal care attendants play in coordinating care, it may be more difficult for people with disabilities and older adults to find an alternate providers who can help them. For example, home care agencies and home-based hospice agencies in rural areas are facing significant financial difficulties staying open. Seven percent of all zip codes in the United States to not have any hospice services available to them.[57] Finding providers competent to treat people with certain disabilities can increase the challenge. Add in the possibility of a case manager or personal care attendant who

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[55] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).
[56] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.
[57] Julie A. Nelson & Barbara Stover Gingerich, *Rural Health: Access to Care and Services*, 22 HOME HEALTH CARE MGMT. PRAC. (2010), *available at* http://globalag.igc.org/ruralaging/us/2010/access.pdf.

objects to helping and the barrier to accessing these services can be insurmountable. Moreover, people with disabilities who identify as LGBTQ or who belong to a historically disadvantaged racial or ethnic group may be both more likely to encounter service refusals and also face greater challenges to receive (or even know about) accommodations.

III. The proposed rule undermines longstanding ethical and legal principles of informed consent

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[58] This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care.

The proposed rule purports to improve communication between patients and providers, but instead, will deter open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. For example, the proposed rule suggests that someone could refuse to offer information, if that information might be used to obtain a service to which the refuser objects. Such an attenuated relationship to informed consent could result in withholding information far beyond the scope of the underlying statutes, and would violate medical standards of care.

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.[59] Informed consent is intended to help balance the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[60] In order to ensure that patient

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[58] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[59] BEAUCHAMP & CHILDRESS, *supra* note 58; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).

[60] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian Health Service and the Sterilization of Native American Women*, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced

decisions are based on free will, informed consent must be upheld in the patient-provider relationship. The proposed rule threatens this principle and may very well force individuals into harmful medical circumstances.

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[61]The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[62] Similarly, pharmacists are called to respect the autonomy and dignity of each patient.[63]

Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.[64] In *Brownfield v. Daniel Freeman Marina Hospital*, a California court addressed the importance of patients' access to information in regard to emergency contraception. The court found that:

> "The duty to disclose such information arises from the fact that an adult of sound mind has 'the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.' [citation omitted] Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available."[65]

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to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

[61] *The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.

[62] *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.

[63] *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).

[64] *See, e.g.*, *State HIV Laws*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/policies/law/states/index.html (last visited Nov. 13, 2017, 1:22PM); *Emergency Contraception*, GUTTMACHER INST. (Oct. 1, 2017), https://www.guttmacher.org/state-policy/explore/emergency-contraception.

[65] *Brownfield v. Daniel Freeman Marina Hospital*, 256 Cal. Rptr. 240 (Ct. App. 1989).

In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as, beneficence, nonmaleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[66] In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.[67] Specifically, the provision of the care should not vary due to the personal characteristics of patients and should ensure that patient values guide all clinical decisions.[68] The expansion of religious refusals as envisioned in the proposed rule may compel providers to furnish care and information that harms the health, well-being, and goals of patients.

In particular, the principles of informed consent, respect for autonomy, and beneficence are important when individuals are seeking end of life care. These patients should be the center of health care decision-making and should be fully informed about their treatment options. Their advance directives should be honored, regardless of the physician's personal objections. Under the proposed rule, providers who object to various procedures could impose their own religious beliefs on their patients by withholding vital information about treatment options— including options such as voluntarily stopping eating and drinking, palliative sedation or medical aid in dying. These refusals would violate these abovementioned principles by ignoring patient needs, their desires, and autonomy and self-determination at a critical time in their lives. Patients should not be forced to bear the brunt of their provider's religious or moral beliefs regardless of the circumstances.

IV. The regulations fail to consider the impact of refusals on persons suffering from substance use disorders (SUD)

The over breadth of this proposed rule could be devastating to people with Substance Use Disorder (SUD). Rather than promoting the evidence-based standard of care, the rule could allow anyone from practitioners to insurers to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

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[66] Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).
[67] INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 3 (Mar. 2001), *available at* http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.
[68] *Id.*

The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.[69] The latest numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.[70]

The clear, evidence-based treatment standard for opioid use disorder (OUD) is medication-assisted treatment (MAT).[71] Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications."[72] Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities.[73] Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.[74] Information about and access to these medications are crucial factors in keeping patients suffering from SUD from losing their jobs, losing their families, and losing their lives.

However, stigma associated with drug use stands in the way of saving lives.[75] America's prevailing cultural consciousness, after decades of treating the disease of addiction as largely a criminal justice and not a public health issue, generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood

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[69] Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).
[70] *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.
[71] U.S. DEP'T HEALTH & HUM. SERV., PUB NO. (SMA)12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS (2012), https://store.samhsa.gov/shin/content/SMA12-4214/SMA12-4214.pdf; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.
[72] World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf
[73] OPEN SOC'Y INST., BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), https://www.opensocietyfoundations.org [https://perma.cc/YF94-88AP].
[74] *See* James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).
[75] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, VOX, Nov. 15, 2017, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.

borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[76] One commissioner even quoted the Bible as he voted to shut it down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.[77]

In this frame of mind, only total abstinence is seen as successful treatment for SUD, usually as a result of a 12-step or faith-based program. MAT is considered by many to be simply "substituting one drug for another drug."[78] This belief is so common that even the former Secretary of the Department is on the record as opposing MAT because he didn't believe it would "move the dial," since people on medication would be not "completely cured."[79] The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease.[80] The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[81]

People with SUD already suffer due to stigma and have a difficult time finding appropriate care. For example, it can be difficult to find access to local methadone clinics in rural areas.[82] Other roadblocks, such as artificial caps on the number of patients to whom doctors can prescribe buprenorphine, further prevent people with SUD from receiving appropriate care.[83] Only one-third of treatment programs across the country provide MAT, even though treatment with MAT can cut overdose mortality rates in half and is considered the gold standard of care. [84] The current Secretary of the

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[76] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible,* Vox, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.

[77] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.

[78] Lopez, *supra* note 75.

[79] Eric Eyre, *Trump officials seek opioid solutions in WV*, CHARLESTON GAZETTE-MAIL, May 9, 2017, https://www.wvgazettemail.com/news/health/trump-officials-seek-opioid-solutions-in-wv/article_52c417d8-16a5-59d5-8928-13ab073bc02b.html.

[80] Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063, http://www.nejm.org/doi/full/10.1056/NEJMp1402780.

[81] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf

[82] Christine Vestal, *In Opioid Epidemic, Prejudice Persists Against Methadone*, STATELINE, Nov. 11, 2016, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/11/11/in-opioid-epidemic-prejudice-persists-against-methadone

[83] 42 C.F.R. §8.610.

[84] Matthais Pierce, et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England*, 111:2 ADDICTION 298 (Nov. 2015); Luis Sordo, et al., Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies, BMJ (2017), http://www.bmj.com/content/357/bmj.j1550.; Alex Azar, Secretary, U.S. Dep't of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018),

Department has noted that expanding access to MAT is necessary to save lives and that it will be "impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.[85] This rule, which allows misinformation and personal feelings to get in the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead trigger countless numbers of deaths.

V. The proposed rule permits health care professionals to opt out of providing medical care that the public expects by allowing them to disregard evidence-based standards of care

Medical practice guidelines and standards of care establish the boundaries of medical care that patients can expect to receive and that providers should be expected to deliver. The health services impacted by refusals are often related to reproductive and sexual health, which are implicated in a wide range of common health treatment and prevention strategies. Information, counseling, referral and provisions of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Many of these conditions disproportionately affect women of color.[86] The expansion of these refusals as outlined in the proposed rule will put women, particularly women of color, who experience these medical conditions at greater risk for harm.

Moreover, a 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[87] While some of these physicians might refer their patients to another provider who could provide the necessary care, one 2007 survey found that as many as one-third of patients (nearly 100 million people) may be receiving

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https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.

[85] Azar, *supra* note 84.

[86] For example, Black women are three times more likely to be diagnosed with lupus than white women. Latinas and Asian, Native American, and Alaskan Native women also are likely to be diagnosed with lupus. Office on Women's Health, *Lupus and women*, U.S. DEP'T HEALTH & HUM. SERV. (May 25, 2017), https://www.womenshealth.gov/lupus/lupus-and-women. Black and Latina women are more likely to experience higher rates of diabetes than their white peers. Office of Minority Health, *Diabetes and African Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Jul. 13, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18; Office of Minority Health, *Diabetes and Hispanic Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (May 11, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=63. Filipino adults are more likely to be obese in comparison to the overall Asian population in the United States. Office of Minority Health, *Obesity and Asian Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Aug. 25, 2017), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=55. Native American and Alaskan Native women are more likely to be diagnosed with liver and kidney/renal pelvis cancer in comparison to non-Hispanic white women. Office of Minority Health, *Cancer and American Indians/Alaska Natives*, U.S. DEP'T OF HEALTH & HUM. SERV. (Nov. 3, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=31.

[87] Debra B. Stulberg M.D. M.A., et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, J. GEN. INTERN. MED. 725-30 (2010) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.

care from physicians who do not believe they have any obligations to refer their patients to other providers.[88] Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and now own one in six hospital beds across the country.[89] The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.[90]

a. Pregnancy prevention

The importance of the ability of women to make decisions for themselves to prevent or postpone pregnancy is well-established within the medical guidelines across a range of practice areas. Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.[91] Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.[92]

Moreover, women who are struggling to make ends meet are disproportionately impacted by unintended pregnancy. In 2011, 45% of pregnancies in the U.S. were unintended – meaning that they were either unwanted or mistimed.[93] Low-income women have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.[94] The Institute of Medicine has

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[88] Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices*, NEW ENG. J. MED. 593–600 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/.

[89] Julia Kaye et al., *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives*, AM. CIVIL LIBERTIES UNION 22 (2017), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[90] Nadia Sawicki, *Mandating Disclosure Of Conscience-Based Limitations On Medical Practice*, 42 AM. J. OF LAW & MED. 85-128 (2016) *available at* http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

[91] AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE S115, S117 (2017), available at: http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf

[92] *Id.* at S114.

[93] *Unintended Pregnancy in the United States*, Guttmacher Inst. (Sept. 2016), https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.

[94] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in rates of unintended pregnancy in the United*

documented negative health effects of unwanted pregnancy for mothers and children. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors as well as low-birth weight babies and insufficient prenatal care.[95]

b. Sexually transmitted infections (STIs)

Religious refusals also impact access to sexual health care more broadly. Contraceptives and access to preventative treatment for sexually transmitted infections are a critical aspect of health care. The CDC estimates that 20 million new sexually transmitted infections occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[96] Consistent use of condoms results in an 80 percent reduction of HIV transmission, and the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the World Health Organization all recommend the condom use be promoted by providers.[97]

c. Ending a Pregnancy

While there are numerous reasons for why a person would seek to end a pregnancy, there are many medical conditions in which ending a pregnancy is recommended as treatment. These conditions include: preeclampsia and eclampsia, certain forms of cardiovascular disease, and complications for chronic conditions. Significant racial disparities exist in rates of and complications associated with preeclampsia.[98] For example, the rate of preeclampsia is 61% higher for Black women than for white women, and 50% higher than women overall.[99] The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state

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States, 1994 and 2001, 38 PERSPECTIVES ON SEXUAL & REPROD. HEALTH 90-6 (2006).

[95] INSTITUTE OF MEDICINE COMMITTEE ON UNINTENDED PREGNANCY, THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES (Sarah S. Brown & Leon Eisenberg eds.,1995).

[96] *Sexually Transmitted Disease Surveillance 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.

[97] American Academy of Pediatrics Committee on Adolescence, *Condom Use by Adolescents*, 132 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (available at http://www.acog.org/publications/patient_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, *Position statement on condoms and HIV prevention*, UNICEF (2009), https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf.

[98] Sajid Shahul et al., *Racial Disparities in Comorbidities, Complication, and Maternal and Fetal Outcomes in Women With Preeclampsia/eclampsia*, 34 HYPERTENSION PREGNANCY (Dec. 4, 2015), http://www.tandfonline.com/doi/abs/10.3109/10641955.2015.1090581?journalCode=ihip20.

[99] Richard Franki, *Preeclampsia/eclampsia rate highest in black women*, OB.GYN. NEWS (Apr. 29., 2017), http://www.mdedge.com/obgynnews/article/136887/obstetrics/preeclampsia/eclampsia-rate-highest-black-women.

that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival.[100] ACOG and American Heart Association recommend that a pregnancy be avoided or ended for certain conditions such as severe pulmonary hypertension.[101] Many medications can cause significant fetal impairments, and therefore the Federal Food and Drug Administration and professional medical associations recommend that women use contraceptives to ensure that they do not become pregnant while taking these medications.[102] In addition, some medical guidelines counsel patients to end a pregnancy if they are taking certain medications for thyroid disease.[103]

d. Emergency contraception

The proposed rule will magnify the harm in circumstances where women are already denied the standard of care. Catholic hospitals have a record of providing substandard care or refusing care altogether to women for a range of medical conditions and crises that implicate reproductive health. For example, in a 2005 study of Catholic hospital emergency rooms by Ibis Reproductive Health for Catholics for Choice, it was found that 55 percent would not dispense emergency contraception under any circumstances.[104] Twenty three percent of the hospitals limited EC to victims of sexual assault.[105]

These hospitals violated the standards of care established by medical providers regarding treatment of sexual assault. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated.[106] At the bare

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[100] AMERICAN ACADEMY OF PEDIATRICS & AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

[101] Mary M. Canobbio et al., *Management of Pregnancy in Patients With Complex Congenital Heart Disease*, 135 CIRCULATION e1-e39 (2017); Debabrata Mukherjee, *Pregnancy in Patients With Complex Congenital Heart Disease*, AM. COLL. CARDIOLOGY (Jan. 24, 2017), http://www.acc.org/latest-in-cardiology/ten-points-to-remember/2017/01/24/14/40/management-of-pregnancy-in-patients-with-complex-chd.

[102] ELEANOR BIMLA SCHWARZ M.D. M.S., et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 Annals of Internal Medicine. (Sept. 18, 2007).

[103] For example, the American College of Obstetricians and Gynecologists specifically recommends that if a woman taking Iodine 131 becomes pregnant, her physician should caution her to consider the serious risks to the fetus, and consider termination. American College of Obstetricians and Gynecologists, *ACOG Practice Bulletin No. 37: Thyroid disease in pregnancy* 100 OBSTETRICS & GYNECOLOGY 387-96 (2002).

[104] Teresa Harrison, *Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff*, 46 ANNALS EMERGENCY MED. 105-10 (Aug. 2005), http://www.annemergmed.com/article/S0196-0644(05)00083-1/pdf

[105] *Id.* at 105.

[106] *Committee Opinion 592: Sexual Assault*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Apr. 2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co592.pdf?dmc=1&ts=20170213T2116487879; *Management of the Patient with the Complaint of Sexual Assault*, AM. COLL. EMERGENCY MED. (Apr. 2014), https://www.acep.org/Clinical---Practice-Management/Management-of-the-Patient-with-the-Complaint-of-Sexual-Assault/#sm.00000bexmo6ofmepmultb97nfbh3r.

minimum, survivors should be given comprehensive information regarding emergency contraception.[107]

e. Artificial Reproductive Technology (ART)

Refusals to provide the standard of care to LGBTQ individuals because of their sexual orientation or gender identity can impact access to care across a broad spectrum of health concerns, which includes primary and specialty care settings. One example of refusals that impacts LGBTQ patients, as well as non-LGBTQ patients, is refusals to educate about, provide, or cover ART procedures for religious reasons. For individuals with cancer, the standard of care includes education and informed consent around fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society.[108] Refusals to educate patients about or to provide ART occur for two reasons: refusal based on religious beliefs about ART itself and refusals to provide ART to LGBTQ individuals because of their LGBTQ identity. In both situations, refusals to educate patients about ART and fertility preservation, and to facilitate ART when requested, are against the standard of care.

The lack of clarity in the rule could lead a hospital or an individual provider to refuse to provide ART to same-sex couples based on religious belief. For some couples, this discrimination would increase the cost and emotional toll of family building. In some parts of the country, however, these refusals would be a complete barrier to parenthood. More broadly, these refusals deny patients the human right and dignity to be able to decide to have children, and cause psychological harm to patients who are already vulnerable because of their health status or their experience of health disparities.

f. HIV Health

For HIV, in addition to consistent condom use, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are an important part of prevention for those at high risk for contracting HIV. The American College of Obstetricians and Gynecologists recommends that PrEP be considered for individuals at high risk of contracting HIV.[109] Under the proposed rule, an insurance company could refuse to cover PrEP or PEP

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[107] *Access to Emergency Contraception H-75.985*, AMA (2014), https://policysearch.ama-assn.org/policyfinder/detail/emergency%20contraception%20sexual%20assault?uri=%2FAMADoc%2FHOD.xml-0-5214.xml.

[108] Alison W. Loren et al., *Fertility Preservation for Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update*, 31 J. CLINICAL ONCOLOGY 2500-10 (July 1, 2013); Ethics Committee of the American Society for Reproductive Medicine, *Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion*, 100 AM. SOC'Y REPROD. MED. 1224-31 (Nov. 2013), http://www.allianceforfertilitypreservation.org/_assets/pdf/ASRMGuidelines2014.pdf; Joanne Frankel Kelvin, *Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources*, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

[109] ACOG *Committee Opinion 595: Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (May 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus.

because of a religious belief. Refusals to promote and facilitate condom use because of religious beliefs and refusals to prescribe PrEP or PEP because of a patient's perceived or actual sexual orientation, gender identity, or perceived or actual sexual behaviors is in violation of the standards of care and harms patients already at risk for experiencing health disparities. Both PrEP and PEP have been shown to be highly effective in preventing HIV infection. Denying access to this treatment would adversely impact vulnerable, highest risk populations including gay and bisexual men.

VI. The proposed rule violates the Establishment Clause

The Establishment Clause of the First Amendment bars the government from granting religious and moral exemptions that would harm any third party.[110] It requires the Department to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[111]

The Supreme Court acknowledged the limitations imposed by the Establishment Clause in *Burwell v. Hobby Lobby Stores, Inc.*, declaring the effect on employees of an accommodation provided to employers under the Religious Freedom Restoration Act (RFRA) "would be precisely zero."[112] Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests."[113] The proposed exemptions clearly impose burdens on and harm others and thus, violate the clear mandate of the Establishment Clause.

VII. The regulations are overly broad, vague, and will cause confusion in the health care delivery system

The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition who can refuse and what they can refuse to do. Under the proposed rule, any one engaged in the health care system could refuse services or care. The proposed rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[114] Under this definition, could any member of the health care workforce refuse to serve a patient in any way – could a nurse assistant refuse to serve lunch to a transgender patient, could a billing specialist refuse to help a patient who had sought contraceptive counseling?

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[110] E.g., *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Cutter v. Wilkinson*, 544 U.S.709, 720, 726 (2005); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989).
[111] *Cutter*, 544 U.S. at 720, 722; see also *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709-10 (1985).
[112] *Hobby Lobby*, 134 S. Ct. 2751, 2760 (2014).
[113] *Id.* at 2786-87 (Kennedy, J., concurring).
[114] 83 Fed. Reg. 3894.

a. Discrimination

The failure to define the term "discrimination" will cause confusion for providers, and as employers, expose them to liability. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.[115] The regulations make no reference to Title VII or current EEOC guidance, which prohibits discrimination against an employee based on that employee's race, color, religion, sex, and national origin.[116] The proposed rule should be read to ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is to be maintained.

If this balance is not maintained, the language in the proposed rule could force health care providers to hire people who intend to refuse to perform essential elements of a position. For example, the proposed rule lacks clarity about whether a Title X-funded health center's decision not to hire a counselor or clinician who objected to provide non-directive options counseling as an essential job function of their position would be deemed discrimination under the rule. Furthermore, the proposed rule does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician to a unit where pregnancy counseling is not done.

By failing to define "discrimination," supervisors in health care settings will be unable to proceed in the orderly delivery of health care services, putting women's health at risk. The proposed rule impermissibly muddies the interpretation of Title VII and current EEOC guidance. If implemented, health care entities may be forced to choose between complying with a fundamentally misguided proposed rule and long-standing interpretation of Title VII.

Finally, the proposed rule's lack of clarity regarding what constitutes discrimination, may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[117] Instead, courts have held that the government has a compelling interest in ending discrimination

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[115] 42 U.S.C. § 2000e-2.; *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

[116] *Id.*

[117] See e.g., *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).

and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[118] The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

b. Assist in the performance

The definition of "assist in the performance" greatly expands the types of services that can be refused beyond any reasonable stretch of the imagination. The proposed rule defines "assistance" to include participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity."[119] In addition, the Department includes activities such as "making arrangements for the procedure."[120] If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The proposed rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with the standard of care.

The regulations also leave unclear whether a worker can assert his or her moral belief in refusing to treat patients on the basis of their identity or deny care for reasons outside of religious or moral beliefs. Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs.[121] Biased counseling can contribute to unwanted health outcomes and exacerbate health disparities.[122] The proposed rule is especially alarming as it does not articulate a definition of moral beliefs. The prejudices of a health care professional could easily inform their beliefs and consequently, serve as the basis of denying care to an individual based on characteristics alone. The proposed rule will foster discriminatory health care settings and interactions between patients and

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[118] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).
[119] 83 Fed. Reg. 3892.
[120] *Id.*
[121] RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; *See generally* Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINKPROGRESS, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ecedea23c4/.
[122] In one study in Massachusetts, women living with intellectual and developmental disabilities, including those who were Black and Latina, faced increased risks of preterm delivery and very low and low birth weight babies. M. Mitra et al., *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, AM. J. PREV. MED. (2015), https://www.ncbi.nlm.nih.gov/pubmed/25547927.

providers that are informed by bias instead of medically accurate, evidence-based, patient-centered care.

Moreover, in the preamble, the proposed rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs.[123] Due to this, health care professionals may think they can deny abortion care and other health services just because they do not want to provide the service. The preamble uses language such as "those who choose not to provide" or "Would rather not" as justification for a refusal. This is more concerning because the proposed rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services or if services were denied, the basis for refusal. This is likely to occur as the proposed rule does not have any provisions that stipulate that patients must be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

c. Referral

The definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information based on which an individual could get the care they need. Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an entity if the information given would lead to a service, activity, or procedure that the entity or health care entity objects. Under this definition, could a medical doctor refuse to provide a website describing the medical conditions which contraception treats? Or could an entity refuse to provide a list of LGBTQ-friendly providers? In addition, the Department states that the underlying statutes of the proposed rule permits entities to deny help to anyone who is likely to make a referral for an abortion or for other services.[124] The breadth and vagueness of this definition will possibly lead providers to refrain from providing information vital to patients out of anxiety and confusion of what the proposed rule permits them to do.

d. Health Care Entity

The proposed rule's definition of "health care entity" conflicts with Federal religious refusal laws such as the Coats and Weldon Amendments, thus fostering confusion regarding which entities are required to comply with the proposed rule and existing Federal religious refusals. Specifically, under the Coats and Weldon Amendments a "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in health care delivery. Under the proposed rule, a plan sponsor "not primarily engaged in the business of health care" would be deemed a "health care entity."[125] This definition would mean that an employer acting as a third party administrator or sponsor could count as a "health care entity" and deny coverage. In

[123] 83 Fed. Reg. 3890-91.
[124] *Id.* at 3895.
[125] *Id.* at 3893.

2016, OCR found that religiously affiliated employers were not health care entities under the Weldon amendment.[126]

Moreover, the Department states that their definition of "health care entity" is "not an exhaustive list" for concern that the Department would "inadvertently omit[ting] certain types of health care professionals or health care personnel."[127] Additionally, the proposed rule incorporates entities as defined in 1 USC 1 which includes corporations, firms, societies, etc.[128] States and public agencies and institutions are also deemed to be entities.[129] The Department's inclusion of entities who are primarily not engaged in the health care delivery system highlights the true purpose of the proposed rule, to permit a greater number of entities to interfere in the provider-patient relationship and deter a patient from making the best decision based on their circumstances, preferences, and beliefs.

Conclusion

National Association of Councils on Developmental Disabilities opposes the proposed rule as it expands religious refusals to the detriment of patients' health and well-being. We are concerned that these regulations, if implemented, will interfere in the patient-provider relationship by undermining informed consent. The proposed rule will allow anyone in the health care setting to refuse health care that is evidence-based and informed by the highest standards of medical care. The outcome of this regulation will harm communities who already lack access to care and endure discrimination.

Thank you for your attention to our comments. If you have any questions, please reach out to Erin Prangley, Public Policy Director at EPrangley@nacdd.org.

[126] Office for Civil Rights, Decision Re: OCR Transaction Numbers: 14-193604, 15-193782 & 15-195665, 4 (Jun. 21, 2016) (letter on file with NHeLP-DC office).
[127] 83 Fed. Reg. 3893.
[128] *Id.*
[129] *Id.*

Exhibit 119

NCLR NATIONAL CENTER FOR LESBIAN RIGHTS

WASHINGTON DC OFFICE
1776 K Street NW, Suite 852
Washington, D.C. 20006

March 26, 2018

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Protecting Statutory Conscience Rights in Health Care (RIN 0945-ZA03)

The National Center for Lesbian Rights (NCLR) writes to urge that the above-referenced Proposed Rule be withdrawn in its entirety, as it would endanger patient health and encourage widespread discrimination in health care delivery.

NCLR is a non-profit, public interest law firm that litigates precedent-setting cases at the trial and appellate court levels, advocates for equitable public policies affecting the lesbian, gay, bisexual, and transgender (LGBT) community, provides free legal assistance to LGBT people and their advocates, and conducts community education on LGBT issues. NCLR has been advancing the civil and human rights of LGBT people and their families across the United States through litigation, legislation, policy, and public education since its founding in 1977. We also seek to empower individuals and communities to assert their own legal rights and to increase public support for LGBT equality through community and public education. NCLR recognizes the critical importance of access to affordable health care for all people, and is concerned about the increasing use of religious exemptions to undercut civil rights protections and access to services for our community.

Our overarching objections to this Proposed Rule are twofold. First, it strays far from the primary mission of the Department of Health & Human Services. Our nation's premier public health agency should always maintain a focus on protecting the health of all, rather than seeking to empower health care providers to withhold care, in contravention of the core principles of informed consent and adherence to accepted standard of care. Second, it exceeds the agency's authority and was promulgated in violation of the Administrative Procedure Act. We provide further detail below.

I. The Proposed Rule disregards HHS's core mission

The Proposed Rule disregards the health care needs of patients and the core mission of the Department of Health & Human Services (HHS). The purpose of our nation's health care delivery system is to deliver health care to the people of this country. As the nation's largest public health agency, and one that is charged with furthering the health of all Americans, HHS is primarily charged with assisting patients in accessing care and health care providers in

delivering high-quality, culturally-competent care to everyone. Access to care, rather than denials of care, should be the goal. This Proposed Rule, in addition to being on questionable legal ground, focuses exclusively on purported rights of health care providers to turn patients away, with virtually no mention of the impact on patient health and well-being or on how access to care will be ensured. The priorities reflected in the Rule represent a sharp departure from the missions of HHS and its Office for Civil Rights (OCR) and should be withdrawn.

A. HHS should be trying to broaden access, not encourage denials of care

The HHS web site states: "It is the mission of the U.S. Department of Health & Human Services (HHS) to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services" (emphasis added).[1] The Proposed Rule departs significantly from that vision as well as the Office for Civil Rights (OCR's) mission to address health disparities and discrimination that harm patients.[2] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended, proposing a regulatory scheme that would be affirmatively harmful to many patients seeking care.

HHS, through OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[3] If finalized, however, the Proposed Rule will undermine HHS's mission of combating discrimination, protecting patient access to care, and eliminating health disparities. Through enforcement of civil rights laws, OCR has in the past worked to reduce discrimination in health care by ending discriminatory practices such as segregation in health care facilities based on race or disability, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[4]

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[1] *See* https://www.hhs.gov/about/index.html.

[2] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").

[3] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity, which would eventually become OCR, would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws, including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has in the past worked to reduce discrimination in health care.

[4] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy*

Despite this past progress, there is still much work to be done, and the Proposed Rule would divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[5] Black women are three to four times more likely than are white women to die during or after childbirth.[6] And the disparity in maternal mortality is growing rather than decreasing,[7] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resultant health disparities. Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care (we discuss this further below).

There is an urgent need for OCR to address these disparities, yet the Proposed Rule seeks instead to prioritize the expansion of existing religious refusal laws beyond their statutory requirements to create new religious exemptions. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.

B. The evidence does not support the existence of the problem the Proposed Rule purports to address

Rather than focusing on the overarching aim of ensuring that all people in this country have access to the health care they need, the Proposed Rule seeks to empower health care providers, whose very jobs are to deliver health care, to instead deny not only health care services but even information about services to which they might personally object. It would create additional barriers to care in a health care system already replete with obstacles, particularly for people with limited incomes or those who are LGBT.

Through prior rulemaking in this area, HHS has already created mechanisms by which any provider who believes they have been subject to discrimination in violation of any of the federal health care refusal statutes may file a complaint with OCR and seek redress. Complaints have been filed and resolved through this process. And HHS has the ability to decline to fund entities that engage in violations of these laws. Individual health care providers who wish to exercise a conscientious objection to participating in certain health care services have the ability to do so and HHS, through OCR, already has the tools it needs to protect those rights. Rather than seeking to engage in a sweeping new rulemaking effort that would inappropriately

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Rights of People Living with HIV/AIDS, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[5] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[6] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[7] *See id.*

shift the balance too far in the direction of care denial, the agency should instead devote its resources to expanding access to health care for all.

1. Discrimination against LGBT people in health care is pervasive

LGBT people, women, and other vulnerable groups already face significant barriers to getting the care they need.[8] The Proposed Rule will compound the barriers to care that LGBT individuals face, particularly the effects of ongoing and pervasive discrimination, by inviting providers to refuse to provide services and information vital to LGBT health.

As a civil rights organization that has been advocating for the LGBT community for over four decades, we at NCLR see firsthand the negative effects of stigma and discrimination on LGBT people seeking care. Despite significant gains in societal acceptance and legal protections, we still face hostility and ill treatment simply for being who we are, and sometimes the consequences are fatal. For example, NLCR currently represents the parents of a transgender youth who died by suicide after being denied appropriate care and discharged prematurely by a hospital in southern California.[9]

LGBT people of all ages continue to face discrimination in health care on the basis of their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes that "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[10] This surfaces in a wide variety of contexts, including physical and mental health care services.[11] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[12] They concluded that discrimination, as well as insensitivity or disrespect on the part of health care providers, were key barriers to health care access.[13]

There is a growing body of research documenting how LGBT people encounter barriers in the health care system and suffer disproportionately from a variety of conditions due to health care

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[8] *See, e.g.*, Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care; Sandy E. James et al., *The Report of the U.S. Transgender Survey* 93–126 (2016), www.ustranssurvey.org/report; 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; 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.

[9] *See* http://www.nclrights.org/cases-and-policy/cases-and-advocacy/case-prescott-v-rchsd/.

[10] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).

[11] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[12] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[13] *Id.*

access issues compounded by stigma and discrimination. In 2010, Lambda Legal found that fifty-six percent of lesbian, gay, and bisexual survey respondents (out of 4,916 total respondents) experienced health-care discrimination in forms such as refusal of health care, excessive precautions used by health-care professionals, and physically rough or abusive behavior by health-care professionals. Seventy percent of transgender and gender nonconforming respondents experienced the same, and sixty-three percent of respondents living with HIV/AIDS had experienced health-care discrimination. In addition, low-income LGBT people and LGBT people of color experienced increased barriers to health care. Approximately seventeen percent of low-income lesbian, gay, and bisexual respondents and twenty-eight percent of low-income transgender respondents reported harsh language from health-care providers compared to under eleven percent of LGB respondents and twenty-one percent of transgender respondents, overall.[14] The 2015 U.S. Transgender Survey found that 23 percent respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[15]

A recent survey conducted by the Center for American Progress found that among lesbian, gay, bisexual, and queer (LGBQ) respondents who had visited a doctor or health care provider in the year before the survey:

- 8 percent said that a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation;
- 6 percent said that a doctor or other health care provider refused to give them health care related to their actual or perceived sexual orientation;
- 7 percent said that a doctor or other health care provider refused to recognize their family, including a child or a same-sex spouse or partner;
- 9 percent said that a doctor or other health care provider used harsh or abusive language when treating them;
- 7 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[16]

Among transgender people who had visited a doctor or health care providers' office in the past year:

- 29 percent said a doctor or other health care provider refused to see them because of their actual or perceived gender identity;

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[14] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination against LGBT People and People with HIV*, 2010, https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isntcaring.pdf.
[15] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf.
[16] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care* (2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care.

- 12 percent said a doctor or other health care provider refused to give them health care related to gender transition;
- 23 percent said a doctor or other health care provider intentionally used the wrong name;
- 21 percent said a doctor or other health care provider used harsh or abusive language when treating them;
- 29 percent said that they experienced unwanted physical contact from a doctor or other health care provider (such as fondling, sexual assault, or rape).[17]

When LGBT patients are turned away or refused treatment, it is much harder—and sometimes simply not possible—for them to find a viable alternative. In the CAP study, nearly one in five LGBT 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. That rate was substantially higher for LGBT people living in non-metropolitan areas, with 41% reporting that it would be very difficult or impossible to find an alternative provider.[18] 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.

Health-care disparities in general are often more pronounced in rural areas in the United States, and this is further compounded for LGBT individuals, often due to a lack of cultural competency. This hinders physical and mental health providers from meeting the health needs of rural communities.[19] The lack of connection to positive, affirming resources also isolates LGBT youth, making them more susceptible to self-destructive behavior patterns.[20] Isolation continues into adulthood, when LGBT populations are more likely to experience depression and engage in high-risk behaviors.[21]

NCLR has been holding convenings of LGBT people in rural communities for the past several years, and we hear consistently about difficulties in accessing adequate health care. The challenges our community faces in these rural settings include having few providers with LGBT competency, difficulty maintaining health insurance coverage due to employment challenges, transportation difficulties to get to what medical providers there are, food deserts, and specific health conditions that are often more prevalent among LGBT people because of having to live with discrimination and social isolation, including poor eating habits, smoking, and substance abuse.

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[17] *Id.*
[18] *Id.*
[19] Cathleen E. Willging, Melina Salvador, and Miria Kano, "Pragmatic Help Seeking: How Sexual and Gender Minority Groups Access Mental Health Care in a Rural State," *Psychiatric Services* 57, no. 6 (June 2006): 871–4, http://doi.org/10.1176/ps.2006.57.6.871.
[20] Colleen S. Poon and Elizabeth M. Saewyc, "Out Yonder: Sexual-Minority Adolescents in Rural Communities in British Columbia," *American Journal of Public Health* 99, no. 1 (January 2009): 118–24, http://doi.org/10.2105/AJPH.2007.122945.
[21] Trish Williams et al., "Peer Victimization, Social Support, and Psychosocial Adjustment of Sexual Minority Adolescents," *Journal of Youth and Adolescence* 34, no. 5 (October 2005): 471–82, https://doi.org/10.1007/s10964-005-7264-x.

In rural areas, if care is denied for religious reasons, there may be no other sources of health and life-preserving medical care.[22] The ability to refuse care to patients would therefore leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[23] with over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[24] Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[25]

In addition to geographic challenges, the problems for patients presented by the expansion of refusal provisions in both federal and state law have been exacerbated by the growth in health care systems owned and operated by religious orders. Mergers between Catholic and nonsectarian hospitals have continued as hospital consolidation has intensified. Catholic hospitals and health systems must follow the church's Ethical and Religious Directives for Catholic Health Care Services ("Directives"), which prohibit a wide range of reproductive health services, such as contraception, sterilization, abortion care, and other needed health care.[26] Nonsectarian hospitals must often agree to comply with these Directives in order to merge with Catholic hospitals.[27]

Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women's care was delayed or they were transferred to other facilities at great risk to their health.[28] The reach of this type of religious refusal of care is growing with the proliferation of religiously affiliated entities that provide health care and related services.[29] New research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than are white women to give birth in Catholic hospitals.[30]

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[22] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[23] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).

[24] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.

[25] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations*, ECON. RESEARCH SERV. (2009), *available at* https://www.ers.usda.gov/publications/pub-details/?pubid=44427.

[26] U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf.

[27] Elizabeth B. Deutsch, *Expanding Conscience, Shrinking Care: The Crisis in Access to Reproductive Care and the Affordable Care Act's Nondiscrimination Mandate*, 124 Yale L. J. 2470, 2488 (2015).

[28] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

[29] *See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

[30] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

Refusals in the context of reproductive health care sometimes run in both directions – they prevent access to contraception and abortion, but also to assisted reproductive technologies (ART) to enable pregnancy. Not only does this infringe on individuals' right to information and care, for those with certain medical conditions it directly contravenes the standard of care. For individuals with cancer, for example, the standard of care includes education and informed consent around fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society.[31] Refusals to educate patients about or to provide ART, or to facilitate ART when requested, are contrary to the standard of care.

While religiously-based objections to contraception and abortion are well known and have posed access barriers for years, less evident is how these types of refusals can also affect the LGBT community. Not only are LGBT people affected by denials of reproductive health care, other types of medically necessary care, such a transition-related care, are also frequently refused.

Many religious health care providers are opposed to infertility treatments altogether or are opposed to providing it to certain groups of people such as members of the LGBT community.[32] Health care providers have even sought exemptions from state antidiscrimination laws to avoid providing reproductive services to lesbian parents.[33] For example, in one case, an infertility practice group subjected a woman to a year of invasive and costly treatments only to ultimately deny her the infertility treatment that she needed because she is a lesbian.[34] When doctors at the practice group recognized that the woman needed in vitro fertilization to become pregnant, every doctor in the practice refused, claiming that their religious beliefs prevented them from performing the procedure for a lesbian.[35] Because this was the only clinic covered by her health insurance plan, the woman had to pay out-of-pocket for the treatment at another clinic, which subjected her to serious financial harm.

The lack of clarity in the Proposed Rule could lead a hospital or an individual provider to refuse to provide ART to same-sex couples based on religious belief. For some couples, this

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[31] Alison W. Loren et al., *Fertility Preservation for Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update*, 31 J. CLINICAL ONCOLOGY 2500-10 (July 1, 2013); Ethics Committee of the American Society for Reproductive Medicine, *Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion*, 100 AM. SOC'Y REPROD. MED. 1224-31 (Nov. 2013), http://www.allianceforfertilitypreservation.org/_assets/pdf/ASRMGuidelines2014.pdf; Joanne Frankel Kelvin, *Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources*, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

[32] U.S. CONF. OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH SERVICES 25 (5th ed. 2009), *available at* http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf. (Directive 41 of the Ethical and Religious Directives for Catholic Health Care states: "Homologous artificial fertilization is prohibited when it separates procreation from the marital act in its unitive significance.")

[33] Douglas Nejaime et al., *Conscience Wars: Complicity-Based Conscience Claims in Religion and Politics*, 124 Yale L.J. 2516, 2518 (2015). *See*, e.g., *N. Coast Women's Care Med. Grp., Inc. v. San Diego Cnty. Superior Court*, 189 P.3d 959 (Cal. 2008) (on the potential impact of healthcare refusal laws on same-sex couples).

[34] *Benitez v. N. Coast Women's Care Med. Grp., Inc.*, 106 Cal. App. 4th 978 (2003); *see also* LAMBDA LEGAL, BENITEZ V. NORTH COAST MEDICAL GROUP (Jul. 1, 2001), http://www.lambdalegal.org/in-court/cases/benitez-v-north-coast-womens-care-medical-group.

[35] *Id.*

discrimination would increase the cost and emotional toll of family building. In some parts of the country, however, these refusals would be a complete barrier to parenthood. More broadly, these refusals deny patients the human right and dignity to be able to decide to have children, and cause psychological harm to patients who are already vulnerable because of their health status or their experience of health disparities.

Religiously-based refusals can also result in the denial of other medically necessary care to LGBT people, particularly those who are transgender and in need of gender-affirming services. The following is one example that we learned about through a call to our Legal Help Line:

- Carl,[36] a transgender man, needed to undergo a hysterectomy and oophorectomy as part of his medically-supervised transition. Working with his healthcare providers, Carl obtained insurance coverage for the procedure. His surgeon, who had privileges at several hospitals in the area, scheduled the procedure at the hospital that was nearest to Carl and the surgeon. That hospital happened to be a religiously-affiliated facility. A few days before the procedure was scheduled to occur, Carl was informed that he could not have the procedure done at the hospital. According to the surgeon, the decision was made by the hospital's Ethics Committee. The reason Carl was given for the decision was that "the hospital does not perform that type of hysterectomy." Due to the short notice of the cancellation, the surgeon was unable to get the procedure moved to another hospital.

The foregoing barriers and challenges are evident in the stories we are hearing from NCLR supporters who are alarmed by the prospect of this Rule, including the following comments that have been submitted already to HHS:[37]

- I and many of my community members struggle to afford healthcare as it is, even with full time jobs. I live in a rural area and even if you do have health insurance, access to healthcare is very difficult. I do not see how my sexual orientation, religion, or other parts of me that one might disagree with at a personal level has anything to do with my right to receive healthcare. This regulation, whatever its intentions, will give those who are discriminatory the ability to act on this in a way that can harm the community and disproportionately provide support based on personal differences. I fear this will only further drive people apart.

- As a retired nurse educator I find this proposed rule unethical, immoral, unconscionable & inhumane. All health professionals essentially take an oath to treat & or take care of any person regardless of their race/religion/age/sexual orientation/ethnic background. And women have a right to choose their own reproduction health care. I strongly oppose this rule which promotes discrimination & urge HHS to withdraw it.

[36] This incident was reported to NCLR Legal Help Line attorneys; the name has been changed to protect the caller's privacy.
[37] Some have been edited slightly for length and clarity.

- If this rule is allowed to exist, it will allow emergency room staff to turn away people maimed by car accidents, mass shootings and terrorist attacks. Do you really want to be waiting for life saving care as you are interviewed (interrogated) to determine that you are the "right" sort of person who aligns with a hospital staff member's religious beliefs? You could easily die as you try to prove that you are "worthy" of their care.

- I happen to be a health care provider and I see LGBT people in my practice regularly. I understand the disadvantages they face every day as they go to work, to school, and even at home in their families and communities. Access to health care is a critical problem for many people, and HHS should not be making the problem worse by inviting health care institutions and providers to turn people away based on religious or moral reasons.

- I am a US citizen, I am also Romani Hindu. I am an intersex female and lesbian. I greatly oppose any rules or laws that would allow any person to establish their personal religious views as a means to hold others as a lesser person. This archaic way of thinking does not create a peaceful and free nation. I live in America that is said to be a free nation. Yet I am not free simply because of who I am. I have a difficult time finding the heath care I need because of discrimination. I am a senior citizen of America and have been denied medical care. Giving any person the right to discriminate for any purpose does great harm to an entire country.

- I am an LBGTX woman, married and the mother of two adult children. I travel frequently for work and have paid into my company's health insurance system for over 40 years. While I'm fairly confident that wouldn't be refused treatment locally, the thought that I might be refused treatment during an emergency while I'm traveling because I am a gay woman is both appalling and frightening.

- I am a 75 year-old lesbian living in San Francisco. As an R.N. and an LCSW, I have worked in the healthcare field for my entire adult life. The proposed rule entitled "Protecting Statutory Conscience Rights in Health Care" would give permission to mistreat or not treat an entire group of citizens. This is outrageous! This would be against any oath that a healthcare provider has taken to provide healthcare to all - without exception. An individual's personal opinions or biases have no place in the healthcare field. HHS should not promote discrimination of any kind. I am sure this proposed rule would prove to be unconstitutional if tested in our courts - and it surely would be. This proposed rule should be withdrawn immediately! It's shocking that it's even been suggested.

- In many small communities there is a limited number of health care providers. Allowing this kind of bigotry and prejudice could be life-threatening to any number of people. I know of no religion that preaches withholding life-saving care from anyone. The whole idea of government sponsored bigotry is outrageous and about as un-American as you can get.

- In the last year alone, I had to be taken by ambulance to Emergency Rooms in Northern and Southern California due to a heart issue. I also had to go to an Emergency Room in

Rochester, NY. I dare to think what might have happened to me if the health care providers refused service because my same sex spouse was with me and they "objected" to our relationship.

- I fear we will return to the days where we could be refused health care because of who we love. In 2008, I had to carry legal papers with me to the emergency room so that my partner, before marriage was legal, could be informed about my illness and be involved in making decisions. We were lucky to have a nurse who was also lesbian and while she was on duty I had excellent care. One of my care givers was not happy that I had a female partner and excused himself from the room to send in another therapist a few hours later. We cannot go back, lives are at stake.

- I have personally known people who have come within inches of death from complications due to HIV/AIDS because of the neglect of a doctor based on that doctor's personal beliefs. Discrimination and personal beliefs should not factor in to medical treatment, ever.

- In our community there is a shortage of health care providers to begin with, and if you reduce the number of providers that LGBT people can use, people will die.

- My children (one of whom is still a minor) are part of the LGBTQ community, and your rule would allow physicians to deny them lifesaving medical treatment, should they fall ill or have a medical emergency, such as a car accident or appendicitis, because they are gay or trans. They could die in the waiting area of the ER while someone who would be willing to treat them is located, and brought to the hospital, or in transit to a hospital where someone would treat them. It would allow doctors providing preventative care like pap smears to turn away my trans son, so that he wouldn't be able to find out if he had ovarian cancer until it was too late. Or to deny them vaccines for preventable diseases, or even just the flu. It would allow pharmacists to deny my children a prescription for antibiotics, because they feel morally or religiously opposed to their "lifestyle choices." It could have allowed one of my best friends to die from the heart attack he had a few years ago, because he's married to another man - because he was taken to a Catholic hospital by the ambulance crew. If it happened again, and your rule is in place, that hospital, one of the largest and most comprehensive in coverage in our area, could start turning people away en mass, for simply not being Catholic. In a predominantly Mormon state, that means about half the population.

The fear expressed throughout these comments is palpable. LGBT people are all too familiar with discrimination and hostile treatment, including in health care settings, and inviting health care institutions and providers to turn away people and deny them care would exacerbate the widespread mistreatment experienced by many LGBT people in the health care system today.

2. The Proposed Rule fits a troubling pattern at HHS

We are concerned that this overemphasis on the right to deny care rather than the right to receive it reflects a broader orientation on the part of the agency. In 2017, HHS adopted rules – with no prior public comment – vastly expanding existing religious exemptions from the

ACA's requirement of birth control coverage. This was followed by a Request for Information (RFI) regarding supposed barriers to participation in health care by religious entities, a puzzling choice given the proliferation of religiously affiliated health care systems in this country. The FY 2018 – 2022 HHS Strategic Plan also overemphasized accommodating religious beliefs and moral convictions of health care providers, while failing to mention key populations (like LGBT people) or include any measurable goals, as such a document is supposed to do. Taken together, these issuances from HHS signal an alarming approach to public health, one that elevates the personal religious beliefs of some health care providers far above patients' well-being.

C. The Proposed Rule fails completely to address its impact on patients

The Proposed Rule is silent with regard to the needs of patients and the impact that expanding religious refusals can have on their health. It includes no limitations to its sweeping exemptions that would protect patients' rights under the law and ensure that they receive medically necessary treatment. Any extension of religious accommodation should always be accompanied by equally extensive protections for patients to ensure that their medical needs remain paramount, and that they are able to receive both accurate information and quality health services.

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care.[38] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions to bind the hands of providers and attempt to limit the types of care they can provide. This has profound implications for the core medical ethical precept of informed consent, and for the ability of health care providers to follow accepted standards of care for their patients.

1. Informed consent

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment.[39] This right relies on two factors: access to relevant and medically-accurate information about treatment choices and alternatives, and provider guidance based on generally

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[38] *See, e.g.*, Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf; *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report;.

[39] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality care.

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[40]The American Nursing Association similarly maintains that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[41] Pharmacists are also expected to respect the autonomy and dignity of each patient.[42]

The Proposed Rule purports to improve communication between patients and providers,[43] but in reality it will have the opposite effect, deterring open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. Informed consent is intended to address the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a "yes or no" question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition.[44] Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[45]

In order to ensure that patient decisions are based on free will, informed consent is essential to the patient-provider relationship. The Proposed Rule threatens this principle by inviting

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[40] *The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.
[41] *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.
[42] *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).
[43] 83 Fed. Reg. 3917.
[44] BEAUCHAMP & CHILDRESS, *supra* note 39; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).
[45] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian Health Service and the Sterilization of Native American Women*, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

institutions and individual providers to withhold information about services to which they personally object, without regard for the patient's needs or wishes.

2. Standards of care

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are not only important services in their own right, they are also part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[46] Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them. It is alarming that a public health agency would actively encourage compromising patient health by facilitating departures from accepted standards of care.

A 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[47] While some of these physicians might refer their patients to another provider who could provide the necessary care, another survey found that as many as one-third of patients (nearly 100 million people) may be receiving care from physicians who do not believe they have any obligations to refer their patients to other providers.[48] Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and they now control one in six hospital beds across the country.[49] The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found

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[46] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

[47] Debra B. Stulberg M.D. M.A., et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, J. GEN. INTERN. MED. 725-30 (2010) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.

[48] Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices*, NEW ENG. J. MED. 593–600 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/.

[49] Julia Kaye et al., *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives*, AM. CIVIL LIBERTIES UNION 22 (2017), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.[50]

As outlined below, there are significant questions regarding the authority of HHS to enforce the statutes cited in the Proposed Rule in the manner suggested. But even if the types of care denials this rule encourages are ultimately found to contravene federal law, we have grave concerns that the very promulgation of this Rule in its current form will encourage some health care providers and institutions to improperly restrict access to care for LGBT people, those seeking reproductive health care, and others, with harmful consequences. The ability to seek legal redress at a later date is cold comfort to a patient denied essential, even life-saving, care.

II. HHS has failed to establish its authority to issue the Proposed Rule

It is incumbent upon HHS to set forth with specificity the source of its purported authority to engage in this rulemaking, through which it seeks to reinterpret the scope of over two dozen federal statutes by, among other things, redefining key terms and adopting a wider array of enforcement tools. Absent such a detailed showing, the Proposed Rule should be withdrawn because, in addition to representing misguided and dangerous public health policy, it goes well beyond the authority of HHS and is therefore unlawful.

A. HHS has exceeded its rulemaking authority

The Proposed Rule exceeds HHS's authority under the various federal refusal statutes it references and seeks to enforce. An agency may not promulgate regulations that purport to have the force of law without delegated authority from Congress.[51] Yet none of the 25 statutory provisions cited by the Proposed Rule delegates authority to HHS to engage in rulemaking as contemplated in the Proposed Rule. Specifically, nothing within the 25 statutes cited by the Proposed Rule gives HHS the authority to require healthcare entities to provide assurances or certifications, to post the extensive notice included as Appendix A of the Proposed Rule, or to keep and make records available for review.[52] Nor does it give HHS the authority to conduct periodic compliance reviews or to subject healthcare entities to the full investigative process described in Section 88.7 of the Proposed Rule.[53]

The Department draws this purported authority not from the cited statutes but from its desire to implement a regulatory scheme "comparable to the regulatory schemes implementing other civil rights laws."[54] This desire arises from HHS's belief that the 25 cited statutes provide rights

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[50] Nadia Sawicki, *Mandating Disclosure Of Conscience-Based Limitations On Medical Practice*, 42 AM. J. OF LAW & MED. 85-128 (2016) *available at* http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.
[51] *Gonzales v. Oregon*, 546 U.S. 243, 274–75 (2006); *United States v. Mead*, 533 U.S. 218, 229–30 (2001); *Motion Picture Ass'n of Am., Inc. v. FCC*, 309 F.3d 796, 801 (D.C. Cir. 2002); *Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1371 (D.C. Cir. 1990)*Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 39–40 (D.D.C. 2014).
[52] *See* 83 Fed. Reg. at 3928–30.
[53] *Id.* at 3930–31.
[54] 83 Fed. Reg. 3904.

"akin to other civil rights to be free from discrimination on the basis of race, national origin, disability, etc."[55] Both the plain text and legislative history of these "other civil rights laws" distinguish them from the 25 statutes cited by the Proposed Rule, however. Each of the "other civil rights laws" cited by the Proposed Rule expressly authorizes HHS to promulgate regulations for their uniform implementation.

Title VI of the Civil Rights Act of 1964,[56] for example, which prohibits discrimination on the basis of race, color, or national origin in federal funding, states that "[e]ach Federal department and agency which is empowered to extend Federal financial assistance to any program or activity . . . is authorized and directed to effectuate the provisions of [Title VI] with respect to such program or activity by issuing rules, regulations, or orders of general applicability."[57] Title VI soon became the model for other nondiscrimination laws.[58]

Most recently, in Section 1557 of the Patient Protection and Affordable Care Act of 2009 (ACA), Congress clarified that the protections of Title VI, Title IX, the Age Discrimination Act, and Section 504 of the Rehabilitation Act of 1973 apply to all health programs or activities that receive federal financial assistance.[59] Congress explicitly granted HHS the authority to promulgate regulations to implement Section 1557.[60] Section 1553 of the ACA, which contains one of the refusal provisions cited by the Proposed Rule, does *not* contain such a grant.[61] Rather, Section 1553 gives HHS the authority to "receive complaints of discrimination" based on its provisions.[62] When Congress has explicitly granted an agency rulemaking authority in one section of a statute, the lack of such a grant in another section of the statute clearly indicates that Congress did not intend the agency to exercise rulemaking authority over that section.[63] The ACA conforms to the pattern Congress has followed for the past half-century: When it intends to grant HHS the kind of rulemaking authority claimed by the Proposed Rule, it does so expressly. The lack of such an explicit grant in any of the 25 cited statutes is

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[55] *Id.* at 3903.
[56] 42 U.S.C. 2000d *et seq*.
[57] Pub. L. No. 88-352, Title VI, § 602, 78 Stat. 252 (1964) (codified at 42 U.S.C. § 2000d-1).
[58] Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990, both of which prohibit disability discrimination, explicitly refer to Title VI's enforcement provisions. *See* 29 U.S.C. § 794a(a)(2) (Section 504); 42 U.S.C. § 12133 (ADA). The Age Discrimination Act of 1975 not only permitted but required the Department to promulgate regulations to carry out its nondiscrimination provisions. 42 U.S.C. § 6103(a)(1). Title IX of the Education Amendments Act of 1972, which prohibits sex discrimination in education, contained delegation language that exactly mirrors that of Title VI. 20 U.S.C. § 1682.
[59] *See* Pub. L. 111-148, Title I, § 1557 (2010) (codified at 42 U.S.C. § 18116(a)). Congress did not include conscience protections in Section 1557, strongly implying that it does not see them as being "akin to," 83 Fed. Reg. at 3904, or "on an equal basis" with "other civil rights laws," *id.* at 3896. See *Gen. Dynamics Land Sys., Inc. v. Cline*, 540 U.S. 581, 600 (2004) (noting that relationship with other federal statutes can be useful in statutory interpretation).
[60] 42 U.S.C. § 18116(c). The Department did so on May 18, 2016. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376 (May 18, 2016) (to be codified at 45 C.F.R. part 92). The final rule contains no mention of conscience protections.
[61] *See* 42 U.S.C. § 18113.
[62] *Id.*
[63] *See Amalgamated Transit Union*, 894 F.2d at 1371 ("[O]n the few occasions when Congress intended to give UMTA broad rulemaking authority . . . it did so expressly.").

therefore clear evidence that HHS does not have congressional authority to promulgate the Proposed Rule.

B. The Proposed Rule violates the Administrative Procedure Act

Even if HHS could promulgate a rule such as this based on its general authority to engage in rulemaking, that authority is not without limits. Under the Administrative Procedure Act (APA), "agency action, findings, and conclusions found to be… arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to a constitutional right," or "in excess of statutory jurisdiction, authority, or limitations" shall be held unlawful and set aside.[64] An agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[65] In addition, an agency can only change an existing policy if it provides a "reasoned explanation" for disregarding or overriding the basis for the prior policy.[66]

1. The Proposed Rule is arbitrary and capricious

In promulgating this Proposed Rule, HHS acted in an arbitrary and capricious manner in violation of the APA, and as a result the rule should be withdrawn in its entirety. The Proposed Rule is arbitrary and capricious on a number of grounds.

HHS fails to provide "adequate reasons" or a "satisfactory explanation" for this rulemaking based on the underlying facts and data. As stated in the Proposed Rule itself, between 2008 and November 2016, the Office of Civil Rights received ten complaints alleging violations of federal religious refusal laws; OCR received an additional 34 such complaints between November 2016 and January 2018. By comparison, during a similar time period from fall 2016 to fall 2017, OCR received *over 30,000 complaints* alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is not warranted.

HHS also fails to adequately assess the costs imposed by this Proposed Rule, both by underestimating quantifiable costs, and by neglecting to address the costs that would result from delayed or denied care. Under Executive Order 12866, when engaging in rulemaking, "each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs."[67] Under Executive Order 13563, an agency must "tailor its regulations to impose the least burden on society" and choose "approaches that maximize net benefits (including

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[64] 5 U.S.C. § 706(2)(A), (B), (C).
[65] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125 (June 20, 2016) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 103 (1983)).
[66] *Id.* at 2125-26.
[67] Executive Order 12866 on Regulatory Planning and Review (September 30, 1993).

potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."[68]

HHS has failed to take the appropriate steps to ensure that the Proposed Rule is consistent with applicable law and does not conflict with the policies or actions of other agencies. Under Executive Order 12866, in order to ensure that agencies does not promulgate regulations that are "inconsistent, incompatible, or duplicative with its other regulations of those of other Federal agencies," each agency must include any significant regulatory actions in the Unified Regulatory Agenda.[69] HHS failed to include any reference to this significant regulation in its regulatory plans, and therefore failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area. In addition, prior to publication in the Federal Register, the Proposed Rule must be submitted to the Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), to provide "meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order [12866] and do not conflict with the policies or actions of another agency."[70] According to OIRA's website, HHS submitted the Proposed Rule to OIRA for review on January 12, 2018, one week prior to the Proposed Rule being published in the Federal Register. Standard review time for OIRA is often between 45 and 90 days; one week was plainly insufficient time for OIRA to review the rule, including evaluating the paperwork burdens associated with implementing it. In addition, it is extremely unlikely that within that one week timeframe, OIRA could or would have conducted the interagency review necessary to ensure that this Proposed Rule does not conflict with other federal statutes or regulations.

The timing of the Proposed Rule also illustrates a lack of sufficient consideration. The Proposed Rule was published just two months after the close of a public comment period for a Request for Information closely related to this Rule.[71] The 12,000-plus public comments were not all posted until mid-December, one month before this Proposed Rule was released. Nearly all of the comments submitted at that time related to the subjects covered by the Proposed Rule—namely, the refusal of care by federally funded health care institutions or their employees on the basis of personal beliefs. This short period of time calls into question the comprehensiveness of the review of the Request for Information and whether the Proposed Rule was developed in an arbitrary and capricious manner.

The Proposed Rule also conflicts with several key federal statutes, as well as the U.S. Constitution. It makes no mention of Title VII,[72] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[73] With respect to religion, Title VII requires reasonable accommodation of

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[68] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Sec. 1 (b).
[69] Executive Order 12866, at Sec. 4(b),(c).
[70] *Id.* at Sec. 6(b).
[71] "Removing Barriers for Religious and Faith-Based Organizations To Participate in HHS Programs and Receive Public Funding," 82 Fed. Reg. 49300 (Oct. 25, 2017).
[72] 42 U.S.C. § 2000e-2 (1964).
[73] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm

employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[74] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[75]

Furthermore, the language in the Proposed Rule could put health care entities in the untenable position of being forced to hire people who intend to refuse to perform essential elements of the job for which they are being hired. For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling. It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

The Proposed Rule also conflicts with the Emergency Medical Treatment and Active Labor Act ("EMTALA"), which requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[76] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[77] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances – such as those experiencing an ectopic pregnancy or miscarriage - not receiving necessary care. The Proposed Rule fails to explain how entities will be able to comply with the new regulatory requirements in a manner consistent with the statutory requirements of EMTALA, making the Proposed Rule unworkable.

Finally, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant

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[74] *See id.*
[75] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.
[76] *See* 42 U.S.C. s 1295dd(a)-(c)
[77] *See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

religious exemptions to existing legal requirements and, in fact, bars granting an exemption when it would detrimentally affect any third party.[78] It requires an agency to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[79] The proposed exemptions clearly impose burdens on and harm others and thus, violate the clear mandate of the Establishment Clause.

In promulgating a regulation that is inconsistent with federal statutes and regulations, as well as the Constitution, HHS engaged in arbitrary and capricious rulemaking, and its conduct was further compounded by a failure by OIRA to engage in appropriate oversight and review. For these reasons, the Proposed Rule should be withdrawn.

2. The Proposed Rule is not in accordance with law and exceeds statutory authority

The Proposed Rule is also not in accordance with law because much of its language exceeds the plain parameters and intent of the underlying statutes it purports to enforce. It defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. Therefore, the Proposed Rule violates the APA and should be withdrawn.

For example, the Church Amendments prohibit federal funding recipients from discriminating against those who refuse to perform, or "assist in the performance" of, sterilizations or abortions on the basis of religious or moral objections, as well as those who choose to provide abortion or sterilization.[80] The statute does not contain a definition for the phrase "assist in the performance." Instead the Proposed Rule creates a definition, but one that is not in accordance with the Church Amendments themselves. The proposed definition includes participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity" and greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[81] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, could now assert a new right to refuse. As Senator Church stated from the floor of the Senate during debate on the Church Amendments: "The amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal

[78] U.S. Const. amend. I; *Cutter v. Wilkinson*. 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[79] *Cutter*, 544 U.S. at 720, 722; see also *Thornton*, 472 U.S. at 709-10.
[80] 42 USC 300a-7.
[81] 83 Fed. Reg. 3892.

to perform what would otherwise be a legal operation."[82] This overly broad definition opens the door for religious and moral refusals from precisely the type of individuals that the amendment's sponsor himself sought to exclude. This arbitrary and capricious broadening of the amendment's scope goes far beyond what was envisioned when the Church Amendments were enacted.

If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The Proposed Rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with applicable standards of care.

The definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information based on which an individual could get the care they need.[83] Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an individual or entity if the information given would lead to a service, activity, or procedure to which the provider objects.

Under the Coats and Weldon Amendments, "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[84] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[85] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but contravenes congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms HHS now attempts to insert.[86]

The Proposed Rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[87] Under this definition, virtually any member of the health care workforce could ostensibly refuse to serve a patient in any way.

The Weldon Amendment is expanded under the Proposed Rule by defining "discrimination" against a health care entity broadly to include a number of activities, including denying a grant

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[82] S9597, https://www.gpo.gov/fdsys/pkg/GPO-CRECB-1973-pt8/pdf/GPO-CRECB-1973-pt8.pdf (emphasis added). Senator Church went on to reiterate that "[t]his amendment makes it clear that Congress does not intend to compel the courts to construe the law as coercing religious affiliated hospitals, doctors, or nurses to perform surgical procedures against which they may have religious or moral objection." S9601 (emphasis added).
[83] 83 Fed. Reg. 3895.
[84] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[85] 83 Fed. Reg. 3893.
[86] The doctrine of expressio unius est exclusio alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[87] 83 Fed. Reg. 3894.

or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[88] Such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion and undermining non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[89] Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[90] In seeking to craft a regulatory scheme mirroring "other civil rights laws," HHS is in fact hampering enforcement of the very civil rights laws it claims to be emulating.

Moreover, the Proposed Rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs – the denial may be for any reason at all.[91] The preamble uses language such as "those who choose not to provide" or "would rather not" as justification for a refusal. This unbounded license to deny care is made more dangerous by the fact that the Proposed Rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services, or if services were denied, the basis for refusal. The Proposed Rule does not have any provisions that stipulate that patients must be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

The Proposed Rule also purports to equip OCR with a range of enforcement tools that it in fact lacks the authority to employ, including referring matters to the Department of Justice "for additional enforcement,"[92] something not contemplated within any of the statutes referenced in the Proposed Rule. These measures, combined with the impermissibly broad definitions and other inappropriately expansive interpretations of the underlying statutes, would have a chilling effect on the provision of a range of medically necessary health care services.

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[88] 83 Fed. Reg. 3892.
[89] *See, e.g., Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).
[90] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).
[91] 83 Fed. Reg. 3890-91.
[92] 83 Fed. Reg. 3898.

Conclusion

The Proposed Rule departs from the core mission of HHS, would undermine patient care, and is contrary to law. We therefore urge that it be withdrawn.

If you have any questions regarding these comments, please contact Julianna S. Gonen, PhD, JD, NCLR Policy Director, at jgonen@nclrights.org or 202-734-3547.

National Center for Lesbian Rights

Exhibit 120

National Center for TRANSGENDER EQUALITY

March 27, 2018

Office for Civil Rights, U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: NPRM on Religious Exemptions for Health Care Entities (RIN 0945-ZA03)

To Whom It May Concern:

The National Center for Transgender Equality (NCTE) submits the following comments to express our strong opposition to expanding exemptions for health care entities based on religious or moral objections.

Founded in 2003, NCTE is one of the nation's leading social justice organizations working for life-saving change for the over 1.5 million transgender Americans and their families. Over our years of advocacy, we have time and again seen the harmful impact that discrimination in health care settings has on transgender people and their loved ones, including discrimination based on religious or moral disapproval of who transgender people are and how they live their lives. Our experience has shown us that discrimination against transgender people in health care—whether it is being turned away from a doctor's office or emergency room, being denied access to basic care, or being mistreated and degraded simply because of one's transgender status—is widespread and creates significant barriers to care. The sweeping and excessive expansions to religious and moral exemptions sought by this rule go far beyond established law and threaten to severely exacerbate the barriers to care that transgender people and other vulnerable patient populations face.

We deeply respect and value freedom of religion, which is already protected by our Constitution, numerous federal statutes, and existing Department regulations. But refusing or obstructing access to medical care is a perversion of that cherished principle. In health care, patients must come first. By opening the door to health care refusals that go far beyond those permitted under federal law, this rule is harmful, unnecessary, and unsupported by federal law, and it would undermine the critical purposes of the Department's programs and the civil rights laws it is responsible for enforcing.

Simply put, the proposed rule is contrary to law and would harm patients. We urge the Department to reject this harmful and unnecessary rule.

I. Expanding religion-based exemptions can exacerbate the barriers to service access that transgender people and other vulnerable populations face.

For many Americans, including transgender Americans, discrimination in health care settings remains a grave and widespread problem and contributes to a wide range of health disparities. The proposed rule

1133 19th Street NW
Suite 302
Washington, DC 20036

202-642-4542
www.TransEquality.org

would exacerbate this urgent problem by encouraging actions that deny or obstruct access to timely medical care.

A. Transgender people face widespread discrimination in health care settings.

An estimated 0.6% of the U.S. adult population is transgender, representing 1.4 million adults over the age of 18, as well as hundreds of thousands of young Americans.[1] The medical and scientific community overwhelmingly recognizes that a person's innate experience of gender is an inherent aspect of the human experience for all people, including transgender people.[2] For example, the American Psychological Association states that having "deeply felt, inherent" gender identity that is different from the gender one was thought to be at birth is part of "healthy and normative" range of variation in human development found across cultures and across history.[3] The Department has previously recognized that "variations in gender identity and expression are part of the normal spectrum of human diversity."[4]

Many, though not all, transgender people experience a medical condition known as gender dysphoria. Gender dysphoria is a serious medical condition that is codified in the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM 5), which defines it as clinically significant distress or impairment related to an incongruence between one's experienced gender and the gender one was thought to be at birth.[5] Like anyone, transgender people need preventive care to stay healthy and acute care when they become sick or injured. Some may also need medical care to treat gender dysphoria. Under the treatment protocol widely accepted by the medical community, medically necessary treatment for gender dysphoria may require steps to help an individual transition from living as one gender to another.[6] This treatment, sometimes referred to as "transition-related care," may include

[1] Andrew R. Flores et al., *How Many Adults Identify as Transgender in the United States?* (2016), http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf. *See also* Jody L. Herman et al. *Age of Individuals who Identify as Transgender in the United States* (2017), https://williamsinstitute.law.ucla.edu/wp-content/uploads/TransAgeReport.pdf (estimating that 0.7% of people in the United States between the ages of 13 and 17, or 150,000 adolescents, are transgender).

[2] *See, e.g.*, Am. Psychological Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 AMERICAN PSYCHOLOGIST 832, 834-35 (2015), https://www.apa.org/practice/guidelines/transgender.pdf; Brief of American Academy of Pediatrics, American Psychiatric Association, American College of Physicians, and 17 Additional Medical and Mental Health Organizations in Support of Respondent, *G. G. v. Gloucester County Sch. Bd.*, No. 16-274 8–9 (Sup. Ct. *filed* March 2, 2017) (affirming that "[e]veryone—whether they are transgender or cisgender—develops awareness of their gender identity along a 'pathway'" with typical stages and that transgender identity is a normal variation of this development); Human Rights Campaign, Am. Acad. of Pediatrics, & Am. College of Osteopathic Pediatricians, *Supporting & Caring for Transgender Children* (2016), https://assets2.hrc.org/files/documents/SupportingCaringforTransChildren.pdf; World Prof. Ass'n for Transgender Health, *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* 16 (7th ed. 2011), https://www.wpath.org/publications/soc.

[3] Am. Psychological Ass'n, Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, *e*, 70(9):832, 834-35 (2015).

[4] Substance Abuse & Mental Health Servs., *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth* 1 (2015), https://store.samhsa.gov/shin/content/SMA15-4928/SMA15-4928.pdf.

[5] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 452 (5th ed. 2013).

[6] *See generally* World Prof. Ass'n for Transgender Health, *supra* note 2; Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 THE JOURNAL OF CLINICAL ENDOCRINOLOGY & METABOLISM 3869 (2017). *See also* Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), http://www.imatyfa.org/assets/ama122.pdf (recognizing WPATH *Standards* as "internationally accepted"); Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012),

counseling, hormone therapy, and/or a variety of possible surgical treatments, depending on the individualized needs of each patient.[7] It is the overwhelming consensus among major medical organizations—including the American Medical Association,[8] the American College of Physicians,[9] the American Psychological Association,[10] the American Psychiatric Association,[11] the American Academy of Family Physicians,[12] the Endocrine Society,[13] the American College of Obstetricians and Gynecologists,[14] and the World Professional Association for Transgender Health[15]—that transition-related treatments are medically necessary, effective, and safe when clinically indicated to alleviate gender dysphoria. For example, the American Psychiatric Association "[a]dvocates for removal of barriers to care…for gender transition treatment," emphasizing that "[s]ignificant and long-standing medical and psychiatric literature exists that demonstrates clear benefits of medical and surgical interventions to gender variant individuals seeking transition" and "[a]ccess to medical care (both medical and surgical) positively impacts the mental health of transgender and gender variant individuals."[16] Numerous studies and meta-analyses have demonstrated the significant benefits of transition-related care in the treatment of gender dysphoria.[17] Indeed, transition-related treatments are the only treatments that have been demonstrated to be effective in treating gender dysphoria.[18]

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http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf (citing WPATH *Standards*); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), http://www.apa.org/about/policy/transgender.aspx (same).

[7] *See* World Prof. Ass'n for Transgender Health, *supra* note 2 at 16.

[8] Am. Medical Ass'n, *supra* note 6.

[9] Am. College of Physicians, *Lesbian, Gay, Bisexual and Transgender Health Disparities: A Policy Position Paper from the American College of Physicians*, 163 ANNALS OF INTERNAL MEDICINE 135, 140 (2015).

[10] Am. Psychological Ass'n, *supra* note 6.

[11] Am. Psychiatric Ass'n, *supra* note 6.

[12] Am. Acad. of Family Physicians, *Resolution No. 1004: Transgender Care* (2012), https://www.aafp.org/dam/AAFP/documents/about_us/special_constituencies/2012RCAR_Advocacy.pdf

[13] Hembree et al., *supra* note 6.

[14] Am. College of Obstetricians & Gynecologists, *Committee Opinion No. 512: Health Care for Transgender Individuals*, 118 OBSTETRICS & GYNECOLOGY 1454 (2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.

[15] World Prof. Ass'n for Transgender Health, *supra* note 2.

[16] Am. Psychiatric Ass'n, *supra* note 6.

[17] *See, e.g.*, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*. J SEXUAL MEDICINE (Jan. 17 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services*, J. AFFECTIVE DISORDERS (Feb. 2018) Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature*, 28 INT'L REV. PSYCHIATRY 44 (2016); William Byne et al., *Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder*, 41 ARCHIVES OF SEXUAL BEHAVIOR 759 (2012); Marco Colizzi, Rosalia Costa, & Orlando Todarello, *Transsexual Patients' Psychiatric Comorbidity and Positive Effect of Cross-Sex Hormonal Treatment on Mental Health: Results from a Longitudinal Study*, 39 PSYCHONEUROENDOCRINOLOGY 65 (2014); Audrey Gorin-Lazard et al., *Hormonal Therapy is Associated with Better Self-Esteem, Mood, and Quality of Life in Transsexuals*, 201 J. NERVOUS & MENTAL DISORDERS 996 (2013); M. Hussan Murad et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 CLINICAL ENDOCRINOLOGY 214 (2010); Griet De Cuypere et al., *Sexual and Physical Health After Sex Reassignment Surgery*, 34 ARCHIVES OF SEXUAL BEHAVIOR 679 (2005); Giuloio Garaffa, Nim A. Christopher, & David J. Ralph, *Total Phallic Reconstruction in Female-to-Male Transsexuals*, 57 EUROPEAN UROLOGY 715 (2010); Caroline Klein & Boris B. Gorzalka, *Sexual Functioning in Transsexuals Following Hormone Therapy and Genital Surgery: A Review*, 6 J. SEXUAL MEDICINE 2922 (2009).

[18] *See, e.g.*, Substance Abuse & Mental Health Servs., *supra* note 3.

Despite the medical consensus regarding the necessity of transition-related care, many transgender people have struggled to get access to medically necessary care—including care recommended to treat gender dysphoria, as well as medical care for unrelated conditions. Numerous studies have documented the widespread and pervasive discrimination experienced by transgender people and their families in the health care system. For example, the 2015 U.S. Transgender Survey, a national study of nearly 28,000 transgender adults in the United States, found that:

- Just in the year prior to taking the survey, one-third (33%) of respondents who saw *any health care provider* during that year were turned away because of being transgender, denied treatment, physically or sexually assaulted in a health care setting, or faced another form of mistreatment or discrimination due to being transgender.[19]
- In the year prior to taking the survey, nearly one-quarter (22%) of respondents who visited a *drug or alcohol treatment program* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.[20]
- In the year prior to taking the survey, 14% of respondents who visited a *nursing home or extended care facility* where staff thought or knew they were transgender were denied equal treatment or service, verbally harassed, or physically assaulted there due to being transgender.[21]
- In the year prior to taking the survey, one-quarter (25%) of respondents *experienced a problem with their health insurance* related to being transgender. This included being denied coverage for treatments for gender dysphoria as well as being denied coverage for a range of unrelated conditions simply because they are transgender.[22]
- In the year prior to taking the survey, 23% of respondents *avoided seeking medical care* when they needed it because of fear of being mistreated, and 33% avoided seeking necessary health care because they could not afford it.[23]

The 2015 U.S. Transgender Survey also revealed patterns of marked health disparities affecting respondents. Respondents were approximately five times more likely than the general population to have been diagnosed with HIV, with elevated rates among people of color and in particular among Black transgender women, who were over 60 times more likely to be living with HIV than the general population.[24] Standard questions based on the K-6 Kessler Psychological Distress Scale revealed that transgender respondents were approximately eight times more likely than the general population to have experienced serious psychological distress in the month prior to taking the survey.[25] Further, respondents were nearly twelve times more likely to have attempted suicide in the previous year than the general population.[26] Rates of suicide attempts and psychological distress were particularly high among respondents who had faced barriers to accessing medical care and anti-transgender discrimination in health care and other settings.

[19] Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 96–97 (2016), www.ustranssurvey.org/report.
[20] *Id.* at 216.
[21] *Id.* at 219.
[22] *Id.* at 95.
[23] *Id.* at 98.
[24] *Id.* at 122.
[25] *Id.* at 105.
[26] *Id.* at 112.

Similarly, a nationally representative 2017 study found that transgender respondents faced high rates of discrimination in health care settings.[27] Out of those who had visited a doctor or health care provider in the previous year:

- Nearly one-third (29%) reported that a health care provider refused to see them because of their actual or perceived gender identity.
- One in eight (12%) said that a health care provider refused to provide them with care related to gender dysphoria.
- More than one in five (21%) said that a health care provider used harsh or abusive language when treating them.
- Nearly one-third (29%) experienced unwanted physical contact or sexual assault by a health care provider.

For many transgender people, especially those living outside of metropolitan areas, simply finding a different provider is not a viable option. Many transgender respondents to the 2017 study reported that it would be very difficult or impossible for them to find alternative providers to get the care they need if they were turned away by a health care provider. For example, nearly one-third (31%) of transgender respondents said it would be "very difficult" or "not possible" to find the same type of service at a different hospital and 30% said it would be "very difficult" or "not possible" to find the same type of service at a different community health center or clinic.[28]

Health disparities facing transgender people have been recognized in a major 2011 report of the National Academy of Medicine (then the Institute of Medicine),[29] and by the Department's Healthy People 2020 initiative.[30] These disparities do not reflect inherent pathology; as the American Psychiatric Association has stated, "[b]eing transgender or gender variant implies no impairment in judgment, stability, reliability, or general social or vocational capabilities; however, these individuals often experience discrimination due to a lack of civil rights protections for their gender identity or expression."[31] Discrimination and barriers to care exacerbate the marked health disparities affecting transgender individuals,[32] including by increasing transgender people's risk factors for poor physical and mental

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[27] 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.

[28] *Id.*

[29] Inst. 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.

[30] Dep't of Health & Human Servs., *Healthy People 2020: LGBT Health Topic Area* (2015), http://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health ("LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights.")

[31] Am. Psychiatric Ass'n, *supra* note 6.

[32] See, e.g., Ilan H. Meyer et al., *Demographic Characteristics and Health Status of Transgender Adults in Select US Regions: Behavioral Risk Factor Surveillance System, 2014*, 107 AM. J. PUB. HEALTH 582 (2017); Joint Comm'n, *Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the LGBT Community: A Field Guide* (2011), http://www.jointcommission.org/assets/1/18/LGBTFieldGuide.pdf.

health[33] and driving high rates of HIV.[34] Numerous studies have found that when transgender people are supported in their environment, including by accessing the health care they need without discrimination, the health disparities they experience decrease substantially.[35]

As leading medical organizations such as American Medical Association[36] and the American Psychological Association[37] have emphasized, robust laws protecting patients from discrimination are essential in addressing these disparities and reducing the barriers to care facing millions of Americans, including transgender Americans, while expanding religious exemptions can dangerously exacerbate those barriers to care. In response to the Department's recent Request for Information regarding "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding," numerous medical organizations expressed concerns with expanding religious exemptions in health care, including the American Psychiatric Association,[38] the American Psychological Association,[39] the American Medical Association,[40] the American Academy of Pediatrics,[41] and the American Academy of Nursing.[42]

B. Other vulnerable populations, including women, lesbian, gay, and bisexual people, communities of color, people with disabilities, and people with limited English proficiency, struggle to access adequate care.

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[33] Ctrs. for Disease Control & Prevention, *Lesbian, Gay, Bisexual, and Transgender Health* (2014), http://www.cdc.gov/lgbthealth/about.htm.

[34] Ctrs. for Disease Control & Prevention, *HIV and Transgender Communities* (2016), https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-transgender-brief.pdf.

[35] *See, e.g.*, Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth*, 56 J. AM. ACAD. CHILD ADOLESC. PSYCHIATRY 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities*, 137 PEDIATRICS (2016); Annelou L. C. de Vries et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS (2014).

[36] Am. Medical Ass'n, *Letter to Director Roger Severino* (Sept. 1, 2017), https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2017-09-01_Letter-to-Severino-re-Section-1557-Identity-Protection.pdf.

[37] Am. Psychological Ass'n, Comment Letter on Request for Information on Patient Protection and Affordable Care Act: Reducing Regulatory Burdens and Improving Health Care Choices to Empower Patients (July 12, 2017), https://www.regulations.gov/document?D=CMS-2017-0078-2528.

[38] Am. Psychiatric Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 22, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-10700.

[39] Am. Psychological Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-8429.

[40] Am. Medical Ass'n, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 17, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327https://www.regulations.gov/document?D=HHS-OS-2017-0002-7327.

[41] Am. Acad. of Pediatrics, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 21, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-12098.

[42] Am. Academy of Nursing, Comment Letter on Request for Information on Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding (Nov. 24, 2017), https://www.regulations.gov/document?D=HHS-OS-2017-0002-11760.

Similarly, a wide range of vulnerable communities face routine discrimination and barriers to care. While the Department's primary focus should be on eliminating these barriers to care, its proposed rule does the opposite and threatens to exacerbate them.

For example, despite the substantial progress made after the enactment of the Affordable Care Act, health care discrimination against women remains rampart.[43] Many health plans continue to exclude treatments that are primarily required by women, such as coverage of pregnancy-related conditions.[44] In many parts of the country, access to reproductive health services is sparse, and some hospitals refuse to treat patients experiencing miscarriages, ectopic pregnancies, and other conditions affecting reproductive health, even when the condition is emergent or the patient has nowhere else to go.[45] Even among providers who do offer reproductive health services, many refuse to provide them to women who are unmarried or who do not conform to sex stereotypes, or subject women to harassment and mistreatment.[46] Women are also more likely than men to receive substandard care for conditions such as heart disease or chronic pain,[47] which further limits women's options when seeking a provider who will meet their needs.

Gender disparities in health care disproportionately affect women of color. Women of color are particularly likely to experience discrimination and harassment in health care.[48] Research has found that women of color face significant barriers to reproductive care: for example many respondents were neglected by medical staff, received inadequate or misleading information about the range of treatment options they had for labor and delivery, or were stigmatized and shamed by medical providers based on racial stereotypes.[49] In many states, women of color are more likely than white women to receive their care at Catholic hospitals, whose ethical directives regarding reproductive care often prevent patients from receiving treatment consistent with medical standards of care.[50] Inadequate access to reproductive care is one of the main drivers in persistent racial disparities in maternal mortality—with Black women being three to four times more likely to die in childbirth than white women[51]—as well as higher rates of

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[43] *See, e.g.*, Nat'l Women's Law Ctr., *Turning to Fairness* (2012), https://nwlc.org/wp-content/uploads/2015/08/nwlc_2012_turningtofairness_report.pdf.

[44] *See, e.g.*, Nat'l Women's Law Ctr., *NWLC Section 1557 Complaint: Sex Discrimination Complaints Against Five Institutions*, http://www.nwlc.org/resource/nwlc-section-1557-complaint-sex-discrimination-complaints-against-five-institutions (Section 1557 complaints filed against five institutions that exclude pregnancy coverage).

[45] *See, e.g.*, Nat'l Women's Law Ctr., *Health Care Refusals Harm Patients: The Threat to Reproductive Health Care* (2014), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/refusals_harm_patients_repro_factsheet_5-30-14.pdf.

[46] *Id.*

[47] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. AM. HEART ASS'N 1 (2015); Jennifer A. Kent, Vinisha Patel, & Natalie A. Varela, *Gender Disparities in Health Care*, 79 MOUNT SINAI J. MED. 555 (2012); Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29 J. LAW, MED. & ETHICS, 13 (2001); Inst. of Med., *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* 75–77 (2011).

[48] Nat'l Public Radio, Robert Wood Johnson Foundation, & Harvard T. H. Chan School of Public Health, *Discrimination in America: Experiences and Views of American Women* (2017), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/21/2017/12/NPR-RWJF-HSPH-Discrimination-Women-Final-Report.pdf.

[49] Ctr. for Reproductive Rights, Nat'l Latina Inst. for Reproductive Health, & SisterSong Women of Color Reproductive Justice Collective, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf.

[50] Kira Shepherd & Katherine Franke, *Bearing Faith: The Limits of Catholic Health Care for Women of Color* (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[51] Ctr. for Reproductive Rights et al., *supra* note 49.

cervical cancer and HIV among women of color.[52] People of color of all genders often face prohibitive barriers to care: for example, people of color are significantly more likely to be uninsured,[53] and people of color in rural America are also more likely to live in an area with a shortage of health professionals, leaving many with no alternatives if they are refused care.

People with disabilities also continue to face discriminatory barriers to care, including physical barriers in health care settings, mistreatment by health care providers, and the unavailability or inaccessibility of health care providers who are competent in meeting their health care needs. These barriers are often especially heighted for people with disabilities who live or spend much of their time in provider-controlled settings, including Medicaid-funded Home and Community-Based Services, where they receive supports and services for daily living, including assistance with dressing, grooming, bathing, transportation to social and health-related appointments, and participating in recreational activities. These services can be intensely intimate and implicate a person's right to pursue and maintain romantic relationships, build a family, and make basic decisions about one's life. In such settings, expansive religious exemptions that encourage aides to interfere with someone's health care can be extremely harmful for the health of a person with a disability and their ability to exercise their right to basic self-determination.

Lesbian, gay, and bisexual people (LGB) experience frequent discrimination when accessing health-related services. For example, a recent study found that 8% of LGB respondents reported that a doctor or other health care provider refused to see them because of their sexual orientation, and 7% experienced unwanted physical contact by a health care provider.[54] Many LGB people, especially those in rural areas, report that finding an alternative provider if they are refused treatment or harassed would be very difficult or even impossible.[55] Additionally, many LGB people struggle to access reproductive and sexual health services, including fertility services and HIV prevention treatments such as pre-exposure prophylaxis (PrEP). Inadequate access to care contributes to significant health disparities affecting the LGB

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[52] *See, e.g.,* Ctrs. for Disease Control & Prevention, *Cervical Cancer Rates by Rates and Ethnicity* (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm; *HIV Among Women* (March 9, 2018), https://www.cdc.gov/hiv/group/gender/women/index.html (noting that at the end of 2015, 59% of women living with diagnosed HIV were Black, 19% were Latina, and 17% were white, and that Black women were more likely to contract HIV through sexual contact than white women).

[53] Kaiser Family Found., *Uninsured Rates for the Nonelderly by Race/Ethnicity* (2016), https://www.kff.org/uninsured/state-indicator/rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

[54] Mirza & Rooney, see *supra* note 27. *See also* Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf; Ning Hsieh & Matt Ruther, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities in Access to Care*, 36 HEALTH AFFAIRS 1786 (Oct. 2017), https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.0455?journalCode=hlthaff; Human Rights Watch, *All We Want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States* (2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[55] Mirza & Rooney, see *supra* note 27 (finding that 18% of LGBT people overall and 41% of LGBT people living outside of metropolitan areas report that it would be "very difficult" or "impossible" to find equivalent treatment at another hospital if they were to be turned away).

population,[56] including higher prevalence of disabilities and chronic conditions,[57] certain cancers,[58] cardiovascular disease,[59] and depression, anxiety, and other mental health conditions.[60] Barriers to accessing care also contribute to high rates of HIV infection among gay and bisexual men, who account for 56% of all people living with HIV in the United States and 70% of new HIV infections.[61]

C. *Transgender people and other vulnerable communities already face barriers to care based on the personal beliefs of health care workers or administrators.*

The personal beliefs of health care providers, administrators, and others in the health care industry have too often been used to deny individuals access to health care and other critical services—a problem that can be significantly worsened by expanding existing exemptions. For example, religious or moral disapproval has been invoked to refuse to provide infertility and reproductive care,[62] treat patients with HIV,[63] treat a newborn because of her parents' same-sex relationship,[64] and provide emergency services and other care for people who are suffering miscarriages.[65] Religious objections have also been invoked to deny transgender people access to medical care—both care related and unrelated to gender transition—or subject transgender people to degrading or abusive treatment in medical settings. Consider the following examples:

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[56] *See generally* Dep't of Health & Human Servs., *supra* note 30.

[57] David J. Lick, Laura E. Durso, & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERSPECTIVES ON PSYCHOLOGICAL SCIENCE 521 (2013), http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities.

[58] *Id.*; Jennifer Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals in the U.S.* (2016), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.

[59] *Id.*

[60] *Id.*; Human Rights Campaign et al., *Health Disparities Among Bisexual People* (2015), http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

[61] Ctrs. for Disease Control & Prevention, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* (2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

[62] Casey Ross, *Catholic Hospitals are Multiplying, Boosting Their Impact on Reproductive Health*, SCIENTIFIC AMERICAN (Sept. 14, 2017), https://www.scientificamerican.com/article/catholic-hospitals-are-multiplying-boosting-their-impact-on-reproductive-health-care; Nat'l Women's Law Ctr., *supra* note 45; *see also North Coast Women's Care Medical Grp., Inc. v. San Diego County Superior Court*, 189 P.3d 959, 959 (Cal. 2008).

[63] *See, e.g.*, Complaint, *Simoes v. Trinitas Reg'l Med. Ctr.*, No. UNNL-1868-12 (N.J. Super. Ct. *filed* May 23, 2012); Nat'l Women's Law Ctr., supra note 45.

[64] Abby Phillip, *Pediatrician Refuses to Treat Baby with Lesbian Parents and There's Nothing Illegal About It*, WASH. POST (Feb. 19, 2015), https://www.washingtonpost.com/news/morning-mix/wp/2015/02/19/pediatrician-refuses-to-treat-baby-with-lesbian-parents-and-theres-nothing-illegal-about-it; *see also* Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop et al. v. Colo. Civil Rights Comm'n et al.*, No. 16-111, 17–19 (Sup. Ct. *filed* Oct. 30, 2017).

[65] Am. Civil Liberties Union, *Health Care Denied: Patients and Physicians Speak out About Catholic Hospitals and the Threat to Women's Health and Lives* (2016), https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied; Nat'l. Women's Law Ctr., *Denied Care When Losing a Pregnancy: Pharmacies Refuse to Fill Needed Prescriptions* (Apr. 16, 2015), http://www.nwlc.org/our-blog/denied-care-when-losing-pregnancy-pharmacies-refuse-fill-needed-prescriptions; Nat'l Women's Law Ctr., *Below the Radar: Health Care Providers' Religious Refusals Can Endanger Pregnant Women's Lives and Health* (2011), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2015/08/nwlcbelowtheradar2011.pdf; Samantha Lachman, *Lawsuits Target Catholic Hospitals for Refusing to Provide Emergency Miscarriage Management*, HUFFINGTON POST (June 10, 2016), https://www.huffingtonpost.com/entry/catholic-hospitals-miscarriage-management_us_5759bf67e4b0e39a28aceea6.

> As my being transgender is a relevant piece of medical information…I revealed this information to [the doctor] when he entered the treatment room. His immediate response was, "I believe the transgender lifestyle is wrong and sinful." … The rest of the time between the examination and him writing the prescription, he asked questions about how transgender women find sexual intimacy. As he had yet to hand over the prescription, I felt compelled by the power dynamic to provide answers to questions I would normally tell an asker are none of his or her business…. [I]t was very creepy having this conversation with this person, and I felt I had the filthy end of the stick and was being subordinated by this doctor because he felt he could. – Karen S.[66]

> My Dignity Health insurance covered my hormones (because my doctor did not specifically note it as trans-related), and scheduled my top surgery before suddenly cancelling their coverage. Someone at their company had "connected the dots" and realized I was seeking transition-related services, which they denied due to their company's Catholic values. I was forced to pay for the surgery out of pocket, destroying my family's finance and putting me in considerable debt.[67]

> I was told by [mental health] professionals that I can only be "fixed" by "accepting Jesus" and denying who I really am when I sought assistance with beginning transition.[68]

In addition, the personal beliefs of hospital administrators and other health care workers have been used to interfere with doctors' exercise of their medical judgment. Some hospitals have invoked their religious affiliation to not only refuse to provide emergency care related to miscarriages, transition-related medical care, and other needs, but also to prevent doctors from providing those treatments at the hospital, in spite of those doctors' best medical judgment.[69] For example, in 2016 a New Jersey hospital approved and scheduled Jionni Conforti's hysterectomy, then abruptly cancelled the procedure at the last minute and refused to allow his surgeon to perform it when an administrator discovered the patient was transgender despite his doctor's determination that the procedure was medically necessary.[70] These practices are especially concerning in light of the rapidly growing number of religiously affiliated hospitals. For example, the number of Catholic hospitals—which represent the largest denomination in the health care field—has increased by 22% since 2001, and Catholic hospitals now own one in six hospital beds across the country.[71] Catholic hospitals must follow religious directives that often restrict the provision of certain treatments, including for emergency contraception, sterilization, abortion, fertility services, and ectopic

[66] Amicus Brief of Transgender Legal Defense and Education Fund et al., *Masterpiece Cakeshop et al. v. Colo. Civil Rights Comm'n et al.*, No. 16-111, 11 (Oct. 30, 2017).
[67] This quotation has been excerpted from a story shared by a 2015 U.S. Transgender Survey respondent after completing of the survey.
[68] This quotation has been excerpted from a story shared by a 2015 U.S. Transgender Survey respondent after their completion of the survey.
[69] For example, complaints have been filed against Catholic hospitals for refusing to allow doctors to provide care to transgender patients that the doctors are regularly allowed to provide for non-transgender people. *See, e.g.*, Complaint, *Hastings v. Seton Med. Ctr.*, No. CGC-07-470336 (Cal. Sf. Super. Ct. Dec. 19, 2007) (case settled). *See also Health Care Denied*, *supra* note 65.
[70] *Conforti v. St. Joseph's Healthcare System*, No. 2:17-cv-00050-JLL-JAD (D.N.J. filed Jan. 5, 2017).
[71] Lois Uttley & Christine Khaikin, *Growth of Catholic Hospitals: 2016 Update of the Miscarriage of Medicine Report* (2016), http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=54%2Fj8Gp90FWPtm7ExSkDGRuC77o%3D.

pregnancies.[72] Providers at such hospitals often find that they are unable to provide the standard of care for treatments such as miscarriage managements,[73] and one study of physicians working at religiously affiliated hospitals found that nearly one in five (19%) experienced a conflict between the religious directives of their hospital and their ability to practice in accordance with medical standards and their clinical judgment.[74]

Religious beliefs have also been invoked to justify refusals to provide critical human services for lesbian, gay, bisexual, and transgender (LGBT) individuals and families, as well as unmarried parents. The potential for harmful discrimination justified by religious beliefs is further illustrated by countless cases of religion being cited as a basis for denial of service or humiliating treatment toward LGBT people in restaurants, hotels, retail stores, and by individual government employees.[75]

For many patients, such refusals do not merely represent an inconvenience: in many cases, they can result in necessary or even emergent care being delayed or denied outright, putting their health and in some instances their lives at risk. These refusals are particularly dangerous in situations where individuals have limited options, such as in emergencies, when needing specialized services, in many rural areas,[76] or in areas where religiously affiliated hospitals are the primary or sole hospital serving a community.[77]

Expanding exemptions beyond established law as the proposed rule attempts to do—and encouraging service providers receiving federal funds to discriminate against intended program beneficiaries—would aggravate these harms even further. Permitting a broader range of service providers that receive taxpayer money to use a religious or moral litmus test to determine which services they provide and who receives care would result in many patients in need being denied access to medical care and other essential

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[72] *See* U.S. Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (2009), http://www.usccb.org/issues-and-action/human-life-and-dignity/health-care/upload/Ethical-Religious-Directives-Catholic-Health-Care-Services-fifth-edition-2009.pdf; Lois Uttley et al., *Miscarriage of Medicine: The Growth of Catholic Hospitals and the Threat to Reproductive Health Care* (2013), http://static1.1.sqspcdn.com/static/f/816571/24079922/1387381601667/Growth-of-Catholic-Hospitals-2013.pdf?token=O2KPmDeCHsArsY1wqp0wFBigKC4%3D.

[73] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458.

[74] Debra B. Stulberg et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, 25 J. GENERAL INTERNAL MED. 725–30 (2010), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970.

[75] *See, e.g.*, Amicus Brief of Lambda Legal Defense and Education Fund et al., *Masterpiece Cakeshop*, No. 16-111 (documenting instances of discrimination against LGBT people, including discrimination based on religious objections, in a variety of settings); Amicus Brief of National LGBTQ Task Force, et al., *Masterpiece Cakeshop*, No. 16-111; Amicus Brief of Transgender Legal Defense and Education Fund et al., *Masterpiece Cakeshop*, No. 16-111 (same); Amicus Brief of Transgender Law Center et al., *Masterpiece Cakeshop*, No. 16-111, 12–13 (Sup. Ct. filed Oct. 30, 2017) (same).

[76] People living in rural areas often struggle to access care due to a variety of factors, including physician shortages, financial and geographic barriers to transportation, and a lack of available specialists who can meet their needs. *See, e.g.*, Martin MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH 1531 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483; Carol Adaire Jones et al., *Health Status and Health Care Access of Farm and Rural Populations*, U.S. DEP'T OF AGRIC. ECON. RESEARCH SERV. (2009), https://www.ers.usda.gov/publications/pub-details/?pubid=44427; Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region*, 40 HEALTH SERVS. RESEARCH 135 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130; Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources*, 20 J. OF WOMEN'S HEALTH 1743 (Nov. 2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064.

[77] *See e.g., Health Care Denied*, *supra* note 65; Uttley et al., *supra* note 72.

services—jeopardizing the welfare of many intended HHS program recipients and compromising the Department's ability to meet its legal obligations and fulfil its mission.

II. Expanding exemptions undermines the Department's mandate to protect the health and well-being of all Americans.

Reducing discrimination and other barriers to accessing health care services, as well as reducing the accompanying health disparities, is core to the Department's mission and its obligations under laws authorizing its programs. Weakening protections and limiting program access by expanding religion-based exemptions fundamentally runs contrary to this mission.

The Department's core mission is to "enhance and protect the health and well-being of all Americans…by providing for effective health and human services."[78] The foremost purpose of the Department is to provide for services and supports for individuals and communities who need them—a purpose that is statutorily prescribed by Congress in the statutes authorizing many of the Department's programs.[79] Ensuring that beneficiaries of Department programs and other patients have fair and equal access to services and reducing barriers to those services is an inseparable and necessary component of this responsibility. The Department's ability to ensure equal, nondiscriminatory access to services would be significantly weakened by the proposed rule. In order to meet its legal obligations and its statutory mission, HHS must prioritize the needs and rights of patients over those of organizations seeking federal funds. Creating new or expanded exemptions for recipients of federal funds at the cost of patients' access to health services prevents the Department from meeting its responsibilities to HHS program beneficiaries and patients around the country.

Protecting religious freedom is an important value, and many health care providers with deeply held religious or moral beliefs have played important roles in addressing our nation's health care needs. Yet the driving force of this value is the core constitutional principle of separation of church and state—a principle that is fundamentally undermined by the expansion of religious exemptions in health care. Health care providers, entities, and grantees should be allowed—and *are* allowed under current practices and policies—to maintain their distinct religious identities when providing health care services, so long as they comply with generally applicable requirements, including nondiscrimination laws, that exist to protect patients. Protecting the right to practice religion does not require the sweeping expansion of religion-based exemptions that this proposed rule attempts to implement, which would amount to government-funded discrimination and subvert HHS' mission and compelling interest in promoting public health and wellbeing.

III. The exemptions proposed in the rule go far beyond what the applicable statutes permit and exceed the Department's authority.

[78] Dep't. of Health & Human Servs., *About HHS* (2017), https://www.hhs.gov/about/index.html.
[79] *See*, *e.g.*, 34 U.S. Code § 11201 (establishing Runaway and Homeless Youth programs because "youth who have become homeless or who leave and remain away from home without parental permission… are urgently in need of temporary shelter and services").

The Department has the authority and responsibility to enforce laws as they are written, including laws creating and delimiting religious and moral exemptions. This rule, however, proposes exemptions that are far broader than permitted under the statutes that the Department cites. By redefining key terms, eliminating important limitations and requirements included in the law, and applying statutes outside of their intended scope, the proposed rule attempts to significantly expand existing exemptions. The Department does not have the statutory authority to expand or create new religious exemptions to its statutorily prescribed programs beyond the exemptions permitted by statutes. Reading additional exceptions into a statute where Congress already contemplated and enumerated specific ones, contrary to fundamental principles of statutory construction, is in excess of the statutory authority provided in the laws the Department seeks to enforce.[80]

A. *The Department's regulation proposes an impermissible and harmful reinterpretation of the Church Amendments.*

The Department's rule proposes a reinterpretation of the Church Amendments that broadens their impact far beyond what the statute permits, potentially allowing a range of refusals that would severely compromise patients' access to medically necessary care.

Redefinition of "assist in the performance"

One of the most concerning transformations proposed by this regulation is the reinterpretation of what it means to "assist in the performance" of a procedure. In the 2008 rule, the Department defined the term as the participation in "any activity with a reasonable connection" to a procedure to which an individual objects.[81] This definition itself is so broad that it could be applied to services and forms of "assistance" even beyond those contemplated by Congress when the law was enacted. The current rule, however, attempts to expand the application of the Church Amendments even further than the 2008 rule did by defining the statutory term to mean "any activity with an *articulable* connection" to a procedure to which an individual objects.[82]

Although the preamble claims that this definition "mirrors the definition used for the term in the 2008 Rule,"[83] the definition is in fact an attempt to radically expand potential refusals. By allowing health care workers to refuse to engage in activities with a merely "articulable" connection to the service to which a provider or entity has an objection, the proposed rule opens the door to refusals to perform activities whose asserted nexus to the procedure being objected to is greatly attenuated and patently unreasonable, as long as it can be put into words.[84] Individuals wishing to obstruct access to care could seek to invoke

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[80] *See, e.g., U.S. v. Smith*, 499 U.S. 160 (1991).
[81] 45 C.F.R. § 88 (2008).
[82] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3923 (proposed Jan. 26, 2018) (to be codified at 45 C.F.R. pt. 88) [hereinafter Proposed Rule].
[83] *Id.* at 3892.
[84] *Compare, e.g., Erzinger v. Regents of Univ. of Cal.*, 137 Cal. App. 3d 389, 394 (Ct. App. 1982), *cert. denied* 462 U.S. 1133 (1983) ("The proscription [of the Church Amendments] applies only when the applicant must participate in acts

the rule to refuse to perform functions whose connection to a sterilization or abortion is extremely remote—such as bringing a meal to a patient after a procedure, handling scheduling tasks that may include booking follow-up appointments for sterilization or abortion procedures, or preparing a patient room. The proposed definition may also be invoked by health care workers or entities who refuse to treat unrelated conditions simply because a patient has had an abortion or sterilization procedure or may have one in the future. For example, it may be invoked by a cardiologist, oncologist, or even an emergency room doctor—as well as nurses, other medical staff, and administrative staff—to refuse to treat a patient for an unrelated condition because they object to asking about or taking into account an abortion or sterilization procedure that a patient has had in the past or intends to have in the future.

Implied redefinition of "sterilization"

The expanded exemptions proposed in the rule might even be construed to permit refusals related to medical treatments that are needed to treat a disease or disorder that may have a merely *incidental* effect of impacting fertility, including certain types of treatments for gender dysphoria. Although the Church Amendments were never intended to reach such medical treatments, the breadth and vagueness of several provisions in the proposed rule may be interpreted to support such an application. For example, twice in the proposed rule, the Department cites *Minton v. Dignity Health*, a case involving denial of care for gender dysphoria, as a purported example of a violation of existing religious exemptions.[85] In this case, a hospital abruptly canceled a hysterectomy for a patient, Evan Minton, after discovering he was transgender and that the procedure was recommended to treat gender dysphoria. The procedure was cancelled in spite of Mr. Minton's doctor's objections and previous determination that the treatment was medically necessary.[86] The same hospital routinely permitted Mr. Minton's physician and other physicians to perform hysterectomies—and in fact, his doctor performed another hysterectomy at the hospital for a non-transgender patient on the very same day that Mr. Minton's hysterectomy was scheduled[87]—but it refused to allow Mr. Minton's procedure to be performed because hospital administrators asserted a religious objection to the use of the procedure to treat gender dysphoria. While Mr. Minton was fortunate to be able to reschedule his procedure—with the same surgeon—at another hospital, many patients who are so abruptly refused care are not so lucky and may face medical complications from delayed treatment.

Applying the Church Amendments in this context—as the Department's citation to the *Minton* case implies—would exceed and contradict the plain meaning of the statute. Like treatments for many other conditions, certain treatments for gender dysphoria, such as hormone treatments and certain surgeries, can have an incidental effect of temporarily or permanently reducing fertility and in some cases eliminating fertility entirely. The primary purpose of such procedures, however, is not to sterilize, but to treat an unrelated medical condition. Similarly, a range of other conditions have treatments that can lead to sterilization. For example, forms of chemotherapy and certain other cancer treatments can and in some cases will necessary lead to permanent sterilization, and many medications, including a variety of antibiotic and seizure control medications, can also have an incidental effect of reducing or eliminating fertility. If religious or moral exemptions related to sterilization were construed to encompass treatments

related to the actual performance of abortions or sterilizations. Indirect or remote connections with abortions or sterilizations are not within the terms of the statute.").

[85] Proposed Rule, 83 Fed. Reg. at 3888–89.

[86] Complaint at 6–7, *Minton v. Dignity Health*, No. 17-558259 (Calif. Super. Ct. *filed* Apr. 19, 2017).

[87] *Id.* at 2.

that have an incidental effect of affecting fertility, this reinterpretation could lead to refusals that substantially exceed the plain language of the statute and open the door for patients to be denied a dangerously wide range of medically necessary treatments.

Application to other services other than abortion or sterilization

We are also concerned that the proposed rule's sweeping and ambiguous language, in conjunction with the preamble, may lead to an expansive misinterpretation of sections (c)(2) and (d) of the Church Amendments that may encourage refusals of *any* health care service for a religious or moral reason, even those with no connection to sterilization or abortion at all—far exceeding the longstanding application of this statute.[88] This ambiguity may lead covered entities to believe that they can refuse to provide or refer for any service—such as vaccines, psychiatric medication, infertility treatments, and HIV-related care—that is inconsistent with their personal beliefs, jeopardizing the health of numerous Americans. It may also lead covered entities to believe that they can refuse to provide services based on objections about who the patient is: it can encourage, for example, a provider who has a moral or religious objections to providing services for LGBT people, women, people with disabilities, or people of color to refuse to treat them at all, regardless of the treatment they require.

B. The proposed rule impermissibly expands the Coats-Snowe and Weldon Amendments.

Redefinition of "referral"

We are deeply troubled by the Department's proposal to reverse its long-standing interpretation of the application of the Weldon Amendment. We are particularly concerned about the Department's attempt to radically redefine what it means to provide a referral for a patient. There is no legal basis to support the proposed transformation of the term from its plain meaning as it is used in medicine—that is, transferring the care of a patient to a particular health care provider[89]—to "the provision of *any* information…pertaining to a health care service" so long as the health care entity believes that the health care service is a "possible outcome" of providing that information.[90] This breathtakingly broad definition attempts to exempt providers not only from transferring care to another health provider, but from supplying information that has even an exceedingly remote connection to a procedure they object to, so long as they simply believe that it is *not impossible* that doing so may lead the patient to receive the objected-to treatment—even if they do not believe that it is likely or plausible. For example, it may embolden a health care provider to refuse to inform a woman about a pregnancy complication she is experiencing, even if it can be treated, based on their belief that it is *possible* though unlikely she will opt to terminate the pregnancy. While the Department claims that statutory language—such as references to "referring for" an abortion or "making arrangements to provide referrals"—suggests that Congress

[88] *See, e.g., Elbaum v. Grace Plaza of Great Neck*, 148 A.D.2d 244, 255–56 (N.Y. App. Div. 1989) (finding that a nursing home's reliance on the Church Amendments to justify refusal to remove feeding tube was "misplaced" because the statute only pertains to sterilization and abortion procedures).
[89] *See, e.g.*, American Acad. of Family Physicians, *Consultations, Referrals, and Transfers of Care* (2017), https://www.aafp.org/about/policies/all/consultations-transfers.html ("A referral is a request from one physician to another to assume responsibility for the management of one or more of a patient's specific problems.… This represents a temporary or partial transfer of care to another physician for a particular condition.")
[90] Proposed Rule, 83 Fed. Reg. at 3924.

intended for this term to be interpreted broadly,[91] the definition that it proposes extends so far beyond the plain meaning of the term that it amounts to a radical revision of the statutory language that undermines rather than effectuates Congress' intent.

Redefinition of "health care entity"

The Department's broad redefinition of the term "health care entity" also ignores Congress' clear intent to limit the entities affected by these statutes. For example, the Coats-Snowe Amendment defines "health care entity" as an "individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions."[92] In contrast, the Department has proposed a far-reaching definition of this term, applicable to all statutes, that combines definitions from multiple statutes.[93] This attempt to supplant the varying statutory definitions of this term with a catch-all list creates confusion about the health care entities that must comply with each statute. It also disregards the congressional intent to cabin the application of each statute, evidenced by the fact that Congress took the time to create separate definitions for each statute rather than to create a universally applicable definition of the term, and by its deliberate decision to include some types of health care entities in each definition while excluding others.

C. The proposed rule impermissibly expands exemptions for Medicare and Medicaid organizations.

The essential care that Medicaid and Medicare programs provide to many Americans are already riddled with expansive exemptions for grantees and other participants, leaving many beneficiaries with no avenue to receive the care they need.[94] It is deeply concerning, therefore, that the proposed rule attempts to expand several exemptions applicable to these programs beyond the statutory language, including the counseling and referral provisions of 42 U.S.C. 1396u-2(b)(3)(B) and 42 U.S.C. 1395w-22(j)(3)(B) and the provisions of the Consolidated Appropriations Act of 2017 related to Medicare Advantage. Expanding religious exemptions in the manner proposed both exceeds the Department's authority and undermines its statutorily prescribed mission to serve beneficiaries and facilitate their access to needed medical care.

Redefinition of "referral"

First, we are troubled by the impact that the expansive redefinition of "referral" could have on patient care for Medicaid and Medicare Advantage recipients. In the context of the counseling and referral

[91] *Id.* at 3895.
[92] 42 U.S.C. § 238n(c)(2). *See also* Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009).
[93] Proposed Rule, 83 Fed. Reg. at 3924.
[94] *See, e.g.,* Amy Littlefield, *How a Catholic Insurer Built a Birth Control Obstacle Course in New York*, REWIRE NEWS (Jan. 26, 2017), https://rewire.news/article/2017/01/26/catholic-insurer-built-birth-control-obstacle-course-new-york (describing the refusal of New York's largest Medicaid plan to cover a range of services based on religious objections). *See also* Catholic Health Association of the United States, *Catholic Health Care in the United States* (2018), https://www.chausa.org/docs/default-source/default-document-library/cha_2018_miniprofile7aa087f4dff26ff58685ff00005b1bf3.pdf?sfvrsn=2 (noting that Catholic hospitals, which are required to comply with ethics guidelines that limit access to reproductive and other care, reported one million Medicaid discharges in 2017).

provisions, the proposed rule may be interpreted as allowing Medicaid managed care organizations and Medicare Advantage organizations not only to refuse to cover a counseling or referral service that they object to, but also to refuse to cover or provide for any provider-patient communication that they believe can *possibly* lead to a service to which they object, no matter how remote the connection. Similarly, this novel definition of "referral" suggests that the Consolidated Appropriations Act of 2017 exempts not only Medicare Advantage organizations who refuse to refer for abortions in the natural reading of the term—that is, to transfer care of the patient to another provider—but also those who refuse to provide or cover the provision of any information that they believe can possibly lead to a patient obtaining an abortion. This attempt to rewrite the statutory language is unsupported by statutory language or congressional intent and threatens the health and safety of the program beneficiaries whom these programs are required to serve.

Attempt to transform a statutory construction provision into a freestanding exemption

Further, the proposed rule misinterprets the counseling and referral provisions of 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B) by turning a statutory construction provision into a freestanding religious exemption. The Department's proposed exemption relies on narrow provisions that are intended only to qualify the statutes' prohibition on interference with doctor-patient communications. The provisions that the Department cites are pulled from a section whose primary purpose is to prohibit covered entities from interfering with a health care provider's ability to advise an enrollee about their health status or available treatments, regardless of whether those treatments are covered.[95] These provisions clarify a limitation to that prohibition: namely, that a covered entity's refusal to cover a procedure or service does not constitute interference with doctor-patient communication under this section. These provisions are not intended to create a general religious exemption for Medicaid MCOs and Medicare Advantage organizations, but rather they are statutory construction clauses that explain specifically how the prohibition on interference with communication is meant to be construed. Congress' limited intent when enacting these statutes is underscored not only by the plain language of this subsection, which clearly qualifies only a specific requirement of the statute, but also by the choice to explicitly label 42 U.S.C. § 1396u-2(b)(3)(B) as "Construction." The proposed rule, however, disregards the congressional intent evidenced in the statutory language and isolates this section from its context, misrepresenting its limited scope and instead presenting it as a standalone religious exemption that allows Medicaid managed care organizations and Medicare Advantage organizations to refuse to cover any counseling or referral service that they disapprove of.

Omission of critical, patient-protective statutory language

[95] 42 U.S.C. 1396u-2(b)(3)(A) ("Subject to subparagraphs (B) and (C), under a contract under section 1396b(m) of this title a medicaid managed care organization (in relation to an individual enrolled under the contract) shall not prohibit or otherwise restrict a covered health care professional…from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the contract…."); 42 U.S.C. 1395w-22(j)(3)(A) ("Subject to subparagraphs (B) and (C), a Medicare Choice organization (in relation to an individual enrolled under a Medicare Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional…from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan….").

Additionally, the proposed rule omits requirements, enumerated in both 42 U.S.C. § 1396u-2(b)(3)(B) and 42 U.S.C. § 1395w-22(j)(3)(B), that organizations that decline to cover certain treatments notify enrollees of their policy. The statutory construction clauses do not exempt an organization merely on the basis that it has a religious or moral objection to covering a service: it also requires, as a condition of the exemption, that the organization "make available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service."[96] The Department's omission of this requirement from its proposed rule will create confusion regarding organizations' legal obligations to disclose their policies to potential and current enrollees and may lead to or encourage noncompliance with the law. Without sufficient enforcement of notification requirements, potential enrollees may be unable to make an informed choice about their health care, and current enrollees may find themselves unable to access care that they would reasonably expect to be covered.

Similarly, the proposed rule misrepresents the exemption provided to entities participating in Medicare Advantage in the Consolidated Appropriations Act of 2017, omitting requirements in the law that ensure that enrollees and the Department itself are notified of objections to covering abortions. The proposed rule asserts that an exemption exists when an "entity will not provide, pay for, provide coverage of, or provide referrals for abortions."[97] In contrast, the statute itself provides an exemption when "the entity *informs the Secretary* that it will not provide, pay for, provide coverage of, or provide referrals for abortions."[98] By excising this important language, the Department may create ambiguity about covered entities' obligations to notify the Department of its objections to covering abortions—a requirement that is necessary to allow the Department to meet its statutory obligation to "make appropriate prospective adjustments to the capitation payment" to entities declining to cover abortions.[99] The statute, furthermore, explicitly states that "a Medicare Advantage organization described in this section shall be responsible for informing enrollees where to obtain information about all Medicare covered services"[100]—a notification requirement that the proposed rule omits, potentially creating confusion regarding a Medicare Advantage organization's responsibilities to inform enrollees about the scope of their coverage.

IV. The proposed exemptions run counter to numerous federal and state laws and raise serious constitutional questions.

A. *Conflict with the Establishment Clause of the Constitution*

Expanding religious exemptions in the manner proposed may run afoul of constitutional restrictions on the scope of religious exemptions. The Supreme Court has noted that there are limits to permissible accommodations based on religious beliefs, and that "at some point, accommodation may devolve into an unlawful fostering of religion."[101] To comply with the Constitution, "an accommodation must be

[96] 42 U.S.C. 1396u-2(b)(3)(B)(ii); 42 U.S.C. 1395w-22(j)(3)(B)(ii).
[97] Proposed Rule, 83 Fed. Reg. at 3926.
[98] Consolidated Appropriations Act of 2017, Pub. L. 115-31, Div. H, Tit. II, sec. 209 (emphasis added).
[99] *Id.*
[100] *Id.*
[101] *Corp. of the Presiding Bishop v. Amos*, 483 U.S. 327, 334-35 (1986) (internal quotation marks omitted).

measured so that it does not override other significant interests"[102] or "impose unjustified burdens on other[s],"[103] and any "detrimental effect on any third party" must be seriously considered.[104] The exemptions proposed in the rule—which would allow many providers and entities to take taxpayer dollars and then refuse to provide a range of needed medical services—would *by definition* impose significant burdens on many intended HHS program recipients. The rule, however, includes no discussion or consideration of the impact its proposed exemptions may have on patients and other third parties, and in fact undermines important statutory limitations on those exemptions that are intended to prevent or mitigate the harms patients may face, thereby raising serious constitutional concerns.

B. ***Conflict with federal statutes***

Additionally, many of the exemptions proposed in the rule may conflict with a range of patient protections included in other federal laws. While these protections are subject to the religious exemptions provided under federal law, they are not subject to exemptions whose scope exceeds federal law, including the expanded exemptions proposed in this rule. Adopting an interpretation of religious exemption laws that conflicts with the requirements of other federal laws would compromise the Department's ability to enforce existing law as required. Further, doing so will cause confusion for covered entities about how to navigate seemingly inconsistent obligations under different laws, and subject them to increased liability.

Emergency Medical Treatment and Active Labor Act (EMTALA)

For example, if the proposed rule is implemented, it can subject hospitals to standards that conflict with their obligations under the Emergency Medical Treatment and Active Labor Act (EMTALA), which requires hospitals that have a Medicare provider agreement and an emergency department to provide medical screening and stabilizing treatments to patients in emergency conditions (including labor).[105] The proposed rule contemplates no exceptions to the broad, automatic exemptions it promotes, such as exceptions for emergencies or life-threatening conditions. A hospital could therefore reasonably interpret the proposed rule as requiring it to exempt essential personnel from providing, for example, comprehensive care for a patient experiencing emergent pregnancy-related complications, even when doing so means that the hospital is unable to provide the patient with stabilizing care, in violation of its obligations under EMTALA. The Department provides no guidance about how a hospital can comply with the expanded refusal rights suggested by this proposed rule in cases where doing so would result in an EMTALA violation—potentially putting the hospital in the impossible position of having to somehow satisfy two conflicting requirements. Indeed, the preamble underscores the potential conflict between EMTALA and the Department's approach when it criticizes an American College of Obstetrics and Gynecologists statement reaffirming that physicians must provide emergency care when a safe transfer

[102] *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005); *see also Estate of Thornton v. Caldor, Inc.* 472 U.S. 703, 709-10 (1985) ("unyielding weighting" of religious interests of those taking exemption "over all other interests" violates Constitution).
[103] *Cutter*, 544 U.S. at 726; *see also Texas Monthly, Inc. v. Bullock*, 480 U.S. 1, 18 n.8 (1989) (religious accommodations may not impose "substantial burdens on nonbeneficiaries").
[104] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014) (citing *Cutter*, 544 U.S. at 720). Indeed, every member of the Court, whether in the majority or in dissent, reaffirmed that religious accommodations cannot unduly burden third parties. *See id.* at 2786–87 (Kennedy, J., concurring); *id.* at 2790, 2790 n.8 (Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., dissenting). *See also Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).
[105] 42 U.S.C. § 1395dd.

is not possible, regardless of their personal beliefs. The preamble suggests that this position—a simple recitation of a widely accepted legal and professional obligation for physicians—is "evidence of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and its implementation "could constitute a violation of Federal health care conscience laws."[106]

Affordable Care Act

The proposed rule is also inconsistent with several provisions of the Affordable Care Act, including Section 1554 and Section 1557. Section 1554 prohibits the Department from promulgating any regulation that "creates any unreasonable barriers to…appropriate medical care" or "impedes timely access to health care services"; that "restricts the ability of health care providers to provide full disclosure of all relevant information to patients" or interferes with their ability to communicate about "a full range of treatment options"; that "violates the principles of informed consent and the ethical standards of health care professionals"; or that "limits the availability of health care treatment for the full duration of a patient's medical needs."[107] This proposed rule violates each and every one of these requirements. Additionally, by pursuing broad exemptions that would likely result in discrimination against patients, the proposed rule conflicts with Section 1557 of the Affordable Care Act, which prohibits discrimination in health care on the basis of race, national origin, disability, age, and sex,[108] and runs counter to clear congressional intent evidenced in this section and throughout the ACA to protect the rights of patients and reduce barriers to accessing health care.

Title VII of the Civil Rights Act of 1964

Further, the proposed rule's approach, which appears to allow for no limitations even when those exemptions unjustifiably harm patients or employers, conflict with the well-established standard under other federal laws, such as Title VII of the Civil Rights Act, creating confusion and increased liability for hospitals and other health care employers. As the Supreme Court has long held, Title VII requires that employers reasonably accommodate employees' religious exercise unless doing so would impose undue hardship on the employer, ensuring that the employer can consider the effect that an accommodation would have on clients, patients, co-workers, and its own operations, as well as factors such as public safety, patient health, and other legal obligations.[109] A standard that appears to allow for none of these considerations, and instead appears to require broad and automatic exemptions regardless of the consequences, would create confusion for employers and undermine the federal government's

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[106] Proposed Rule, 83 Fed. Reg. at 3887–3888 (criticizing an American College of Obstetrics and Gynecologists ethics committee that reaffirms a physicians' duty to provide emergency care when transfer is not feasible and suggesting that it is "evidence of discrimination toward, and attempted coercion of, those who object to certain health care procedures based on religious or moral convictions" and "could constitute a violation of Federal health care conscience laws").

[107] 42 U.S.C. § 18114.

[108] 42 U.S.C. § 18116.

[109] *See, e.g., Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 70 (1986) ("In enacting [Title VII], Congress was understandably motivated by a desire to assure the individual additional opportunity to observe religious practices, but it did not impose a duty on the employer to accommodate at all costs"). *See also, e.g., Wilson v. U.S. West Communications*, 58 F.3d 1337 (8th Cir. 1995) (affirming that Title VII requires reasonable accommodation employee only when the accommodation does not create an undue hardship on the employer); *Noesen v. Med. Staffing Network, Inc.*, 2006 WL 152996, at *4 (W.D. Wis. June 1, 2006), *aff'd* 232 F. App'x 581 (7th Cir. 2007); *Grant v. Fairview Hosp. & Healthcare Servs.*, 2004 WL 326694 at *4 (D. Minn. Feb. 18, 2004).

ability to properly enforce federal laws.[110] Such a standard could require health care employers to hire individuals who refuse to do essential components of their job. For example, it could require small hospitals to staff their emergency rooms with employees who are unwilling to provide emergency treatment to pregnant or transgender patients even when doing so makes it impossible for the hospital to provide life-saving care to patients or comply with other legal obligations such as under EMTALA. Similarly, this standard could require a clinic that is funded under Title X—and that is therefore statutory required to provide non-directive pregnancy options counseling[111]—to employ medical or administrative staff who refuse to discuss or even simply schedule appointments for pregnancy counseling, even when doing so prevents the clinic from serving its patients or complying with other laws.

C. *Conflict with state and local laws*

Finally, the proposed rule threatens to interfere with the enforcement of hundreds of state and local laws—including laws that protect patients from malpractice and discrimination, laws requiring providers to disclose important information to patients, and laws that prohibit unfair insurance practices and set other minimum standards for private insurance or Medicaid programs. The Department's claims that "this rulemaking does not impose substantial direct effects on States or political subdivision of States" and "does not implicate" federalism concerns under Executive Order 13,132[112] are, as a factual matter, false: as the Department itself recognizes in the preamble, the principles and requirements espoused in its proposed rule conflict with many state and local laws,[113] and the Department challenges several state laws and policies throughout its preamble.[114] While the Department argues that it is merely enforcing existing law and thus minimally impacts state and local governments, its proposed rule in fact represents a significant and unwarranted expansion of existing federal laws—an expansion that is fundamentally at odds with the prevailing interpretation on which many state and local governments have relied when enacting laws to protect their residents.

V. The proposed rule erodes core tenets of the medical system.

The propose rule undermines longstanding ethical and legal principles of informed consent. Informed consent—a fundamental principle of patient-centered care—relies on the disclosure of medically accurate information by providers in order to allow patients to make competent and voluntary decisions about their medical treatment.[115] Health care providers must provide information that is accurate and sufficient to allow a patient to provide informed consent to a course of treatment or lack of treatment, and a health care provider's refusal to provide adequate information can constitute a violation of both medical

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[110] Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel raised concerns about potential conflict with established Title VII standards and emphasized that Title VII should remain the legal standard for determining religious accommodations. Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html
[111] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).
[112] Proposed Rule, 83 Fed. Reg. at 3919.
[113] *Id.* at 3888.
[114] *See, e.g., id.* at 3886.
[115] *See, e.g.*, Tom Beauchamp & James Childress, *Principles of Biomedical Ethics* (4th ed. 1994).

standards of care[116] and legal standards.[117] The proposed rule, however, encourages providers to flout their obligations to provide patients with necessary medical information. By encouraging health care providers and entities to refuse to provide key information and disregarding statutory requirements that patients be given notice that they may not receive complete and accurate information, the proposed rule degrades trust and open communication between doctors and patients and prevents patients from being able to make an informed decision about their health care.

For example, by proposing to expand the definition of "referral" to the provision of *any* information by a health care worker who believes that it could *possibly* lead a patient to obtain a treatment to which they object, the Department encourages health care providers to withhold critical information about available treatments, their risks and benefits, or even the patient's diagnosis. As discussed above, the proposed rule even omits statutory requirements that health care entities inform patients of their objections to certain treatments or policies of refusing to provide or cover them. By omitting these notification requirements from its proposed rule, the Department creates confusion about what information health care providers must give to patients about their or their employees' religious or moral objections and encourages entities to ignore these obligations. Especially in light of studies indicating that most patients are unaware that religiously affiliated health care institutions might refuse to provide treatments based on religious objections,[118] the Department's apparent reluctance to fully enforce disclosure requirements jeopardizes patients' ability to make informed decisions about their health care.

VI. The Department's failure to follow required rulemaking procedures and base its rule on available evidence suggests an arbitrary and capricious process.

The Department failed to follow normal rulemaking procedures in issuing the proposed rule in several respects and to consider important evidence regarding the rule's impact. Together with the fact that the rule exceeds the Department's statutory authority, runs counter to existing laws, and undermines the constitutional and other legal rights of patients, this rushed and inadequate rulemaking procedure strongly suggests a violation of the Administrative Procedure Act.[119]

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[116] *See, e.g., The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html ("The physician's obligation is to present the medical facts accurately to the patient.... The physician has an ethical obligation to help the patient make choices from among therapeutic alternatives consistent with good practice."); Am. Nurses Ass'n, *Code of Ethics for Nurses with Interpretive Statements* (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html ("Patients have the moral and legal right to determine what will be done with their own person; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens, and available options in their treatments...."); Am. Pharmacists Ass'n, *Code of Ethics for Pharmacists* (1994).

[117] *See., e.g., Brownfield v. Daniel Freeman Marina Hosp.*, 256 Cal. Rptr. 240 (Ct. App. 1989).

[118] Ensuring that disclosure requirements are rigorously enforced is particularly important in light of research indicating that most patients are unaware that some religiously affiliated health care entities may refuse to provide treatments based on their religious beliefs. *See, e.g.*, Nadia Sawicki, *Mandating Disclosure of Conscience-Based Limitations on Medical Practice*, 42 AM. J. LAW & MED. 85 (2016), http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.

[119] The Administrative Procedure Act instructs a reviewing court to hold agency actions as unlawful when they are found to be "(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence...; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court." 5 U.S.C. § 706.

A. Failure to include the rule in the Department's Unified Regulatory Agenda

First, under longstanding Executive Orders governing the rulemaking process, proposed rules must first appear in the agency's Regulatory Agenda.[120] Executive Order 13,771, signed by President Trump, reaffirms that "no regulation shall be issued by an agency if it was not included on the most recent version or update of the published Unified Regulatory Agenda...unless the issuance of such regulation was approved in advance in writing by the Director" of the Office of Management and Budget.[121] We are aware of no circumstance that would justify the Director approving an exception to this normal process in this instance. We are concerned that the failure of the Department to comply with these requirements reflects a hasty development of the rule that lacked sufficient review of its impact and factual and legal basis.

B. Failure to conduct a meaningful federalism analysis

The Department also failed to comply with the requirements of Executive Order 13,132, which requires agencies to conduct a thorough review of any federalism implications of its regulations, including by identifying effects the regulation would have on existing state and local laws and on the ability of states to exercise power in realms traditionally reserved for them, as well as identifying and in some cases providing funding for costs that would be incurred by state and local governments.[122] The Department's cursory review of federalism implications meets none of those basic requirements. Its conclusion that the regulation has *no* federalism implications is directly contradicted the Department's own statements that its regulation could upend numerous existing state and local laws and policies, require changes to state programs such as Medicaid, and limit the manner in which many states can regulate health care in the future.[123] Regardless of the merits of the Department's interpretation of existing federal law, it is required to make a fact-based federalism assessment that recognizes these impacts of the regulation on state and local laws.

C. Failure to assess the costs of denied or delayed health care

Additionally, the Department failed to comply with Executive Order 13,563, which permits agencies to propose a rule only after conducting an accurate assessment of costs and benefits, and after reaching a reasoned determination that the benefits outweigh the costs and that the regulations are tailored "to impose the least burden on society."[124] While the Department considered the substantial financial costs that its new notification requirements may have on certain health care entities, it failed to even attempt to assess the most significant cost its rule would have if adopted: the cost incurred by patients whose access to care may be denied, delayed, or limited, including substantial financial and health-related costs to patients, to health care entities, and to government-funded health programs. Neglecting to take this cost into consideration or even acknowledge it—despite the Department's past recognition of the pervasiveness of barriers to health care faced by many patients[125]—is suggestive of an arbitrary and

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[120] *E.g.*, Exec. Order No. 13,771, 82 Fed. Reg. 9339, 9340 (Jan. 30, 2017); Exec. Order No. 12,866, 58 Fed. Reg. 190 (Oct. 4, 1993).
[121] *Id.*
[122] Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999).
[123] *See, e.g,* Proposed Rule, 83 Fed. Reg. at 3886–3888.
[124] Exec. Order No. 13,563, 76 Fed. Reg. 3821 (Jan. 21, 2011).
[125] *See, e.g.*, Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (2016).

capricious process that entirely failed to consider a crucially important aspect of the issued addressed in the rule.

D. Failure to adequately consider comments from the Department's closely related RFI

We are further concerned that the timing of the publication of the proposed rule reflects an insufficient consideration of public comments to the Department's recent Request for Information on a closely related topic, "Removing Barriers for Religious and Faith-Based Organizations to Participate in HHS Programs and Receive Public Funding." The Department completed its comment period on the Request for Information in November 24, only two months before the publication of this rule, and received over 12,000 comments—the vast majority of which were not posted publicly until mid-December.[126] Many, if not most, of these public comments focused on the precise topic of this proposed rule: religious exemptions for health care workers and institutions. Yet despite the clear and close connection between the RFI and the proposed rule, the brief period of time between them suggests that it is unlikely that the proposed rule reflects a serious, reasoned analysis of the many comments the Department received on the RFI.

This hasty rule development stands in sharp contrast with the typical process for HHS and other agency rules, which commonly spans over several months or years instead of only a few weeks. An illustrative example is the Department's rulemaking process implementing Section 1557 of the Affordable Care Act, which began with a Request for Information in 2013, a proposed rule in 2015, and a final rule in 2016 issued after thorough consideration of more than 25,000 public comments.[127] Given that this proposed rule invokes dozens of distinct statutes, affects numerous areas of both health care service provision and coverage, and imposes sweeping and burdensome new notice and certification requirements—all without any change in the governing statutory or case law—it deserves at least as much deliberation.

VII. Expanding religion-based exemptions is unnecessary.

In addition to raising legal and constitutional questions, an expansion of religion-based exemptions is unnecessary as a matter of policy. Federal statutes and existing regulations, including the existing OCR conscience rule, already provide a broad range of special exemptions for health care providers or entities with religious or moral objections to many services, and these exemptions provide more than adequate protections, as evidenced by the large number of faith-based organizations that have received and continue to receive federal grants and other federal funding.

Among the laws and regulations that protect health care entities, in addition to the statutes cited by the proposed rule, is the Religious Freedom Restoration Act (RFRA). RFRA protects any grantee from any government action (including a denial or limitation of a grant or contract) that substantially burdens their exercise of religion, unless the government can meet the high burden of demonstrating that the action is narrowly tailored to serve a compelling interest. The protections in RFRA are more than sufficient to ensure that faith-based organizations and providers with religious or moral objections to certain procedures can receive case-by-case accommodations, as appropriate, to have a fair opportunity to

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[126] Dan Diamond, *HHS Defends Withholding Comments Critical of Abortion, Transgender Policy*. POLITICO (Dec. 18, 2017), https://www.politico.com/story/2017/12/18/hhs-faith-based-rule-withholding-comments-236759.
[127] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. at 31,376.

receive federal funds. Existing Department regulations explicitly acknowledge that their requirements are subject to limitations under RFRA and other federal laws.[128]

Conclusion

We strongly urge the Department to refrain from expanding health care refusal rights as proposed in this rule. Doing so would undermine vulnerable populations' access to essential health services and compromise the Department's ability to meet its responsibilities to legal beneficiaries and its legal obligations. Protecting religious freedom is important, and a range of existing laws and regulations already provide more than adequate protections for individuals and entities with religious or moral objections to providing specific services. It is therefore unwise and unnecessary for the Department to put patients at risk by allowing them to be mistreated or denied care using the federal dollars that are intended to help them. Moreover, the proposed rule is contrary to law in numerous respects. We strongly urge the Department to abandon this unnecessary, untenable, and harmful proposed rule and instead maintain the existing 2011 rule on the topic, while preserving OCR's primary focus on enforcing the civil rights and privacy rights of patients.

Thank you for your consideration.

[128] *See, e.g.*, 45 C.F.R. pt. 92 §92.2(b)(2).

Exhibit 128

National
Family Planning
& Reproductive Health Association

March 27, 2018

US Department of Health and Human Services
Office for Civil Rights
Attention: Conscience NPRM, RIN 0945-ZA03
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Attn: Protecting Statutory Conscience Rights in Health Care NPRM, RIN 0945-ZA03

The National Family Planning & Reproductive Health Association (NFPRHA) is pleased to provide comments on the US Department of Health and Human Services' (HHS) notice of proposed rulemaking (NPRM), "Protecting Statutory Conscience Rights in Health Care," RIN 0945-ZA03.

NFPRHA is a national membership organization representing the nation's publicly funded family planning providers, including nurse practitioners, nurses, administrators, and other key health care professionals. NFPRHA's members operate or fund a network of more than 3,500 health centers and service sites that provide high-quality family planning and other preventive health services to millions of low-income, uninsured, or underinsured individuals in 50 states and the District of Columbia. Services are provided through state, county, and local health departments as well as hospitals, family planning councils, Planned Parenthoods, federally qualified health centers and other private nonprofit organizations.

NFPRHA is deeply concerned that this NPRM ignores the needs of the patients and individuals served by HHS' programs and creates confusion about the rights and responsibilities of health care providers and entities. Because they receive Title X, Medicaid, and other HHS funds, NFPRHA members would have no choice but to comply with this rule: failure to do so could lead to termination of current or pending HHS funds, as well as return of money previously paid to NFPRHA members for services they have provided. This means hundreds of millions of dollars in federal funding are at stake for NFPRHA members if they run afoul of the rule. Without federal support, many of our members would be forced to drastically scale back the services they provide to their patients or to close completely. Because NFPRHA members represent the vast majority of Title X clinical locations that serve people who cannot afford to pay for health care on their own, this would leave many low-income and uninsured or under-insured patients without access to family planning and other critical health care services.

Although this NPRM claims the authority to interpret numerous statutes of concern and interest, NFPRHA will limit its comments primarily to the unjustified and unauthorized expansion of the Church amendments (42 USC 300a-7), Coats-Snowe amendment (42 USC 238n), and Weldon amendment (e.g. Consolidated Appropriations Act, 2017, Pub. L. 115-31, Div. H, Tit. V, sec. 507(d)) (together, "Federal health care refusal statutes"). Because this NPRM encourages unprecedented discrimination against patients and opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program, it should be withdrawn.

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Background on the 2008 Health Care Refusal Regulations

In the decades-long history of the federal health care refusal statutes, none of which delegate rulemaking authority to HHS, regulations purporting to clarify and interpret these laws have been promulgated only once, in late 2008.

In 2008, HHS promulgated an NPRM purporting to interpret and enforce the federal health care refusal statutes claiming "concern…that there is a lack of knowledge on the part of States, local governments, and the health care industry" of the refusal rights contained within these statutes. (73 Fed. Reg. at 50, 278). Despite allowing only a 30-day comment period, HHS received more than 200,000 comments in response to the proposed rule—the vast majority of which opposed the rule as unnecessary, unauthorized, and overbroad.[1] Notably, HHS conceded, it received "no Comments indicating that there were any [federal] funding recipients not currently compliant with [the underlying statutes]" (73 Fed. Reg. at 78,095). HHS published a final rule on December 19, 2008, which did not materially differ from the NPRM and was immediately subject to legal challenge by multiple parties, including NFPRHA and seven state attorneys general.[2]

In 2011, HHS rescinded those aspects of the 2008 rule that were "unclear and potentially overbroad in scope," but maintained those parts of the rule establishing an enforcement process for the Federal health care refusal statutes and began an "initiative designed to increase the awareness of health care providers about the protections provided by the health care provider conscience statutes, and the resources available to providers who believe their rights have been violated." (76 Fed. Reg. at 9969). This rule remains in effect.

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[1] Comments to Provider Conscience Regulations, 73 Fed. Reg. 50274 (August 26, 2008) (to be codified at 45 CFR 88).

[2] *National Family Planning and Reproductive Health Association et al v. Leavitt*, No. 09-cv-00055 (Dist. Conn. Jan. 15, 2009) *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009); *Planned Parenthood Federation of America v. Leavitt*, No. 09-cv-00057 (Dist. Conn. Jan. 15, 2009); *State of Conn. et al. v. United States of America*, No. 09-cv-00054 (Dist. Conn. Jan. 15, 2009).

According to the current NPRM, since 2008, "OCR [Office for Civil Rights] has received a total of forty-four complaints [related to Federal health care refusal laws], the large majority of which (thirty-four) were filed since the November 2016 election." (83 Fed. Reg. at 3886). To place that figure into context, OCR in total received approximately 30,166 complaints in fiscal year (FY) 2017.

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The NPRM overstates statutory authority and seeks to dramatically expand the reach of the underlying statutes.

For decades, federal health care refusal statutes have given specified individuals and institutions certain rights to refuse to perform, assist in the performance, and/or refer for abortion and/or sterilization services. Despite the lack of a congressional mandate to do so, the NPRM seeks to dramatically expand the scope and reach of these laws, as well as grant overall responsibility for ensuring and enforcing compliance with those statutes to OCR, using identical language to many aspects of the now-rescinded 2008 regulation that faced widespread opposition at that time.[3]

The Church amendments were enacted by Congress in the 1970s in response to debates about whether the receipt of federal funds required recipients to provide abortion or sterilization services. These provisions make clear, among other things, that:

- The receipt of federal funding under the Public Health Service Act (PHSA) (42 U.S.C. § 201 et seq.) does not itself obligate any individual to perform or assist in the performance of sterilization or abortion procedures if those procedures are contrary to the individual's religious or moral beliefs (Church (b)(1)); and,
- Health care personnel employed by certain federally funded programs and facilities cannot be discriminated against in terms of employment, promotion, or the extension of staff or other privileges for performing or assisting in the performance of sterilization or abortion services, or refusing to perform or assist in the performance of such services based on their religious or moral beliefs (Church (c)(1)).

In 1996, Congress adopted the Coats amendment in response to a decision by the accrediting body for graduate medical education to require OB/GYN residency programs to provide or permit abortion training. The Coats amendment prohibits federal, state, and local governments from discriminating against health care entities, such as "individual physicians, postgraduate physician training programs, or . . . participant[s] in a program of training in the health profession," that refuse to provide or require training in abortions or individuals who refuse to be trained to provide abortions.

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[3] Comment of the National Family Planning & Reproductive Health Association to Provider Conscience Regulations, Tracking Number 8072403d to 73 Fed. Reg. 50274 (proposed August 26, 2008) (comment dated September 25, 2008) (to be codified at 45 CFR 88).

Since 2004, Congress has attached the Weldon amendment to the annual appropriations measure that funds the Departments of Labor, Health and Human Services, and Education (Labor-HHS). That amendment prohibits federal agencies and programs and state and local governments that receive money under the Labor-HHS Appropriations Act from discriminating against individuals, health care facilities, insurance plans, and other entities because they refuse to provide, pay for, provide coverage of, or refer for abortion.

The Church, Coats-Snowe, and Weldon amendments were never intended to provide individual health care providers and/or entities with the myriad and expansive rights of refusal this NPRM seeks to achieve. Without statutory authorization, the NPRM expands the reach of the Church, Coats-Snowe, and Weldon Amendment beyond what was contemplated by Congress and is permitted by existing federal law, by expanding the categories of individuals and entities whose refusals to provide information and services are protected; expanding the types of services that individuals and entities are allowed to refuse to provide; and expanding the types of entities that are required to accept such refusals. For example:

- Despite the plain language of the Weldon amendment, the NPRM attempts to extend it to apply to funding beyond that appropriated by Labor-HHS appropriations and to non-governmental entities, as well. The statute of the Weldon amendment states:

  > "(1) None of the funds ***made available in this Act*** may be made available to ***a Federal agency or program, or to a State or local government***, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

  Yet § 88.3(c) of the NPRM adds new language that applies the Weldon amendment's prohibitions not only to federal agencies and programs and state and local governments that receive Labor-HHS funds, but also to "***[a]ny entity that receives funds through a program administered by the Secretary or under an appropriations act for the Department that contains the Weldon amendment***" [emphasis added].

  This language broadens Weldon's reach in two impermissible ways: 1) it extends the restrictions to entities that do not even receive funding via Labor-HHS appropriations, to apply to funding through any program administered by HHS; and, 2) it applies the restrictions of the Weldon amendment beyond the statutory reach of federal agencies or programs, or state or local governments, to any entity receiving certain federal funds. These extensions of Weldon's reach are clearly contrary to both the plain language of the Weldon amendment and to congressional intent.

- While the Church amendment prevents PHSA funds from being used to require individuals and institutions to, among other things, "assist in the performance" of abortions and sterilizations, and prevents employment discrimination against those who refuse to do so, § 88.3 of the NPRM

transforms this statutory shield into a sword, creating out of whole cloth a categorical right of refusal for any recipient of PHSA funds. Moreover, § 88.2 of the NPRM provides an unprecedentedly and unjustifiably broad definition of the term "assist in the performance" that runs counter to congressional intent and common sense. The NPRM would define "assist in the performance" as participating "in ***any activity*** with an ***articulable connection*** to a procedure, health service or health service program, or research activity" [emphasis added]. In other words, HHS proposes to create refusal rights for anyone who can ***simply express a connection*** between something they do not want to do and an abortion or sterilization procedure (e.g., scheduling appointments, processing payments, or treating complications). Even the sole instance of previous rulemaking under the Church amendments in 2008, which was rescinded before it ever took effect, was not so broad.

- Likewise, the NPRM's definition of referral/refer seeks to dramatically expand the scope and reach of the Coats-Snowe and Weldon amendments and runs counter to congressional intent and common sense. Section 88.2 of the NPRM defines "referral/refer for" abortion to include:

  > "the provision of any information (including but not limited to name, address, phone number, email, website, instructions, or description) by any method (including but not limited to notices, books, disclaimers, or pamphlets, online or in print), pertaining to a health care service, activity, or procedure, including related to availability, location, training, information resources, private or public funding or financing, or directions that could provide any assistance in a person obtaining, assisting, training in, funding, financing, or performing a particular health care service, activity, or procedure, where the entity or health care entity making the referral sincerely understands that particular health care service, activity, or procedure to be a purpose or possible outcome of the referral."

  This definition would impair the ability of health care professionals to fulfill their legal and ethical duties of providing complete, accurate, and unbiased information to their patients. For example, as discussed further below, the NPRM could be read to permit employees of Title X-funded health centers and other federally funded entities to refuse to provide information and referrals to patients, without ever addressing patient needs and in clear violation of the fundamental tenets of informed consent.

As interpreted by the NPRM, the Church, Coats-Snowe, and Weldon amendments would be radically expanded to create far-reaching protections for individuals and entities that would refuse to provide patients not only with health care services, but also the most basic information about their medical options and that seek to obstruct the ability of certain patients to access any care at all. This is impermissible and, as discussed below, would cause unprecedented harm to patients and undermine the integrity of key HHS programs.

This NPRM goes beyond HHS' statutory authority and should be withdrawn. If HHS promulgates a final rule, however, it must identify the source of its legal authority, if any at all, to promulgate these regulations and to alter and expand the meaning of the statutory language.

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The NPRM attempts to grant OCR oversight authority and enforcement discretion that is overly broad and vague; unduly punitive; and ripe for abuse.

While some of the investigative authority and enforcement powers of the current NPRM appear to comport with similar provisions in other areas subject to OCR oversight and enforcement authority, the NPRM 1) includes new, troubling provisions that are vague, overly broad, and overly punitive; and 2) as a whole, appear to impart in OCR authority and enforcement discretion that is ripe for abuse.

Indeed, while the NPRM claims to "borrow...from enforcement mechanisms already available to OCR to enforce similar civil rights laws," the NPRM contains troubling differences. For example, the NPRM states that investigations may be based on anything from 3rd party-complaints to news reports, and yet at the same time appears to give OCR the authority to withhold federal financial assistance and suspend award activities, based on "threatened violations" alone, without first allowing for the completion of an informal resolution process. (See 83 Fed. Reg. at 3891, 3930-31). By contrast, the Department of Justice (DOJ) regulations implementing Title VI of the Civil Rights Act of 1964 (prohibiting discrimination on the basis of race in federally funded programs) state that DOJ will not take such drastic steps to respond to actual or threatened violations unless noncompliance cannot first be corrected by informal means. (See 28 C.F.R. § 42.108(a)). When combined with other aspects of the NPRM, concern over the breadth and potential harm of such provisions is obvious and legitimate. For instance:

- Under § 88.6, the NPRM includes a 5-year reporting requirement that requires any recipient or sub-recipient subject to an OCR compliance review, investigation, or complaint related to the health care refusal rules to inform any current HHS "funding component" of the review/investigation/complaint, as well as to disclose that information in any application for new or renewed "Federal financial assistance or Departmental funding." Once again, this is distinct from the DOJ regulations enforcing Title VI, which only require disclosure of compliance reviews (not every investigation or complaint, regardless of whether it is unfounded) over the past two years. (28 C.F.R. § 42.406(3)). Yet the NPRM fails to explain the purpose of the vastly expanded reporting requirement and period. In light of the broad investigative authority and harsh penalties described above, this leaves affected entities with significant concern about how such information is intended to be used and whether it will unfairly prejudice consideration of applicants for federal funds or penalize currently funded entities in ways that could be extremely harmful.

The NPRM also includes very troubling language that appears to be little more than a pretext for defunding entire classes of providers, which it cannot do. The preamble text accompanying § 88.7

states, "The Director may, in coordination with a relevant Department component, restrict funds for noncompliant entities in whole or in part, including by ***limiting funds to certain programs and particular covered entities, or by restricting a broader range of funds or broader categories of covered entities***" [emphasis added]. This delegation of authority is not only far beyond the scope of the underlying laws but seems designed to grant arbitrary authority that is ripe for abuse, with no mechanism of due process or oversight to prevent entire categories of providers or programs from being penalized without cause. To the extent § 88.7 seeks to create a back door to excluding certain family planning providers from the Title X and Medicaid programs—efforts that have been repeatedly rejected by the courts—it, again, exceeds the scope of the agency's authority and will do nothing more than harm the health and well-being of patients.

Given the lack of evidence that the system currently in place cannot adequately handle complaints, as well as any sufficient justification for departing from the processes used to ensure compliance with other federal statutes, HHS must, at a minimum, adequately explain the reason for these changes, what safeguards exist to prevent abuse, and demonstrate that this language is not simply a pretext for unlawfully excluding certain categories of providers from participating in federally funded programs.

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The NPRM opens the door to undermining the intent and integrity of key HHS programs, including the Title X family planning program.

The NPRM ignores the reality that some individuals and entities are opposed to the essential health services that are the foundation of longstanding, critical HHS programs like Title X. In the arena of health care, and particularly family planning and sexual health, HHS-funded programs cannot achieve their fundamental, statutory objectives if grantees, providers, and contractors have a categorical right to refuse to provide essential services, such as non-directive pregnancy options counseling.

The Title X family planning program was created by Congress in 1970 "to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services" (42 USC 300). Title X projects are designed to "consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children" (42 CFR 59).

In 2014, more than 20.2 million women in the United States were in need of publicly funded contraceptive services. Women in need of publicly funded family planning services is defined as follows: "1) they were sexually active (estimated as those who have ever had voluntary vaginal intercourse, 2) they were able to conceive (neither they nor their partner had been contraceptively sterilized, and they did not believe they were infecund for any other reason); 3) they were neither intentionally pregnant nor trying to become pregnant; and, 4) they have a family income below 250% of the federal poverty level. In addition, all women younger than 20 who need contraceptive services, regardless of their family income are assumed to need publicly funded care because of their heightened need—for reasons of

confidentiality—to obtain care without depending on their family's resources or private insurance."[4] In the face of this widespread need, publicly funded family planning and sexual health care provides a crucial safety net for women and families. The impact of these services cannot be underestimated. Without publicly funded family planning services, there would be 67% more unintended pregnancies (1.9 million more) annually than currently occur.[5]

Congress has specifically required that "all pregnancy counseling shall be non-directive" (Public Law 110-161, p. 327), and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination (42 CFR 59.5(a)(5)). Despite the incredible success of the Title X program and the critical services it provides, Title X has been chronically underfunded, with no new service dollars allocated in nearly a decade. It is a testament to the dedication of the existing Title X network to meeting the goals of the program that, despite limited resources, these providers still serve more than four million patients per year.[6]

However, in addition to the overly broad definitions of "referral" and "assist in the performance" discussed above, by proposing a definition of "discrimination" that appears to jettison the longstanding framework that balances individual conscience rights with the ability of health care entities to continue to provide essential services to their patients, the NPRM seems designed to allow entities that refuse to provide women with the basic information, options counseling, and referrals required by law to compete on the same footing for federal money with family planning providers who adhere to the law and provide full and accurate information and services to patients. The NPRM thus threatens to divert scarce family planning resources away from entities that provide comprehensive family planning services to organizations that refuse to provide basic family planning and sexual health care services. Diverting funds away from providers offering the full range of family planning and sexual health services would not only seriously undermine public health, especially for the low-income, uninsured, and under-insured, but would also be contrary to congressional intent and explicit statutory requirements of the Title X family planning program.

The NPRM likewise creates confusion about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. To the extent that the rule seeks to immunize subrecipients who refuse to provide essential services and complete information about all of a woman's pregnancy options, it undermines the very foundation of the Title X program and the health of the patients who rely on it.

In addition to potential issues with the selection of grantees and subrecipients, the proposed definition of "discrimination" also poses significant employment issues for all Title X-funded health centers. As

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[4] Jennifer Frost et al, *Contraceptive Needs and Services, 2014 Update* (New York: Guttmacher Institute, 2016).
[5] Jennifer Frost et al, *Publicly Funded Contraceptive Services at U.S. Clinics, 2015* (New York: Guttmacher Institute, April 2017).
[6] Christina Fowler, *Family Planning Annual Report: 2016 national summary* (Research Triangle Park, NC: RTI International, 2017).

discussed further below, the language in the NPRM could put Title X-funded health centers in the position of being forced to hire people who intend to refuse to perform essential elements of a position. For example, the rule provides no guidance about whether it is impermissible "discrimination" for a Title X-funded health center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the individual refuses to provide non-directive options counseling. Furthermore, the NPRM does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician out of the health department's family planning project to a unit where pregnancy counseling is not done.

Because the NPRM threatens to undermine the integrity of key HHS programs, including the Title X family planning program, HHS must, at a minimum, clarify that any final rule does not conflict with preexisting legal requirements for and obligations of participants in the Title X program, or of employers, as set forth under Title VII of the Civil Rights Act of 1964, discussed below.

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The NPRM fails to sufficiently address patient needs or achieve the careful balance struck by existing civil rights laws and encourages unprecedented discrimination against patients that will likely impede their access to care and harm their health.

The stated mission of HHS is "to enhance and protect the health and well-being of all Americans." Yet, the NPRM elevates the religious and moral objections of health care providers over the health care needs of the patients who HHS is obligated to protect. The NPRM appears to allow individuals to refuse to provide health care services or information about available health care services to which they object on religious or moral grounds, with virtually no mention of the needs of the patient who is turned away. Patients should not be forced to bear the brunt of the objector's religious or moral beliefs, particularly to the detriment of their own health. In fact, legal and ethical principles of informed consent require health care providers to tell their patients about all of their treatment options, including those the provider does not offer or favor, so long as they are supported by respected medical opinion. As such, health care professionals must endeavor to give their patients complete and accurate information about the services available to them.

Furthermore, the NPRM fails to address serious questions as to whether its purpose is to upset the careful balance struck in current federal law between respecting employee's religious and moral beliefs and employers' ability to provide their patients with health care services. Title VII provides a balance between health care employers' obligations to accommodate their employees' religious beliefs and practices (including their refusal to participate in specific health care services to which they have religious objection) with the needs of the patients they serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs, unless doing so places an "undue hardship" on the employer. This law provides protection for individual belief while still ensuring patient access to health care services. The NPRM provides no guidance about how, if at all, health care

employers are permitted to consider patients' needs when faced with an employee's refusal to provide services.

The NPRM ignores the needs of patients and fails to consider whether an employer can accommodate such a refusal without undue hardship. In so doing, the NPRM invites health care professionals to violate their legal and ethical duties of providing complete, accurate, and unbiased information necessary to obtain informed consent. The failure of health care professionals to provide such information threatens patients' autonomy and their ability to make informed health care decisions.

Title VII is an appropriate standard that protects the needs of patients and strikes an appropriate balance. At a minimum, HHS should clarify that any final rule does not conflict with Title VII.

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The NPRM vastly underestimates the financial burden it would impose on federally funded health care providers who already operate with limited resources.

NFPRHA is particularly well positioned to comment upon the extremely burdensome effect the NPRM will have on the variety of public and private entities awarded federal dollars to provide health services to underserved communities.

As an initial matter, for a non-lawyer to simply read and understand the regulatory language and the lengthy preamble of the NPRM requires numerous hours – much longer than the roughly "10 minutes per law" estimated by HHS. (See 83 Fed. Reg. at 3913). A Final Rule, which would respond to prior comments and provide explanation and commentary elaborating on the Regulation, would require the same at minimum. Moreover, given the magnitude of funds at stake, the complexity and ambiguity of the NPRM's employment provisions, and the diverse staffing arrangements among recipients of federal funds, many NFPRHA members will need to pay for the time of legal counsel to review and consult with them on how to adjust their policies and practices prior to certifying compliance. This will also require time and cost for legal counsel to research and advise how, or if, it is possible for an entity to achieve compliance with the rule as well as with potentially conflicting obligations under State or other Federal laws. A reasonable estimate of these tasks alone would include at least several hours of attorney as well as multiple hours of executive and management staff time – not just the average of 4 hours (total) per year of lawyer and staff time estimated by HHS. (See 83 Fed. Reg. at 3913).

In particular, it appears that policies and practices to comply with the Department's articulated standard will be different than those necessary to comply with existing federal laws such as Title VII. Thus, in estimating an average of 4 hours (total) per year to update policies and procedures *and* retrain staff (see 83 Fed. Reg. at 3913), the NPRM utterly fails to account for:

- Time and cost for legal and human resources or executive staff to review and revise job postings, job descriptions, job application materials, interview and hiring policies and practices, and other employment recruitment and hiring materials.

- Time and cost for legal and human resources or executive staff to review and revise employee manuals and handbooks, and other employment related policies and documents.

- Time and cost to devise and provide trainings for managers and other supervisory staff on interviewing, hiring, and responding to accommodation requests from employees and volunteers who object to participating in the provision of certain health care services.

- Time and cost of hiring and training additional employees and/or paying and retraining existing employees for additional hours to accommodate other employees who refuse to provide services.

While these comments do not attempt to identify and detail each of the likely costs that NFPRHA members and other regulated entities would face if the NPRM was finalized, they demonstrate the qualitatively and quantitatively substantial costs overlooked by HHS in its NPRM. In light of these burdens and the HHS's inability to demonstrate a countervailing need for the rule, NFPRHA strongly urges HHS to withdraw the NPRM. Failure to do so will result in substantial resources being diverted away from providing critical health care to patients in an already underfunded family planning safety net.

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NFPRHA appreciates the opportunity to comment on the NPRM, "Protecting Statutory Conscience Rights in Health Care." If you require additional information about the issues raised in these comments, please contact Robin Summers at rsummers@nfprha.org or 202-552-0150.

Sincerely,

Clare M. Coleman

Clare Coleman
President & CEO

Exhibit 130

NHeLP
NATIONAL HEALTH LAW PROGRAM

March 27, 2018

Via Electronic Submission

The Honorable Alex M. Azar II
Secretary, U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 209F
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0945-ZA03–Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar,

On behalf of National Health Law Program, we submit these comments to the federal Department of Health and Human Services ("Department") and its Office for Civil Rights ("OCR") in opposition to the proposed regulation entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority."

The regulations as proposed would introduce broad and poorly defined language to the existing law that already provides ample protection for the ability of health care providers to refuse to participate in a health care service to which they have moral or religious objections. While the proposed regulations purport to provide clarity and guidance in implementing existing federal religious exemptions, in reality they are vague and confusing. The proposed rule creates the potential for exposing patients to medical care that fails to comply with established medical practice guidelines, negating long-standing principles of informed consent, and undermines the ability of health facilities to provide care in an orderly and efficient manner.

Most important, the regulations fail to account for the significant burden that will be imposed on patients, a burden that will fall disproportionately and most harshly on women, people of color, people living with disabilities, and Lesbian, Gay, Bisexual, Transgender, and Queer ("LGBTQ") individuals. These

1444 I Street NW, Suite 1105 · Washington, DC 20005 · (202) 289-7661
3701 Wilshire Boulevard, Suite 750 · Los Angeles, CA 90010 · (310) 204-6010
200 N. Greensboro Street, Suite D-13 · Carrboro, NC 27510 · (919) 968-6308
www.healthlaw.org

communities already experience severe health disparities and discrimination, conditions that will be exacerbated by the proposed rule, possibly ending in in poorer health outcomes. By issuing the proposed rule along with the newly created "Conscience and Religious Freedom Division," the Department seeks to use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons, the National Health Law Program calls on the Department and OCR to withdraw the proposed rule in its entirety.

I. Under the guise of civil rights, the proposed rule seeks to deny medically necessary care

Civil rights laws and Constitutional guarantees, such as due process and equal protection, are designed to ensure full participation in civil society. The proposed rule, while cloaked in the language of non-discrimination, is designed to deny care and exclude disadvantaged and vulnerable populations. The adverse consequences of health care refusals and other forms of discrimination are well documented. As the Department stated in its proposed rulemaking for § 1557 of the Affordable Care Act ("ACA"),

> "[e]qual access for all individuals without discrimination is essential to achieving" the ACA's aim to expand access to health care and health coverage for all, as "discrimination in the health care context can often…exacerbate existing health disparities in underserved communities."[1]

The Department and OCR have an important role to play in ensuring equal health opportunity and ending discriminatory practices that contribute to health disparities. Yet, this proposed rule represents a dramatic, harmful, and unwarranted departure from OCR's historic and key mission. The proposed rule appropriates language from civil rights statutes and regulations that were designed to improve access to health care and applies that language to deny medically necessary care.

The federal government argues that robust religious refusals, as implemented by this proposed rule, will facilitate open and honest conversations between patients and physicians.[2] As an outcome of this rule, the government believes that patients, particularly those who are "minorities", including those who identify as people of faith, will face fewer obstacles in accessing care.[3] The proposed rule will not achieve these outcomes. Instead, the proposed rule will increase barriers to care, harm patients by allowing health care professionals to ignore established medical guidelines, and undermine open communication between providers and patients. The harm caused by this proposed rule will fall hardest on those most in need of care.

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[1] Nondiscrimination in Health Programs and Activities, 80 Fed. Reg. 54,172, 54,194 (Sept. 8, 2015) (codified at 45 C.F.R. pt. 2).
[2] U.S. Dep't. of Health & Human Serv., Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3917 (Jan. 26, 2018) (hereinafter "proposed rule").
[3] *Id.*

II. The expansion of religious refusals under the proposed rule will disproportionately harm communities who already lack access to care

Women, individuals living with disabilities, LGBTQ persons, people living in rural communities, and people of color face severe health and health care disparities, and these disparities are compounded for individuals who hold these multiple identities. For example, among adult women, 15.2 percent of those who identified as lesbian or gay reported being unable to obtain medical care in the last year due to cost, as compared to 9.6 percent of straight individuals.[4] Women of color experience health care disparities such as high rates of cervical cancer and are disproportionately impacted by HIV.[5] Meanwhile, people of color in rural America are more likely to live in an area with a shortage of health professionals, with 83 percent of majority-Black counties and 81 percent of majority-Latino/a counties designated by the federal Health Resources and Services Administration (HRSA) as Health Professional Shortage Areas (HPSAs).

The expansion of refusals as proposed under this rule will exacerbate these disparities and undermine the ability of these individuals to access comprehensive and unbiased health care, including sexual and reproductive health information and services. Any efforts by providers or other health care personnel to limit the information and access that patients are entitled to receive, even when the organization may not provide those services itself, is incompatible with true consumer choice and individual decision making.

a. The proposed rule will block access to care for low-income women, including immigrant women and African American women

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but can particularly harm low-income women. The burdens on low-income women can be insurmountable when women and families are uninsured,[6] underinsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services nor travel to another location. This is especially true for immigrant women. In comparison to their U.S. born peers, immigrant women are more likely to be uninsured.[7] Notably, immigrant, Latina women have far higher rates of uninsurance than Latina women born in the United States (48 percent versus 21 percent, respectively).[8]

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[4] Brian P. Ward et al., *Sexual Orientation and Health Among U.S. Adults: National Health Interview Survey*, NAT'L CTR. FOR HEALTH STATISTICS, 2013 9 (2014), https://www.cdc.gov/nchs/data/nhsr/nhsr077.pdf.
[5] In 2014, Latinas had the highest rates of contracting cervical cancer and Black women had the highest death rates. *Cervical Cancer Rates By Rates and Ethnicity*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jun. 19, 2017), https://www.cdc.gov/cancer/cervical/statistics/race.htm.; At the end of 2014, of the total number of women diagnosed with HIV, 60 percent were Black. *HIV Among Women,* CTRS. FOR DISEASE CONTROL & PREVENTION, Nov. 17, 2017, https://www.cdc.gov/hiv/group/gender/women/index.html.
[6] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. KAISER FAMILY FOUND., *Women's Health Insurance Coverage* 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.
[7] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf.
[8] *Id.* at 8, 16.

According to a recent report, doctors often fail to inform Black women of the full range of reproductive health options regarding labor or delivery possibly due to stereotypes about Black women's sexuality and reproduction.[9] Young Black women noted that they were shamed by providers when seeking sexual health information and contraceptive care in part, due to their age, and in some instances, sexual orientation.[10]

New research also shows that women of color in many states disproportionately receive their care at Catholic hospitals, subjecting them to treatment that does not comply with the standards of care.[11] In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[12] In New Jersey, for example, women of color make up 50 percent of women of reproductive age in the state, yet have twice the number of births at Catholic hospitals compared to their white counterparts.[13] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on wide range of hospital matters, including reproductive health care. In practice, the ERDs prohibit the provision of emergency contraception, sterilization, abortion, fertility services, and some treatments for ectopic pregnancies. Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals and as a result, women were delayed care or transferred to other facilities, risking their health.[14] The proposed rule will give health care providers a license, such as Catholic hospitals, to opt out of evidence-based care that the medical community endorses. If this rule were to be implemented, more women, particularly women of color, will be put in situations where they will have to decide between receiving compromised care or seeking another provider to receive quality, comprehensive reproductive health services. For many, this choice does not exist.

b. The proposed rule will negatively impact rural communities

The ability to refuse care to patients will leave many individuals in rural communities with no health care options. Medically underserved areas already exist in every state,[15] with

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[9] CTR. FOR REPROD. RIGHTS, NAT'L LATINA INST. FOR REPROD. HEALTH & SISTERSONG WOMEN OF COLOR REPROD. JUSTICE COLLECTIVE, *Reproductive Injustice: Racial and Gender Discrimination in U.S. Health Care* 20-22 (2014), *available at* https://www.reproductiverights.org/sites/crr.civicactions.net/files/documents/CERD_Shadow_US_6.30.14_Web.pdf [hereinafter *Reproductive Injustice*]; IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUSTICE AGENDA, *The State of Black Women & Reproductive Justice* 32-33 (2017), *available at* http://blackrj.org/wp-content/uploads/2017/06/FINAL-InOurVoices_Report_final.pdf.

[10] *Reproductive Injustice*, *supra* note 9, at 16-17.

[11] Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT (2018), *available at* https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[12] *Id* at 12.

[13] *Id* at 9.

[14] Lori R. Freedman et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

[15] Health Res. & Serv. Admin, *Quick Maps – Medically Underserved Areas/Populations*, U.S. DEP'T OF HEALTH & HUM. SERV., https://datawarehouse.hrsa.gov/Tools/MapToolQuick.aspx?mapName=MUA, (last visited Mar. 21, 2018).

over 75 percent of chief executive officers of rural hospitals reporting physician shortages.[16] Many rural communities experience a wide array of mental health, dental health, and primary care health professional shortages, leaving individuals in rural communities with less access to care that is close, affordable, and high quality, than their urban counterparts.[17] Among the many geographic and spatial barriers that exist, individuals in rural areas often must have a driver's license and own a private car to access care, as they must travel further distances for regular checkups, often on poorer quality roads, and have less access to reliable public transportation.[18] This scarcity of accessible services leaves survivors of intimate partner violence (IPV) in rural areas with fewer shelter beds close to their homes, with an average of just 3.3 IPV shelter beds per rural county as compared to 13.8 in urban counties.[19] Among respondents of one survey, more than 25 percent of survivors of IPV in rural areas have to travel over 40 miles to the nearest support service, compared to less than one percent of women in urban areas.[20]

Other individuals in rural areas, such as people with disabilities, people with Hepatitis C, and people of color, have intersecting identities that further exacerbate existing barriers to care in rural areas. Racial and ethnic minority communities often live in concentrated parts of rural America, in communities experiencing rural poverty, lack of insurance, and health professional shortage areas.[21] People with disabilities experience difficulties finding competent physicians in rural areas who can provide experienced and specialized care for their specific needs, in buildings that are barrier free.[22] Individuals with Hepatitis C infection find few providers in rural areas with the specialized knowledge to manage the emerging treatment options, drug toxicities and side effects.[23] All of these barriers will worsen if providers are allowed to refuse care to particular patients.

Meanwhile, immigrant, Latina women and their families often face cultural and linguistic barriers to care, especially in rural areas.[24] These women often lack access to

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[16] M. MacDowell et al., *A National View of Rural Health Workforce Issues in the USA*, 10 RURAL REMOTE HEALTH (2010), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760483/.
[17] Carol Jones et al., *Health Status and Health Care Access of Farm and Rural Populations*, ECON. RESEARCH SERV. (2009), *available at* https://www.ers.usda.gov/publications/pub-details/?pubid=44427.
[18] Thomas A. Arcury et al., *The Effects of Geography and Spatial Behavior on Health Care Utilization among the Residents of a Rural Region*, 40 HEALTH SERV. RESEARCH (2005) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1361130/.
[19] Corinne Peek-Asa et al., *Rural Disparity in Domestic Violence Prevalence and Access to Resources*, 20 J. OF WOMEN'S HEALTH (Nov. 2011) *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3216064/.
[20] *Id.*
[21] Janice C. Probst et al., *Person and Place: The Compounding Effects of Race/Ethnicity and Rurality on Health*, AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1695.
[22] Lisa I. Iezzoni et al., *Rural Residents with Disabilities Confront Substantial Barriers to Obtaining Primary Care*, 41 HEALTH SERV. RESEARCH (2006), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1797079/.
[23] Sanjeev Arora et al., *Expanding access to hepatitis C virus treatment – Extension for Community Healthcare Outcomes (ECHO) Project: Disruptive Innovation in Specialty Care*, 52 HEPATOLOGY (2010), *available at* http://onlinelibrary.wiley.com/doi/10.1002/hep.23802/full.
[24] Michelle M. Casey et al., *Providing Health Care to Latino Immigrants: Community-Based Efforts in the Rural Midwest*, AM. J. PUB. HEALTH (2011), *available at* http://ajph.aphapublications.org/doi/full/10.2105/AJPH.94.10.1709.

transportation and may have to travel great distances to get the care they need.[25] In rural areas, there may simply be no other sources of health and life preserving medical care. When these women encounter health care refusals, they have nowhere else to go.

c. *The proposed rule would harm LGBTQ communities who continue to face rampant discrimination and health disparities*

The proposed rule will compound the barriers to care that LGBTQ individuals face, particularly the effects of ongoing and pervasive discrimination by potentially allowing providers to refuse to provide services and information vital to LGBTQ health.

LGBTQ people continue to face discrimination in many areas of their lives, including health care, based on their sexual orientation and gender identity. The Department's Healthy People 2020 initiative recognizes, "LGBT individuals face health disparities linked to societal stigma, discrimination, and denial of their civil and human rights."[26] LGBTQ people still face discrimination in a wide variety of services affecting access to health care, including reproductive services, adoption and foster care services, child care, homeless shelters, and transportation services – as well as physical and mental health care services.[27] In a recent study published in *Health Affairs*, researchers examined the intersection of gender identity, sexual orientation, race, and economic factors in health care access.[28] They concluded that discrimination as well as insensitivity or disrespect on the part of health care providers were key barriers to health care access and that increasing efforts to provide culturally sensitive services would help close the gaps in health care access.[29]

i. Discrimination against the transgender community

Discrimination based on gender identity, gender expression, gender transition, transgender status, or sex-based stereotypes is necessarily a form of sex discrimination.[30] Numerous

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[25] NAT'L LATINA INST. FOR REPROD. HEALTH & CTR. FOR REPROD. RIGHTS, NUESTRA VOZ, NUESTRA SALUD, NUESTRO TEXAS: THE FIGHT FOR WOMEN'S REPRODUCTIVE HEALTH IN THE RIO GRANDE VALLEY, 7 (2013), *available at* http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[26] *Healthy People 2020, Lesbian, Gay, Bisexual, and Transgender Health*, U.S. DEPT. HEALTH & HUMAN SERV., https://www.healthypeople.gov/2020/topics-objectives/topic/lesbian-gay-bisexual-and-transgender-health, (last accessed on Mar. 8, 2018).

[27] HUMAN RIGHTS WATCH, *All We want is Equality: Religious Exemptions and Discrimination against LGBT People in the United States*, (Feb. 2018), https://www.hrw.org/report/2018/02/19/all-we-want-equality/religious-exemptions-and-discrimination-against-lgbt-people.

[28] Ning Hsieh and Matt Ruther, HEALTH AFFAIRS, *Despite Increased Insurance Coverage, Nonwhite Sexual Minorities Still Experience Disparities In Access To Care* (Oct. 2017) 1786–1794.

[29] *Id.*

[30] *See, e.g.*, *EEOC v. R.G. & G.R. Harris Funeral Homes*, No. 16-2424 (6th Cir. Mar. 7, 2018); *Whitaker v. Kenosha Unified Sch. Dist.*, 858 F.3d 1034 (7th Cir. 2017) (Title IX and Equal Protection Clause); *Dodds v. U.S. Dep't of Educ.*, 845 F.3d 217 (6th Cir. 2016) (Title IX and Equal Protection Clause); *Barnes v. City of Cincinnati*, 401 F.3d 729 (6th Cir. 2005) (Title VII of the 1964 Civil Rights Act); Smith v. City of Salem, 378 F.3d 566 (6th Cir. 2004) (Title VII); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213 (1st Cir. 2000) (Equal Credit Opportunity Act); *A.H. ex rel. Handling v. Minersville Area School District*, 3:17-CV-391, 2017 WL 5632662 (M.D. Pa. Nov. 22, 2017) (Title IX and Equal Protection Clause); *Stone v. Trump*, ---F.Supp.3d ---, No. 17–2459 (D. Md. Nov. 21, 2017) (Equal Protection Clause); Doe v. Trump, ---F.Supp.3d ---, 2017 WL

federal courts have found that federal sex discrimination statutes reach these forms of gender-based discrimination.[31] In 2012, the Equal Employment Opportunity Commission (EEOC) likewise held that "intentional discrimination against a transgender individual because that person is transgender is, by definition, discrimination based on sex and such discrimination therefore violates Title VII."[32]

Twenty-nine percent of transgender individuals were refused to be seen by a health care provider because of their perceived or actual gender identity and 29 percent experienced unwanted physical contact from a health care provider.[33] Additionally, the 2015 U.S. Transgender Survey found that 23 percent of respondents did not see a provider for needed health care because of fears of mistreatment or discrimination.[34]
Data obtained by Center for American Progress (CAP) under a FOIA request indicates the Department's enforcement was effective in resolving issues of anti-LGBTQ discrimination. CAP received information on closed complaints of discrimination based on sexual orientation, sexual orientation-related sex stereotyping, and gender identity that were filed with the Department under § 1557 of the ACA from 2012 through 2016.

- "In approximately 30% of these claims, patients alleged denial of care or insurance coverage simply because of their gender identity – not related to gender transition."

4873042 (D.D.C. Oct. 30, 2017) (Equal Protection Clause); *Prescott v. Rady Children's Hospital-San Diego*, ---F.Supp.3d ---, 2017 WL 4310756 (S.D. Cal. Sept. 27, 2017) (Section 1557); *E.E.O.C. v. Rent-a-Center East, Inc.*, ---F.Supp.3d ---, 2017 WL 4021130 (C.D. Ill. Sept. 8, 2017) (Title VII); *Brown v. Dept. of Health and Hum. Serv.*, No. 8:16DCV569, 2017 WL 2414567 (D. Neb. June 2, 2017) (Equal Protection Clause); *Smith v. Avanti*, 249 F.Supp.3d 1194 (D. Colo. 2017) (Fair Housing Act); *Students & Parents for Privacy v. U.S. Dep't of Educ.*, No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill. Oct. 18, 2016) (Title IX); *Mickens v. Gen. Elec. Co.* No. 16-603, 2016 WL 7015665 (W.D. Ky. Nov. 29, 2016) (Title VII); *Fabian v. Hosp. of Cent. Conn.*, 172 F.Supp.3d 509 (D. Conn. 2016) (Title VII); *Cruz v. Zucker*, 195 F.Supp.3d 554 (S.D.N.Y. Jul. 5, 2016) (Section 1557); *Doe v. State of Ariz.*, No. CV-15-02399-PHX-DGC, 2016 WL 1089743 (D. Ariz. Mar. 21, 2016) (Title VII); *Dawson v. H&H Elec., Inc.*, No. 4:14CV00583 SWW, 2015 WL 5437101 (E.D. Ark. Sept. 15, 2015) (Title VII); *U.S. v. S.E. Okla. State Univ.*, No. CIV–15–324–C, 2015 WL 4606079 (W.D. Okla. 2015) (Title VII); *Rumble v. Fairview Health Serv.*, No. 14–cv–2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015) (Section 1557); *Finkle v. Howard Cty.*, 12 F.Supp.3d 780 (D. Md. 2014) (Title VII); *Schroer v. Billington*, 577 F. Supp. 2d 293 (D.D.C. 2008) (Title VII); *Lopez v. River Oaks Imaging & Diagnostic Grp.*, Inc., 542 F.Supp.2d 653 (S.D. Tex. 2008) (Title VII); *Mitchell v. Axcan Scandipharm,* Inc., No. Civ.A. 05-243, 2006 WL 456173 (W.D. Pa. 2006) (Title VII); *Tronettiv. Healthnet Lakeshore Hosp.*, No. 03–CV–0375E, 2003 WL 22757935 (W.D.N.Y. Sept. 26, 2003) (Title VII).

[31] *See, e.g., Smith v. City of Salem*, 378 F.3d 566, 572-75 (6th Cir. 2004); *Rosa v. Park West Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000) (Equal Credit Opportunity Act); *Schwenk v. Hartford*, 204 F.3d 1187 (9th Cir. 2000) (Gender Motivated Violence Act). *See also* Statement of Interest of the United States at 14, *Jamal v. Saks*, No. 4:14-cv-02782 (S.D. Tex. Jan. 26, 2015).

[32] *Macy v. Holder*, E.E.O.C. App. No. 0120120821, 2012 WL 1435995, *12 (Apr. 20, 2012).

[33] Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AMERICAN PROGRESS, (Jan. 18, 2018), https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/?link_id=2&can_id=d90c309ac9b5a0fa50d294d0b1cdf0b2&source=email-rx-for-discrimination&email_referrer=&email_subject=rx-for-discrimination.

[34] NAT'L CTR. FOR TRANSGENDER EQUALITY, *The Report of the 2015 U.S. Transgender Survey* 5 (2016), *available at* https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf [hereinafter *2015 U.S. Transgender Survey*].

- "Approximately 20% of the claims were for misgendering or other derogatory language."
- "Patients denied care due to their gender identity or transgender status included a transgender woman denied a mammogram and a transgender man refused a screening for a urinary tract infection."[35]

As proposed, the rule could allow religiously affiliated hospitals to not only refuse to provide transition related treatment for transgender people, but to also deny surgeons who otherwise have admitting privileges to provide transition related surgery in the hospital. Transition-related care is not only medically necessary, but for many transgender people it is lifesaving.

ii. Discrimination based upon sexual orientation

Many LGBTQ people lack insurance and providers are not competent in health care issues and obstacles that the LGBTQ community experiences.[36] According to one survey, 8 percent of LGBQ individuals had an experience within the year prior to the survey where a doctor or other health care provider refused to see them because of their actual or perceived sexual orientation and 7 percent experienced unwanted physical contact and violence from a health care provider.[37]

Fear of discrimination causes many LGB people to avoid seeking health care, and, when they do seek care, LGB people are frequently not treated with the respect that all patients deserve. The study "When Health Care Isn't Caring" found that 56 percent of LGB people reported experiencing discrimination from health care providers – including refusals of care, harsh language, or even physical abuse – because of their sexual orientation.[38] Almost 10 percent of LGB respondents reported that they had been denied necessary health care expressly because of their sexual orientation.[39] Delay and avoidance of care due to fear of discrimination compound the significant health disparities that affect the lesbian, gay, and bisexual population. These disparities include:

- LGB individuals are more likely than heterosexuals to rate their health as poor, have more chronic conditions, and have higher prevalence and earlier onset of disabilities.[40]

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[35] Sharita Gruberg & Frank J. Bewkes, Center for American Progress, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (March 7, 2018), *available at* https://www.americanprogress.org/issues/lgbt/reports/2018/03/07/447414/acas-lgbtq-nondiscrimination-regulations-prove-crucial/.

[36] Medical schools often do not provide instruction about LGBTQ health concerns that are not related to HIV/AIDS. Jen Kates et al., *Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S*, KAISER FAMILY FOUND.12 (2017), http://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US.

[37] Mirza, *supra* note 33.

[38] LAMBDA LEGAL, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination Against LGBT People and People with HIV* 5 (2010), *available at* .http://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring.pdf.

[39] *Id.*

[40] David J. Lick, Laura E. Durso & Kerri L. Johnson, *Minority Stress and Physical Health Among Sexual Minorities*, 8 PERS. ON PSYCHOL. SCI. 521 (2013), *available at*

- Lesbian and bisexual women report poorer overall physical health than heterosexual women.[41]
- Gay and bisexual men report more cancer diagnoses and lower survival rates, higher rates of cardiovascular disease and risk factors, as well as higher total numbers of acute and chronic health conditions.[42]
- Gay and bisexual men and other men who have sex with men (MSM) accounted for more than half (56 percent) of all people living with HIV in the United States, and more than two-thirds (70 percent) of new HIV infections.[43]
- Bisexual people face significant health disparities, including increased risk of mental health issues and some types of cancer.[44]

This discrimination affects not only the mental health and physical health of LGBTQ people, but that of their families as well. One pediatrician in Alabama reported that "we often see kids who haven't seen a pediatrician in 5, 6, 7 years, because of fear of being judged, on the part of either their immediate family or them [identifying as LGBTQ]".[45] It is therefore crucial that LGBTQ individuals, who have found unbiased and affirming providers, be allowed to remain with them. If turned away by a health care provider, 17 percent of all LGBTQ people, and 31 percent of LGBTQ people living outside of a metropolitan area, reported that it would be "very difficult" or "not possible" to find the same quality of service at a different community health center or clinic.[46]

The proposed rule allowing providers to deny needed care would reverse recent gains in combatting discrimination and health care disparities for LGBTQ persons. Refusals also implicate standards of care that are vital to LGBTQ health. Medical professionals are expected to provide LGBTQ individuals with the same quality of care as they would anyone else. The American Medical Association recommends that providers use culturally appropriate language and have basic familiarity and competency with LGBTQ issues as they pertain to any health services provided.[47] The World Professional Association for Transgender Health guidelines provide that gender-affirming interventions, when sought by transgender individuals, are medically necessary and part of the standard of care.[48] The

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http://williamsinstitute.law.ucla.edu/research/health-and-hiv-aids/minority-stress-and-physical-health-among-sexual-minorities/.

[41] *Id.*

[42] *Id.*

[43] CTRS FOR DISEASE CONTROL & PREVENTION, *CDC Fact Sheet: HIV Among Gay and Bisexual Men* 1(Feb. 2017), https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/cdc-msm-508.pdf.

[44] HUMAN RIGHTS CAMPAIGN ET AL., *Health Disparities Among Bisexual People* (2015) *available at* http://hrc-assets.s3-website-us-east-1.amazonaws.com//files/assets/resources/HRC-BiHealthBrief.pdf.

[45] HUMAN RIGHTS WATCH, *supra* note 27.

[46] Mirza, *supra* note 33.

[47] *Community Standards of Practice for the Provision of Quality Health Care Services to Lesbian, Gay, Bisexual, and Transgender Clients*, GAY LESBIAN BISEXUAL & TRANSGENDER HEALTH ACCESS PROJECT, http://www.glbthealth.org/CommunityStandardsofPractice.htm (last visited Jan. 26, 2018, 12:59 PM); *Creating an LGBTQ-friendly Practice*, A.M.A., https://www.ama-assn.org/delivering-care/creating-lgbtq-friendly-practice#Meet a Standard of Practice (last visited Jan. 26, 2018, 12:56 PM).

[48] *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People*, WORLD PROF. ASS'N FOR TRANSGENDER HEALTH (2011), https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20(2)(1).pdf.

American College of Obstetricians and Gynecologists ("ACOG") warns that failure to provide gender-affirming treatment can lead to serious health consequences for transgender individuals.[49] LGBTQ individuals already experience significant health disparities, and denying medically necessary care based on sexual orientation or gender identity exacerbates these disparities.

In addition, LGBTQ individuals face disparities in medical conditions that may implicate the need for reproductive health services. For example, lesbian and bisexual women report heightened risk for and diagnosis of some cancers and higher rates of cardiovascular disease.[50] The LGBTQ community is significantly at risk for sexual violence.[51] Eighteen percent of LGB students have reported being forced to have sex.[52] Transgender women, particularly women of color, face high rates of HIV.[53]

Refusals to treat individuals according to medical standards of care put patients' health at risk, particularly for women and LGBTQ individuals. Expanding religious refusals will further put needed care, including reproductive health care, out of reach for many. Given the broadly written and unclear language of the proposed rule, if implemented, some providers may misuse this rule to deny services to LGBTQ individuals based on perceived or actual sexual orientation and gender identity. Allowing providers to flout established medical guidelines and deny medically accurate, evidence-based care impairs the ability of patients to make a health decision that expresses their self-determination.

Finally, the proposed rule threatens to turn back the clock to the darkest days of the AIDS pandemic when same-sex partners were routinely denied hospital visitation and health care providers scorned sick and dying patients.

d. The proposed rule will hurt people living with disabilities

Many people with disabilities receive home and community-based services (HCBS), including residential and day services, from religiously-affiliated providers. Historically, people with disabilities who rely on these services have sometimes faced discrimination, exclusion, and a loss of autonomy due to provider objections. Group homes have, for example, refused to allow residents with intellectual disabilities who were married to live together in the group home.[54] Individuals with HIV – a recognized disability under the

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[49] *Committee Opinion 512: Health Care for Transgender Individuals*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Dec. 2011), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Health-Care-for-Transgender-Individuals.
[50] Kates, *supra* note 36, at 4.
[51] Forty-six percent of bisexual women have been raped and 47 percent of transgender people are sexually assaulted at some point in their lifetime. This rate is particularly higher for transgender people of color. Kates, *supra* note 36, at 8.; *2015 U.S. Transgender Survey*, *supra* note 34, at 5.
[52] *Health Risks Among Sexual Minority Youth*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/healthyyouth/disparities/smy.htm (last updated May 24, 2017).
[53] More than 1 in 4 transgender women are HIV positive. Kates, *supra* note 36, at 6.
[54] See *Forziano v. Independent Grp. Home Living Prog.*, No. 13-cv-00370 (E.D.N.Y. Mar. 26, 2014) (dismissing lawsuit against group homes, including a religiously affiliated group home, that refused to allow married couple with intellectual disabilities live together). Recent regulations have reinforced protections to ensure available choice of roommates and guests. 42 C.F.R. §§ 441.301(c)(4)(vi)(B) & (D).

American Disabilities Act – have repeatedly encountered providers who deny services, necessary medications, and other treatments citing religious and moral objections. One man with HIV was refused care by six nursing homes before his family was finally forced to relocate him to a nursing home 80 miles away.[55] Given these and other experiences, the extremely broad proposed language at 45 C.F.R. § 88.3(a)(2)(vi) that would allow any individual or entity with an "articulable connection" to a service, referral, or counseling described in the relevant statutory language to deny assistance due to a moral or religious objection is extremely alarming and could seriously compromise the health, autonomy, and well-being of people with disabilities.

Many people with disabilities live or spend much of their day in provider-controlled settings where they often receive supports and services. They may rely on a case manager to coordinate necessary services, a transportation provider to get them to community appointments, or a personal care attendant to help them take medications and manage their daily activities. Under this broad new proposed language, any of these providers could believe they are entitled to object to providing a service covered under the regulation and not even tell the individual where they could obtain that service, how to find an alternative provider, or even whether the service is available to them. A case manager might refuse to set up a routine appointment with a gynecologist because contraceptives might be discussed. A personal home health aide could refuse to help someone take a contraceptive. An interpreter for a deaf individual could refuse to mediate a conversation with a doctor about abortion. In these cases, a denial based on someone's personal moral objection can potentially affect every facet of life for a person with disabilities – including visitation rights, autonomy, and access to the community.

Finally, due to limited provider networks in some areas and to the important role that case managers and personal care attendants play in coordinating care, it may be more difficult for people with disabilities and older adults to find alternate providers who can help them. For example, home care agencies and home-based hospice agencies in rural areas are facing significant financial difficulties staying open. Seven percent of all zip codes in the United States do not have any hospice services available to them.[56] Finding providers competent to treat people with certain disabilities can increase the challenge. Add in the possibility of a case manager or personal care attendant who objects to helping and the barrier to accessing these services can be insurmountable. Moreover, people with disabilities who identify as LGBTQ or who belong to a historically disadvantaged racial or ethnic group may be both more likely to encounter service refusals and also face greater challenges to receive (or even know about) accommodations.

III. The proposed rule undermines longstanding ethical and legal principles of informed consent

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[55] NAT'L WOMEN'S LAW CTR., *Fact Sheet: Health Care Refusals Harm Patients: The Threat to LGBT People and Individuals Living with HIV/AIDS,* (May 2014), *available at* https://nwlc.org/wp-content/uploads/2015/08/lgbt_refusals_factsheet_05-09-14.pdf.

[56] Julie A. Nelson & Barbara Stover Gingerich, *Rural Health: Access to Care and Services*, 22 HOME HEALTH CARE MGMT. PRAC. (2010), *available at* http://globalag.igc.org/ruralaging/us/2010/access.pdf.

The proposed rule threatens informed consent, a necessary principle of patient-centered decision-making. Informed consent relies on disclosure of medically accurate information by providers so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[57] This right relies on two factors: access to relevant and medically accurate information about treatment choices and alternatives, and provider guidance based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care.

The proposed rule purports to improve communication between patients and providers, but instead, will deter open, honest conversations that are vital to ensuring that a patient is able to be in control of their medical circumstances. For example, the proposed rule suggests that someone could refuse to offer information, if that information might be used to obtain a service to which the refuser objects. Such an attenuated relationship to informed consent could result in withholding information far beyond the scope of the underlying statutes, and would violate medical standards of care.

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.[58] Informed consent is intended to help balance the unequal balance of power between health providers and patients and ensure patient-centered decision-making. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted and the full range of treatment options for a patient's medical condition. Without informed consent, patients will be unable to make medical decisions that are grounded in agency, their beliefs and preferences, and that meet their personal needs. This is particularly problematic, as many communities, including women of color and women living with disabilities, have disproportionately experienced abuse and trauma at the hands of providers and institutions.[59] In order to ensure that patient decisions are based on free will, informed consent must be upheld in the patient-provider relationship. The proposed rule threatens this principle and may very well force individuals into harmful medical circumstances.

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[57] TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[58] BEAUCHAMP & CHILDRESS, *supra* note 58; Robert Zussman, *Sociological perspectives on medical ethics and decision-making*, 23 ANN. REV. SOC. 171-89 (1997).

[59] Gutierrez, E. R. *Fertile Matters: The Politics of Mexican Origin Women's* Reproduction, 35-54 (2008) (discussing coercive sterilization of Mexican-origin women in Los Angeles); Jane Lawrence, *The Indian Health Service and the Sterilization of Native American Women*, 24 AM. INDIAN Q. 400, 411-12 (2000) (referencing one 1974 study indicating that Indian Health Services would have coercively sterilized approximately 25,000 Native American Women by 1975); Alexandra Minna Stern, *Sterilized in the Name of Public Health*, 95 AM. J. PUB. H. 1128, 1134 (July 2005) (discussing African-American women forced to choose between sterilization and medical care or welfare benefits and Mexican women forcibly sterilized). *See also Buck v. Bell*, 274 U.S. 200, 207 (1927) (upholding state statute permitting compulsory sterilization of "feeble-minded" persons); Vanessa Volz, *A Matter of Choice: Women With Disabilities, Sterilization, and Reproductive Autonomy in the Twenty-First Century*, 27 WOMEN RTS. L. REP. 203 (2006) (discussing sterilization reform statutes that permit sterilization with judicial authorization).

According to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."[60] The American Nurses Association ("ANA") similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. According to the ANA, "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[61] Similarly, pharmacists are called to respect the autonomy and dignity of each patient.[62]

Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.[63] In *Brownfield v. Daniel Freeman Marina Hospital*, a California court addressed the importance of patients' access to information concerning emergency contraception. The court found that:

> "The duty to disclose such information arises from the fact that an adult of sound mind has 'the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.' [citation omitted] Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available."[64]

In addition, the proposed rule does not provide any protections for health care professionals who want to provide, counsel, or refer for health care services that are implicated in this rule, for example, reproductive health or gender affirming care. The proposed rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[65] Due to the rule's aggressive enforcement mechanisms and its vague and confusing language, providers may fear to give care or information. The inability of providers to give comprehensive, medically accurate information and options that will help patients make the best health decisions violates medical principles such as,

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[60] *The AMA Code of Medical Ethics' Opinions on Informing Patients: Opinion 9.09 – Informed Consent*, 14 AM. MED. J. ETHICS 555-56 (2012), http://journalofethics.ama-assn.org/2012/07/coet1-1207.html.
[61] *Code of ethics for nurses with interpretive statements, Provision 1.4 The right to self-determination*, AM. NURSES ASS'N (2001), https://www.truthaboutnursing.org/research/codes/code_of_ethics_for_nurses_US.html.
[62] *Code of Ethics for Pharmacists*, AM. PHARMACISTS ASS'N (1994).
[63] *See, e.g., State HIV Laws*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/hiv/policies/law/states/index.html (last visited Nov. 13, 2017, 1:22PM); *Emergency Contraception*, GUTTMACHER INST. (Oct. 1, 2017), https://www.guttmacher.org/state-policy/explore/emergency-contraception.
[64] *Brownfield v. Daniel Freeman Marina Hospital*, 256 Cal. Rptr. 240 (Ct. App. 1989).
[65] *See* 42 U.S.C. § 300a-7(c).

beneficence, nonmaleficence, respect for autonomy, and justice. In particular, the principle of beneficence "requires that treatment and care do more good than harm; that the benefits outweigh the risks, and that the greater good for the patient is upheld."[66] In addition, the proposed rule undermines principles of quality care. Health care should be safe, effective, patient-centered, timely, efficient, and equitable.[67] Specifically, the provision of the care should not vary due to the personal characteristics of patients and should ensure that patient values guide all clinical decisions.[68] The expansion of religious refusals as envisioned in the proposed rule may compel providers to furnish care and information that harms the health, well-being, and goals of patients.

In particular, the principles of informed consent, respect for autonomy, and beneficence are important when individuals are seeking end of life care. These patients should be the center of health care decision-making and should be fully informed about their treatment options. Their advance directives should be honored, regardless of the physician's personal objections. Under the proposed rule, providers who object to various procedures could impose their own religious beliefs on their patients by withholding vital information about treatment options— including options such as voluntarily stopping eating and drinking, palliative sedation or medical aid in dying. These refusals would violate these abovementioned principles by ignoring patient needs, their desires, and autonomy and self-determination at a critical time in their lives. Patients should not be forced to bear the brunt of their provider's religious or moral beliefs regardless of the circumstances.

IV. The regulations fail to consider the impact of refusals on persons suffering from substance use disorders (SUD)

The over breadth of this proposed rule could be devastating to people with Substance Use Disorder (SUD). Rather than promoting the evidence-based standard of care, the rule could allow anyone from practitioners to insurers to refuse to provide, or even recommend, Medication Assisted Treatment (MAT) and other evidence-based interventions due simply to a personal objection.

The opioid epidemic continues to claim too many lives. According to the Centers for Disease Control and Prevention (CDC), over 63,000 people in the U.S. died from drug overdose in 2016.[69] The latest numbers show a 2017 increase in emergency department overdose admissions of 30% across the country, and up to 70% in some areas of the Midwest.[70]

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[66] Amy G. Bryant & Jonas J. Schwartz, *Why Crisis Pregnancy Centers Are Legal but Unethical*, 20 AM. MED. ASS'N J. ETHICS 269, 272 (2018).
[67] INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 3 (Mar. 2001), *available at* http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf.
[68] *Id.*
[69] Holly Hedegaard M.D., et al. *Drug Overdose Deaths in the United States, 1999-2016*, NAT'L CTR. FOR HEALTH STATISTICS1-8 (2017).
[70] *Vital Signs*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vitalsigns/opioid-overdoses/.

The clear, evidence-based treatment standard for opioid use disorder (OUD) is MAT.[71] Buprenorphine, methadone, and naltrexone are the three FDA-approved drugs for treating patients with opioid use disorder. MAT is so valuable to treatment of addiction that the World Health Organization considers buprenorphine and methadone "Essential Medications."[72] Buprenorphine and methadone are, in fact, opioids. However, while they operate on the same receptors in the brain as other opioids, they do not produce the euphoric effect of other opioids but simply keep the user from experiencing withdrawal symptoms. They also keep patients from seeking opioids on the black market, where risk of death from accidental overdose increases. Patients on MAT are less likely to engage in dangerous or risky behaviors because their physical cravings are met by the medication, increasing their safety and the safety of their communities.[73] Naloxone is another medication key to saving the lives of people experiencing an opioid overdose. This medication reverses the effects of an opioid and can completely stop an overdose in its tracks.[74] Information about and access to these medications are crucial factors in keeping patients suffering from SUD from losing their jobs, losing their families, and losing their lives.

However, stigma associated with drug use stands in the way of saving lives.[75] America's prevailing cultural consciousness, after decades of treating the disease of addiction as largely a criminal justice and not a public health issue, generally perceives drug use as a moral failing and drug users as less deserving of care. For example, a needle exchange program designed to protect injection drug users from contracting blood borne illnesses such as HIV, Hepatitis C, and bacterial endocarditis was shut down in October 2017 by the Lawrence County, Indiana County Commission due to their moral objection to drug use, despite overwhelming evidence that these programs are effective at reducing harm and do not increase drug use.[76] One commissioner even quoted the Bible as he voted to shut it

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[71] U.S. DEP'T HEALTH & HUM. SERV., PUB NO. (SMA)12-4214, MEDICATION-ASSISTED TREATMENT FOR OPIOID ADDICTION IN OPIOID TREATMENT PROGRAMS (2012), https://store.samhsa.gov/shin/content/SMA12-4214/SMA12-4214.pdf; National Institute on Drug Abuse, *Effective Treatments for Opioid Addiction*, https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction.

[72] World Health Organization, 19th WHO Model List of Essential Medicines (April 2015), http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf

[73] OPEN SOC'Y INST., BARRIERS TO ACCESS: MEDICATION-ASSISTED TREATMENT AND INJECTION-DRIVEN HIV EPIDEMICS 1 (2009), https://www.opensocietyfoundations.org [https://perma.cc/YF94-88AP].

[74] *See* James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994).

[75] Ellen M. Weber, *Failure of Physicians to Prescribe Pharmacotherapies for Addiction: Regulatory Restrictions and Physician Resistance*, 13 J. HEALTH CARE L. & POL'Y 49, 56 (2010); German Lopez, *There's a highly successful treatment for opioid addiction. But stigma is holding it back.*, VOX, Nov. 15, 2017, https://www.vox.com/science-and-health/2017/7/20/15937896/medication-assisted-treatment-methadone-buprenorphine-naltrexone.

[76] German Lopez, *An Indiana county just halted a lifesaving needle exchange program, citing the Bible,* VOX, Oct. 20, 2017, https://www.vox.com/policy-and-politics/2017/10/20/16507902/indiana-lawrence-county-needle-exchange.

down. Use of naloxone to reverse overdose has been decried as "enabling these people" to go on to overdose again.[77]

In this frame of mind, only total abstinence is seen as successful treatment for SUD, usually as a result of a 12-step or faith-based program. MAT is considered by many to be simply "substituting one drug for another drug."[78] This belief is so common that even the former Secretary of the Department is on the record as opposing MAT because he didn't believe it would "move the dial," since people on medication would be not "completely cured."[79] The scientific consensus is that SUD is a chronic disease, and yet many recoil from the idea of treating SUD with medication like any other illness such as diabetes or heart disease.[80] The White House's own opioid commission found that "negative attitudes regarding MAT appeared to be related to negative judgments about drug users in general and heroin users in particular."[81]

People with SUD already suffer due to stigma and have a difficult time finding appropriate care. For example, it can be difficult to find access to local methadone clinics in rural areas.[82] Other roadblocks, such as artificial caps on the number of patients to whom doctors can prescribe buprenorphine, further prevent people with SUD from receiving appropriate care.[83] Only one-third of treatment programs across the country provide MAT, even though treatment with MAT can cut overdose mortality rates in half and is considered the gold standard of care.[84] The current Secretary of the Department has noted that expanding access to MAT is necessary to save lives and that it will be "impossible" to quell the opioid epidemic without increasing the number of providers offering the evidence-based standard of care.[85] This rule, which allows misinformation and personal feelings to get in

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[77] Tim Craig & Nicole Lewis, *As opioid overdoses exact a higher price, communities ponder who should be saved*, WASH. POST, Jul. 15, 2017, https://www.washingtonpost.com/world/as-opioid-overdoses-exact-a-higher-price-communities-ponder-who-should-be-saved/2017/07/15/1ea91890-67f3-11e7-8eb5-cbccc2e7bfbf_story.html?utm_term=.4184c42f806c.
[78] Lopez, *supra* note 75.
[79] Eric Eyre, *Trump officials seek opioid solutions in WV*, CHARLESTON GAZETTE-MAIL, May 9, 2017, https://www.wvgazettemail.com/news/health/trump-officials-seek-opioid-solutions-in-wv/article_52c417d8-16a5-59d5-8928-13ab073bc02b.html.
[80] Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063, http://www.nejm.org/doi/full/10.1056/NEJMp1402780.
[81] Report of the President's Commission on Combating Drug Addiction and the Opioid Crisis, Nov. 1, 2017, https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf
[82] Christine Vestal, *In Opioid Epidemic, Prejudice Persists Against Methadone*, STATELINE, Nov. 11, 2016, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/11/11/in-opioid-epidemic-prejudice-persists-against-methadone
[83] 42 C.F.R. §8.610.
[84] Matthais Pierce, et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-Related Poisoning: A National Cohort Study in England*, 111:2 ADDICTION 298 (Nov. 2015); Luis Sordo, et al., Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-Analysis of Cohort Studies, BMJ (2017), http://www.bmj.com/content/357/bmj.j1550.; Alex Azar, Secretary, U.S. Dep't of Health & Hum. Serv., Plenary Address to National Governors Association, (Feb. 24, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/plenary-addres-to-national-governors-association.html.
[85] Azar, *supra* note 84.

the way of science and lifesaving treatment, will not help achieve the goals of the administration; it will instead trigger countless numbers of deaths.

V. The proposed rule permits health care professionals to opt out of providing medical care that the public expects by allowing them to disregard evidence-based standards of care

Medical practice guidelines and standards of care establish the boundaries of medical care that patients can expect to receive and that providers should be expected to deliver. The health services impacted by refusals are often related to reproductive and sexual health, which are implicated in a wide range of common health treatment and prevention strategies. Information, counseling, referral and provisions of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer. Many of these conditions disproportionately affect women of color.[86] The expansion of these refusals as outlined in the proposed rule will put women, particularly women of color, who experience these medical conditions at greater risk for harm.

Moreover, a 2007 survey of physicians working at religiously-affiliated hospitals found that nearly one in five (19 percent) experienced a clinical conflict with the religiously-based policies of the hospital.[87] While some of these physicians might refer their patients to another provider who could provide the necessary care, one 2007 survey found that as many as one-third of patients (nearly 100 million people) may be receiving care from physicians who do not believe they have any obligations to refer their patients to other providers.[88] Meanwhile, the number of Catholic hospitals in the United States has increased by 22 percent since 2001, and now own one in six hospital beds across the

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[86] For example, Black women are three times more likely to be diagnosed with lupus than white women. Latinas and Asian, Native American, and Alaskan Native women also are likely to be diagnosed with lupus. Office on Women's Health, *Lupus and women*, U.S. DEP'T HEALTH & HUM. SERV. (May 25, 2017), https://www.womenshealth.gov/lupus/lupus-and-women. Black and Latina women are more likely to experience higher rates of diabetes than their white peers. Office of Minority Health, *Diabetes and African Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Jul. 13, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=18; Office of Minority Health, *Diabetes and Hispanic Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (May 11, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=63. Filipino adults are more likely to be obese in comparison to the overall Asian population in the United States. Office of Minority Health, *Obesity and Asian Americans*, U.S. DEP'T OF HEALTH & HUM. SERV. (Aug. 25, 2017), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=55. Native American and Alaskan Native women are more likely to be diagnosed with liver and kidney/renal pelvis cancer in comparison to non-Hispanic white women. Office of Minority Health, *Cancer and American Indians/Alaska Natives*, U.S. DEP'T OF HEALTH & HUM. SERV. (Nov. 3, 2016), https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=31.

[87] Debra B. Stulberg M.D. M.A., et al., *Religious Hospitals and Primary Care Physicians: Conflicts over Policies for Patient Care*, J. GEN. INTERN. MED. 725-30 (2010) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2881970/.

[88] Farr A. Curlin M.D., et al., *Religion, Conscience, and Controversial Clinical Practices*, NEW ENG. J. MED. 593–600 (2007) *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2867473/.

country.[89] The increase of Catholic hospitals poses a danger for women seeking reliable access to medical services, many of whom do not understand the full range of services that may be denied them. One public opinion survey found that, among the less than one-third of women who understood that a Catholic hospital might limit care, only 43 percent expected limited access to contraception, and a mere 6 percent expected limited access to the morning-after pill.[90]

a. Pregnancy prevention

The importance of the ability of women to make decisions for themselves to prevent or postpone pregnancy is well established within the medical guidelines across a range of practice areas. Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.[91] Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.[92]

Moreover, women who are struggling to make ends meet are disproportionately impacted by unintended pregnancy. In 2011, 45% of pregnancies in the U.S. were unintended – meaning that they were either unwanted or mistimed.[93] Low-income women have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.[94] The Institute of Medicine has documented negative health effects of unwanted pregnancy for mothers and children. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors as well as low-birth weight babies and insufficient prenatal care.[95]

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[89] Julia Kaye et al., *Health Care Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives*, AM. CIVIL LIBERTIES UNION 22 (2017), *available at* https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[90] Nadia Sawicki, *Mandating Disclosure Of Conscience-Based Limitations On Medical Practice*, 42 AM. J. OF LAW & MED. 85-128 (2016) *available at* http://journals.sagepub.com/doi/pdf/10.1177/0098858816644717.
[91] AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE S115, S117 (2017), available at: http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf
[92] *Id.* at S114.
[93] *Unintended Pregnancy in the United States*, Guttmacher Inst. (Sept. 2016), https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states.
[94] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in rates of unintended pregnancy in the United States, 1994 and 2001*, 38 PERSPECTIVES ON SEXUAL & REPROD. HEALTH 90-6 (2006).
[95] INSTITUTE OF MEDICINE COMMITTEE ON UNINTENDED PREGNANCY, THE BEST INTENTIONS: UNINTENDED PREGNANCY AND THE WELL-BEING OF CHILDREN AND FAMILIES (Sarah S. Brown & Leon Eisenberg eds.,1995).

b. Sexually transmitted infections (STIs)

Religious refusals also affect access to sexual health care more broadly. Contraceptives and access to preventative treatment for STIs are a critical aspect of health care. The CDC estimates that 20 million new STIs occur each year. Chlamydia remains the most commonly reported infectious disease in the U.S., while HIV/AIDS remains the most life threatening. Women, especially young women, and Black women, are hit hardest by Chlamydia—with rates of Chlamydia 5.6 times higher for Black than for white Americans.[96] Consistent use of condoms results in an 80 percent reduction of HIV transmission, and the American Academy of Pediatrics, ACOG, and the World Health Organization all recommend that providers promote condom use.[97]

c. Ending a pregnancy

While there are numerous reasons for why a person would seek to end a pregnancy, there are many medical conditions in which ending a pregnancy is recommended as treatment. These conditions include: preeclampsia and eclampsia, certain forms of cardiovascular disease, and complications for chronic conditions. Significant racial disparities exist in rates of and complications associated with preeclampsia.[98] For example, the rate of preeclampsia is 61 percent higher for Black women than for white women, and 50 percent higher than women overall.[99] ACOG and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival.[100] ACOG and American Heart Association recommend that a pregnancy be avoided or ended for certain conditions such as severe pulmonary hypertension.[101] Many medications can

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[96] *Sexually Transmitted Disease Surveillance 2016*, CTR. FOR DISEASE CONTROL & PREVENTION (Sept. 2017), https://www.cdc.gov/std/stats16/CDC_2016_STDS_Report-for508WebSep21_2017_1644.pdf.
[97] American Academy of Pediatrics Committee on Adolescence, *Condom Use by Adolescents*, 132 PEDIATRICS (Nov. 2013), http://pediatrics.aappublications.org/content/132/5/973; American Academy of Pediatrics, American College of Obstetricians and Gynecologists, March of Dimes Birth Defects Foundation. Guidelines for perinatal care. 6th ed. Elk Grove Village, IL; Washington, DC: American Academy of Pediatrics; American College of Obstetricians and Gynecologists; 2007; American College of Obstetricians and Gynecologists. Barrier methods of contraception. Brochure (*available at* http://www.acog.org/publications/patient_education/bp022.cfm). Washington, DC: American College of Obstetricians and Gynecologists; 2008 July; World Health Organization, UNAIDS, UNFPA, *Position statement on condoms and HIV prevention*, UNICEF (2009), https://www.unicef.org/aids/files/2009_position_paper_condoms_en.pdf.
[98] Sajid Shahul et al., *Racial Disparities in Comorbidities, Complication, and Maternal and Fetal Outcomes in Women With Preeclampsia/eclampsia*, 34 HYPERTENSION PREGNANCY (Dec. 4, 2015), http://www.tandfonline.com/doi/abs/10.3109/10641955.2015.1090581?journalCode=ihip20.
[99] Richard Franki, *Preeclampsia/eclampsia rate highest in black women*, OB.GYN. NEWS (Apr. 29., 2017), http://www.mdedge.com/obgynnews/article/136887/obstetrics/preeclampsia/eclampsia-rate-highest-black-women.
[100] AMERICAN ACADEMY OF PEDIATRICS & AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).
[101] Mary M. Canobbio et al., *Management of Pregnancy in Patients With Complex Congenital Heart Disease*, 135 CIRCULATION e1-e39 (2017); Debabrata Mukherjee, *Pregnancy in Patients With Complex Congenital Heart Disease*, AM. COLL. CARDIOLOGY (Jan. 24, 2017), http://www.acc.org/latest-in-cardiology/ten-points-to-remember/2017/01/24/14/40/management-of-pregnancy-in-patients-with-complex-chd.

cause significant fetal impairments, and therefore the U.S. Food and Drug Administration and professional medical associations recommend that women use contraceptives to ensure that they do not become pregnant while taking these medications.[102] In addition, some medical guidelines counsel patients to end a pregnancy if they are taking certain medications for thyroid disease.[103]

d. Emergency contraception

The proposed rule will magnify the harm in circumstances where women are already denied the standard of care. Catholic hospitals have a record of providing substandard care or refusing care altogether to women for a range of medical conditions and crises that implicate reproductive health. For example, in a 2005 study of Catholic hospital emergency rooms by Ibis Reproductive Health for Catholics for Choice, it was found that 55 percent would not dispense emergency contraception under any circumstances.[104] Twenty three percent of the hospitals limited EC to victims of sexual assault.[105]

These hospitals violated the standards of care established by medical providers regarding treatment of sexual assault. Medical guidelines state that survivors of sexual assault should be provided emergency contraception subject to informed consent and that it should be immediately available where survivors are treated.[106] At the bare minimum, survivors should be given comprehensive information regarding emergency contraception.[107]

e. Artificial Reproductive Technology (ART)

Refusals to provide the standard of care to LGBTQ individuals because of their sexual orientation or gender identity can affect access to care across a broad spectrum of health concerns, which includes primary and specialty care settings. One example of refusals that affects LGBTQ patients, as well as non-LGBTQ patients, is refusals to educate about, provide, or cover ART procedures for religious reasons. For individuals with cancer, the

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[102] ELEANOR BIMLA SCHWARZ M.D. M.S., et al., *Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women*, 147 Annals of Internal Medicine. (Sept. 18, 2007).

[103] For example, the American College of Obstetricians and Gynecologists specifically recommends that if a woman taking Iodine 131 becomes pregnant, her physician should caution her to consider the serious risks to the fetus, and consider termination. American College of Obstetricians and Gynecologists, *ACOG Practice Bulletin No. 37: Thyroid disease in pregnancy* 100 OBSTETRICS & GYNECOLOGY 387-96 (2002).

[104] Teresa Harrison, *Availability of Emergency Contraception: A Survey of Hospital Emergency Department Staff*, 46 ANNALS EMERGENCY MED. 105-10 (Aug. 2005), http://www.annemergmed.com/article/S0196-0644(05)00083-1/pdf

[105] *Id.* at 105.

[106] *Committee Opinion 592: Sexual Assault*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Apr. 2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co592.pdf?dmc=1&ts=20170213T2116487879; *Management of the Patient with the Complaint of Sexual Assault*, AM. COLL. EMERGENCY MED. (Apr. 2014), https://www.acep.org/Clinical---Practice-Management/Management-of-the-Patient-with-the-Complaint-of-Sexual-Assault/#sm.00000bexmo6ofmepmultb97nfbh3r.

[107] *Access to Emergency Contraception H-75.985*, AMA (2014), https://policysearch.ama-assn.org/policyfinder/detail/emergency%20contraception%20sexual%20assault?uri=%2FAMADoc%2FHOD.xml-0-5214.xml.

standard of care includes education and informed consent around fertility preservation, according to the American Society for Clinical Oncology and the Oncology Nursing Society.[108] Refusals to educate patients about or to provide ART occur for two reasons: refusals based on religious beliefs about ART itself and refusals to provide ART to LGBTQ individuals because of their LGBTQ identity. In both situations, refusals to educate patients about ART and fertility preservation, and to facilitate ART when requested, are against the standard of care.

The lack of clarity in the rule could lead a hospital or an individual provider to refuse to provide ART to same-sex couples based on religious belief. For some couples, this discrimination would increase the cost and emotional toll of family building. In some parts of the country, however, these refusals would be a complete barrier to parenthood. More broadly, these refusals deny patients the human right and dignity to be able to decide to have children, and cause psychological harm to patients who are already vulnerable because of their health status or their experience of health disparities.

f. HIV Health

For HIV, in addition to consistent condom use, pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are an important part of prevention for those at high risk for contracting HIV. ACOG recommends that PrEP be considered for individuals at high risk of contracting HIV.[109] Under the proposed rule, an insurance company could refuse to cover PrEP or PEP because of a religious belief. Refusals to promote and facilitate condom use because of religious beliefs and refusals to prescribe PrEP or PEP because of a patient's perceived or actual sexual orientation, gender identity, or perceived or actual sexual behaviors is in violation of the standards of care and harms patients already at risk for experiencing health disparities. Both PrEP and PEP have been shown to be highly effective in preventing HIV infection. Denying access to this treatment would adversely affect vulnerable, highest risk populations including gay and bisexual men.

VI. The proposed rule misinterprets statutory language governing Medicaid managed care organizations

The proposed rule misinterprets narrowly tailored language governing Medicaid managed care organizations (MCOs), and instead creates a freestanding religious exemption.[110]

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[108] Alison W. Loren et al., *Fertility Preservation for Patients With Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update*, 31 J. CLINICAL ONCOLOGY 2500-10 (July 1, 2013); Ethics Committee of the American Society for Reproductive Medicine, *Fertility preservation and reproduction in patients facing gonadotoxic therapies: a committee opinion*, 100 AM. SOC'Y REPROD. MED. 1224-31 (Nov. 2013), http://www.allianceforfertilitypreservation.org/_assets/pdf/ASRMGuidelines2014.pdf; Joanne Frankel Kelvin, *Fertility Preservation Before Cancer Treatment: Options, Strategies, and Resources*, 20 CLINICAL J. ONCOLOGY NURSING 44-51 (Feb. 2016).

[109] ACOG *Committee Opinion 595: Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (May 2014), https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Preexposure-Prophylaxis-for-the-Prevention-of-Human-Immunodeficiency-Virus.

[110] 83 Fed. Reg. 3926.

Under current law, MCOs are prohibited from restricting a provider's ability to offer counseling and information regarding treatment and care that is within the lawful scope of the provider's practice regardless of whether these services are covered by the MCO.[111] However, the MCO does not need to pay for counseling or referral related to a service to which they object on the basis of religious or moral beliefs.[112] The underlying religious exemption is intended only to qualify the statute's prohibition on interference with doctor-patient communications of Medicaid managed care enrollees. Because the underlying statutory exemption is a provision of statutory construction, Congress could not have intended this provision to be a blanket provision for Medicaid managed care organizations.[113] Moreover, the proposed rule omits enrollee protections required by the underlying statute when a Medicaid managed care organization declines to cover referral or counseling on the basis of religious of moral beliefs. Current and prospective enrollees must receive written notice and information on policies regarding counseling or referral or changes to such policies before and during enrollment and within 90 days after a change to policy has occurred.[114] The language of the proposed rule misinterprets and far exceeds the plain language of the statute and may discourage Medicaid managed care organizations from complying with notice requirements to the detriment of enrollees.

VII. The proposed rule does not take into account the law governing emergency health situations

In addition, the proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[115] Under EMTALA, every hospital is required to comply – even those that are religiously affiliated.[116] Because the proposed rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may

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[111] 42 U.S.C. § 1396u-2(b)(3)(A).
[112] *Id.* § 1396u-2(b)(3)(B)(i).
[113] *See e.g.*, *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 376 n.5 (1986) (stating that statutes may provide their own rules of statutory construction to ensure that the statute is read correctly). Moreover, when a general statement of policy is qualified by an exception, the exception is read narrowly to preserve the primary operation of the provision. *C.I.R. v. Clark*, 489 U.S. 726, 739 (1989) (citing *Phillips, Inc. V. Walling*, 324 U.S. 490, 493 (1945) ("To extend an exemption to other than those plainly and unmistakably within its terms and spirit is to abuse the interpretative process and to frustrate the announced will of the people").
[114] 42 U.S.C. § 1396u-2(b)(3)(B)(ii).
[115] 42 U.S.C. § 1295dd(a)-(c) (2003).
[116] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g.*, *Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000); In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).

believe they are not required to comply with EMTALA's requirements. As a result, patients experiencing medical emergencies may not receive the care they need.

VIII. The proposed rule violates the Establishment Clause

The Establishment Clause of the First Amendment bars the government from granting religious and moral exemptions that would harm any third party.[117] It requires the Department to "take adequate account of the burdens" that an exemption "may impose on nonbeneficiaries" and must ensure that any exemption is "measured so that it does not override other significant interests."[118]

The Supreme Court acknowledged the limitations imposed by the Establishment Clause in *Burwell v. Hobby Lobby Stores, Inc.*, declaring the effect on employees of an accommodation provided to employers under the Religious Freedom Restoration Act (RFRA) "would be precisely zero."[119] Justice Kennedy emphasized that an accommodation must not "unduly restrict other persons, such as employees, in protecting their own interests."[120] The proposed exemptions clearly impose burdens on, and harm others, and thus, violate the clear mandate of the Establishment Clause.

IX. The regulations are overly broad, vague, and will cause confusion in the health care delivery system

The regulations dangerously expand the application of the underlying statutes by offering an extremely broad definition of who can refuse and what they can refuse to do. Under the proposed rule, any one engaged in the health care system could refuse services or care. The proposed rule defines workforce to include "volunteers, trainees or other members or agents of a covered entity, broadly defined when the conduct of the person is under the control of such entity."[121] Under this definition, could any member of the health care workforce refuse to serve a patient in any way – could a nurse assistant refuse to serve lunch to a transgender patient, could a billing specialist refuse to help a patient who had sought contraceptive counseling?

a. Discrimination

The failure to define the term "discrimination" will cause confusion for providers, and as employers, expose them to liability. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer.[122] The regulations make no reference to Title VII or current EEOC guidance, which prohibits discrimination against an employee based on that employee's race, color, religion, sex, and

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[117] E.g., *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Cutter v. Wilkinson*, 544 U.S.709, 720, 726 (2005); *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989).
[118] *Cutter*, 544 U.S. at 720, 722; see also *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709-10 (1985).
[119] *Hobby Lobby*, 134 S. Ct. 2751, 2760 (2014).
[120] *Id.* at 2786-87 (Kennedy, J., concurring).
[121] 83 Fed. Reg. 3894.
[122] 42 U.S.C. § 2000e-2.; *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.

national origin.[123] The proposed rule should be read to ensure that the long-standing balance set in Title VII between the right of individuals to enjoy reasonable accommodation of their religious beliefs and the right of employers to conduct their businesses without undue interference is to be maintained.

If this balance is not maintained, the language in the proposed rule could force health care providers to hire people who intend to refuse to perform essential elements of a position. For example, the proposed rule lacks clarity about whether a Title X-funded health center's decision not to hire a counselor or clinician who objected to provide non-directive options counseling as an essential job function of their position would be deemed discrimination under the rule. Furthermore, the proposed rule does not provide guidance on whether it is impermissible "discrimination" for a Title X-funded state or local health department to transfer such a counselor or clinician to a unit where pregnancy counseling is not done. By failing to define "discrimination," supervisors in health care settings will be unable to proceed in the orderly delivery of health care services, putting women's health at risk. The proposed rule impermissibly muddies the interpretation of Title VII and current EEOC guidance. If implemented, health care entities may be forced to choose between complying with a fundamentally misguided proposed rule and long-standing interpretation of Title VII.

Finally, the proposed rule's lack of clarity regarding what constitutes discrimination, may undermine non-discrimination laws. Because of the potential harm to individuals if religious refusals were allowed, courts have long rejected arguments that religiously affiliated organizations can opt out of anti-discrimination requirements.[124] Instead, courts have held that the government has a compelling interest in ending discrimination and that anti-discrimination statutes are the least restrictive means of doing so. Indeed, the majority opinion in *Burwell v. Hobby Lobby Stores, Inc.* makes it clear that the decision should not be used as a "shield" to escape legal sanction for discrimination in hiring on the basis of race, because such prohibitions further a "compelling interest in providing an equal opportunity to participate in the workforce without regard to race," and are narrowly tailored to meet that "critical goal."[125] The uncertainty regarding how the proposed rule will interact with non-discrimination laws is extremely concerning.

b. Assist in the performance

The definition of "assist in the performance" greatly expands the types of services that can be refused beyond any reasonable stretch of the imagination. The proposed rule defines

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[123] *Id.*

[124] *See e.g.*, *Bob Jones Univ. v. United States*, 461 U.S. 574 (1983) (holding that the government's interest in eliminating racial discrimination in education outweighed any burdens on religious beliefs imposed by Treasury Department regulations); *Newman v. Piggie Park Enters., Inc.*, 390 U.S. 400 (1968) (holding that a restaurant owner could not refuse to comply with the Civil Rights Act of 1964 and not serve African-American customers based on his religious beliefs); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1392 (4th Cir. 1990) (holding a religious school could not compensate women less than men based on the belief that "the Bible clearly teaches that the husband is the head of the house, head of the wife, head of the family"); *Hamilton v. Southland Christian Sch., Inc.*, 680 F.3d 1316 (11th Cir. 2012) (reversing summary judgment for religious school that claimed a religious right to fire teacher for becoming pregnant outside of marriage).

[125] *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, slip op. at 46 (2014).

"assistance" to include participation "in any activity with an *articulable connection* to a procedure, health service or health service program, or research activity."[126] In addition, the Department includes activities such as "making arrangements for the procedure."[127] If workers in very tangential positions, such as schedulers, are able to refuse to do their jobs based on personal beliefs, the ability of any health system or entity to plan, to properly staff, and to deliver quality care will be undermined. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. The proposed rule creates the potential for a wide range of workers to interfere with and interrupt the delivery of health care in accordance with the standard of care.

The regulations also leave unclear whether a worker can assert his or her moral belief in refusing to treat patients based on their identity or deny care for reasons outside of religious or moral beliefs. Even though women living with disabilities report engaging in sexual activities at the same rate as women who do not live with disabilities, they often do not receive the reproductive health care they need for multiple reasons, including lack of accessible provider offices and misconceptions about their reproductive health needs.[128] Biased counseling can contribute to unwanted health outcomes and exacerbate health disparities.[129] The proposed rule is especially alarming, as it does not articulate a definition of moral beliefs. The prejudices of a health care professional could easily inform their beliefs and consequently, serve as the basis of denying care to an individual based on characteristics alone. The proposed rule will foster discriminatory health care settings and interactions between patients and providers that are informed by bias instead of medically accurate, evidence-based, patient-centered care.

Moreover, in the preamble, the proposed rule states that the exemptions that Weldon provides is not limited to refusals of abortion care on the basis of religious or moral beliefs.[130] Due to this, health care professionals may think they can deny abortion care and other health services just because they do not want to provide the service. The preamble uses language such as "those who choose not to provide" or "Would rather not" as justification for a refusal. This is more concerning because the proposed rule contains no mechanism to ensure that patients receive the care they need if their provider refuses to furnish a service. The onus will be on the patient to question whether her hospital, medical doctor, or health care professional has religious, moral, or other beliefs that would lead them to deny services or if services were denied, the basis for refusal. This is likely to occur, as the proposed rule does not have any provisions that stipulate that patients must

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[126] 83 Fed. Reg. 3892.
[127] *Id.*
[128] RM Haynes et al., *Contraceptive Use at Last Intercourse Among Reproductive-Aged Women with Disabilities: An Analysis of Population-Based Data from Seven States*, CONTRACEPTION (2017), https://www.ncbi.nlm.nih.gov/pubmed/29253580; *See generally* Alex Zielinski, *Why Reproductive Health Can Be A Special Struggle for Women with Disabilities*, THINKPROGRESS, Oct. 1, 2015, https://thinkprogress.org/why-reproductive-health-can-be-a-special-struggle-for-women-with-disabilities-73ececea23c4/.
[129] In one study in Massachusetts, women living with intellectual and developmental disabilities, including those who were Black and Latina, faced increased risks of preterm delivery and very low and low birth weight babies. M. Mitra et al., *Pregnancy Outcomes Among Women with Intellectual and Developmental Disabilities*, AM. J. PREV. MED. (2015), https://www.ncbi.nlm.nih.gov/pubmed/25547927.
[130] 83 Fed. Reg. 3890-91.

be given notice that they may be refused certain health care services on the basis of religious or moral beliefs.

c. Referral

The definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information based on which an individual could get the care they need. Any information distributed by any method, including online or print, regarding any service, procedure, or activity could be refused by an entity if the information given would lead to a service, activity, or procedure that the entity or health care entity objects. Under this definition, could a medical doctor refuse to provide a website describing the medical conditions which contraception treats? Or could an entity refuse to provide a list of LGBTQ-friendly providers? In addition, the Department states that the underlying statutes of the proposed rule permits entities to deny help to anyone who is likely to make a referral for an abortion or for other services.[131] The breadth and vagueness of this definition will possibly lead providers to refrain from providing information vital to patients out of anxiety and confusion of what the proposed rule permits them to do.

d. Health Care Entity

The proposed rule's definition of "health care entity" conflicts with federal religious refusal laws such as the Coats and Weldon Amendments, thus fostering confusion regarding which entities are required to comply with the proposed rule and existing federal religious refusals. Specifically, under the Coats and Weldon Amendments a "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in health care delivery. Under the proposed rule, a plan sponsor "not primarily engaged in the business of health care" would be deemed a "health care entity."[132] This definition would mean that an employer acting as a third party administrator or sponsor could count as a "health care entity" and deny coverage. In 2016, OCR found that religiously affiliated employers were not health care entities under the Weldon amendment.[133]

Moreover, the Department states that their definition of "health care entity" is "not an exhaustive list" for concern that the Department would "inadvertently omit[ting] certain types of health care professionals or health care personnel."[134] Additionally, the proposed rule incorporates entities as defined in 1 U.S.C. 1 which includes corporations, firms, societies, etc.[135] States and public agencies and institutions are also deemed to be entities.[136] The Department's inclusion of entities who are primarily not engaged in the health care delivery system highlights the true purpose of the proposed rule, to permit a greater number of entities to interfere in the provider-patient relationship and deter a patient from making the best decision based on their circumstances, preferences, and beliefs.

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[131] *Id.* at 3895.
[132] *Id.* at 3893.
[133] Office for Civil Rights, Decision Re: OCR Transaction Numbers: 14-193604, 15-193782 & 15-195665, 4 (Jun. 21, 2016) (letter on file with NHeLP-DC office).
[134] 83 Fed. Reg. 3893.
[135] *Id.*
[136] *Id.*

X. The Department failed to follow procedural requirements

This proposed rule suffers from a number of additional inadequacies, including:

- The Department fails to provide "adequate reasons" or a "satisfactory explanation" for this rulemaking based on the underlying facts and data. Under the Administrative Procedures Act, an agency must provide "adequate reasons" for its rulemaking, in part by "examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the fact found and the choice made."[137] As stated in the proposed rule, between 2008 and November 2016, OCR received 10 complaints alleging violations of federal religious refusal laws; OCR received an additional 34 similar complaints between November 2016 and January 2018.[138] By comparison, during a similar time period from fall 2016 to fall 2017, OCR received *over 30,000 complaints* alleging either civil rights or HIPAA violations. These numbers demonstrate that rulemaking to enhance enforcement authority over religious refusal laws is not warranted.

- The Department fails to adequately assess the costs imposed by this proposed rule, including both underestimating quantifiable costs, and completely neglecting to address the costs that would result from delayed or denied care. Under Executive Order 13563, an agency must "tailor its regulations to impose the least burden on society" and choose "approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity)."[139] The Department completely neglects to address the costs that would result from delayed or denied care. This proposed rule completely fails to account for increased medical and social costs that come from delayed or denied care. Health care refusals without adequate safeguards may also have negative consequences on the long-term socioeconomic status of women. A recent study in the American Journal of Public Health found that women who were denied a wanted abortion were three times more likely to be unemployed than women who obtained abortions.[140] Thus, the health care refusals that may increase because of this rule could lead to delays or effective denials of care that would not only affect women's immediate health costs but also have fundamental negative consequences in the long term—factors that the Department completely fails to acknowledge or take into account in this proposed rule.

- The Department and Office of Management and Budget ("OMB") have failed to take the appropriate steps to ensure that the regulation does not conflict with the policies or actions of other agencies. Under Executive Order 12866, in order to ensure that each agency does not promulgate regulations that are "inconsistent, incompatible, or

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[137] *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2125 (June 20, 2016) (citing *Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 103 (1983)).
[138] 83 Fed. Reg. 3886.
[139] Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Sec. 1 (b).
[140] Foster et al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 AM. J. PUB. H. 407 (2018), http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.2017.304247.

duplicative with its other regulations of those of other Federal agencies," each agency must include any significant regulatory actions in the Unified Regulatory Agenda.[141] The Department failed to include any reference to this significant regulation in its regulatory plans, and therefore failed to put impacted entities, including other federal agencies, on notice of possible rulemaking in this area. In addition, prior to publication in the Federal Register, the proposed rule must be submitted to the Office of Information and Regulatory Affairs (OIRA), within the OMB, to provide "meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order [12866] and do not conflict with the policies or actions of another agency."[142] According to OIRA's website, the Department submitted the proposed rule to OIRA for review on January 12, 2018, one week prior to the proposed rule being issued in the Federal Register. Standard review time for OIRA is often between 45 and 90 days. One week was plainly insufficient time for OIRA to review the rule, including evaluating the paperwork burdens associated with implementing this proposed rule. In addition, it is extremely unlikely that within that one-week timeframe, OIRA could or would have conducted the interagency review necessary to ensure that this proposed rule does not conflict with other federal statutes or regulations.

Conclusion

The National Health Law Program opposes the proposed rule as it expands religious refusals to the detriment of patients' health and well-being. We are concerned that these regulations, if implemented, will interfere in the patient-provider relationship by undermining informed consent. The proposed rule will allow any one in the health care setting to refuse health care that is evidence-based and informed by the highest standards of medical care. The outcome of this regulation will harm communities who already lack access to care and endure discrimination.

Thank you for your attention to our comments. If you have any questions, please reach out to Susan Berke Fogel, Director of Reproductive Health, at fogel@healthlaw.org.

Sincerely,

Elizabeth G. Taylor
Executive Director

[141] Executive Order 12866, at § 4(b),(c).
[142] *Id.* at § 6(b).

Exhibit 133

National Institute for Reproductive Health

March 23, 2018

VIA ELECTRONIC SUBMISSION

Secretary Alex Azar
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Attention: Comments on RIN 0945-ZA03 – Proposed Rule Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Dear Secretary Azar,

The National Institute for Reproductive Health (NIRH) believes a health care provider's personal beliefs should never determine the care a patient receives. That is why we strongly oppose the Department of Health and Human Services' (the "Department") proposed rule ("Proposed Rule"), which seeks to permit discrimination in all aspects of health care.[1]

The Proposed Rule seeks to unlawfully expand refusals to provide care by attempting to allow individuals and health care entities who receive federal funding to refuse to provide *any* part of a health service or program. In addition, the Proposed Rule unlawfully attempts to create new refusals seemingly out of thin air. Such expansions exceed the Department's authority; violate the Constitution; undermine the ability of states to protect their citizens; undermine critical HHS programs like Title X; interfere with the provider-patient relationship; and threaten the health and well-being of people across the country and around the world.

By issuing the Proposed Rule and creating a new division within the Office of Civil Rights ("OCR") – the new "Conscience and Religious Freedom Division" – the Department seeks to inappropriately use OCR's limited resources in order to affirmatively allow institutions, insurance companies, and almost anyone involved in patient care to use their personal beliefs to deny people the care they need. For these reasons the National Institute for Reproductive Health calls on the Department and OCR to withdraw the Proposed Rule in its entirety.

[1] Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880 (proposed Jan. 26, 2018) (*to be codified at* 45 C.F.R. pt. 88) [*hereinafter* Rule].

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The Proposed Rule Unlawfully Exceeds the Department's Authority by Impermissibly Expanding Religious Refusals to Provide Care

The Proposed Rule attempts to expand the reach not only of existing harmful refusal of care laws but also to create new refusals of care where none were intended.

a. The Proposed Rule Seeks to Allow the Refusal of any Health Service Based on Personal Belief

The Proposed Rule will exacerbate health inequities by expanding the ability to refuse critical services, including abortion and transition-related care. Specifically, the Department and OCR are attempting to require a broad swath of entities to allow individuals to refuse "*any* lawful health service or activity based on religious beliefs or moral convictions (emphasis added)."[2] Read in conjunction with the rest of the Proposed Rule, it is clear this is intended to allow any entity involved in a patient's care—from a hospital board of directors to the receptionist that schedules procedures—to use their personal beliefs to determine a patient's access to care.

b. The Proposed Rule Unlawfully Expands Already Harmful Abortion/Sterilization Refusal of Care Laws

Already existing refusal of care laws are used across the country to deny patients the care they need.[3] The Proposed Rule attempts to expand these laws in numerous ways that are directly contrary to the stated purpose of the existing laws. For example, one provision of the Church Amendments allows individuals who work for or with entities receiving grants or contracts for biomedical or behavioral research entities to refuse to participate in "any lawful health services or research activity" based on religious beliefs or moral convictions specifically related to the service or research activity to which they object.[4] But the Proposed Rule attempts to broaden this provision to allow individuals to refuse to perform aspects of their jobs based on a mere reference to a religious or moral belief regardless of whether it relates to the specific biomedical or behavioral service or research activity they are working on.[5] Such an attempted expansion goes beyond what the statute enacted by Congress allows. Furthermore, the Proposed Rule would expansively apply other provisions of the Church Amendments to, among other things,

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[2] *See id.* at 12.
[3] *See, e.g.*, *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc.org/resources/refusals-to-provide-health-care-threaten-the-health-and-lives-of-patients-nationwide/; Catherine Weiss, et al., *Religious Refusals and Reproductive* Rights, AM. CIVIL LIBERTIES UNION (2002), https://www.aclu.org/report/religious-refusals-and-reproductive-rights-report; Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf; Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[4] The Church Amendments, 42 U.S.C. § 300a-7 (2018).
[5] *See* Rule *supra* note 1, at 185.

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individuals working under global health programs funded by the Department thereby allowing global health providers and entities to refuse individuals the care they need contrary to the very purpose of such programs.

Similarly, the Proposed Rule defines common phrases and words used throughout existing refusals of care laws and civil rights laws in ways that stretch their intended meaning beyond recognition. For example, the definition of "assist in the performance" greatly expands the types of services that can be refused to include merely "making arrangements for the procedure" no matter how tangential.[6] This means individuals not "assisting in the performance" of a procedure within the ordinary meaning of the term, such as the hospital room scheduler, the technician charged with cleaning surgical instruments, and other hospital employees, can now assert a new right to refuse. The Proposed Rule's definition of "referral" similarly goes beyond any understanding of the term, allowing refusals to provide any information, including location or funding, that could help an individual to get the care they need.[7]

Furthermore, the Proposed Rule's new and unwarranted expanded definitions often exceed, or are not in accordance with, existing definitions contained within the statutes the Proposed Rule seeks to enforce. Specifically, under the Coats and Weldon Amendments "health care entity" is defined to encompass a limited and specific range of individuals and entities involved in the delivery of health care.[8] The Proposed Rule attempts to combine separate definitions of "health care entity" found in different statutes and applicable in different circumstances into one broad term.[9] Such an attempt to expand the meaning of a statutory term Congress already took the time to define not only fosters confusion, but goes directly against congressional intent. By expressly defining the term "health care entity" Congress implicitly rejected the inclusion of the other terms the Department now attempts to insert.[10]

When these impermissibly broad definitions are combined with the expansive interpretations of the underlying statutes, they work together to further expand refusals of care to allow more individuals and entities to refuse to provide access to health care. For example, one way the Weldon Amendment is expanded under the Proposed Rule is through the definition of "discrimination."[11] In particular, the Proposed Rule defines "discrimination" against a health care entity broadly to include a number of activities, including denying a grant or employment as well as an unspecified catch-all phrase "any activity reasonably regarded as discrimination."[12] In

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[6] *Id.* at 180.
[7] *Id.* at 183.
[8] The Weldon Amendment, Consolidated Appropriations Act, Pub. L. No. 111-117, 123 Stat 3034 (2009); Public Health Service Act, 42 U.S.C. § 238n (2018).
[9] *See* Rule *supra* note 1, at 182.
[10] The doctrine of expression unius est exclusion alterius (the expression of one thing implies the exclusion of others) as applied to statutory interpretation creates a presumption that when a statute designates certain persons, things, or manners of operation, all omissions should be understood as exclusions.
[11] *See* Rule *supra* note 1, at 180.
[12] *Id.*

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a Proposed Rule that seeks to protect those who want to discriminate, this broad definition is nonsensical and inappropriate. Further such a vague and inappropriate definition provides no functional guidance to entities on how to comply with the applicable requirements, thereby fostering confusion.

The Proposed Rule Carries Severe Consequences for Patients and will Exacerbate Already Existing Inequities

a. Refusals of Care Make it Difficult for Many Individuals to Access the Care They Need

Across the country refusals of care based on personal beliefs have been invoked in countless ways to deny patients the care they need.[13] One woman experiencing pregnancy complications rushed to the only hospital in her community, a religiously affiliated facility, where she was denied the miscarriage management she needed because the hospital objected to this care.[14] Another woman experiencing pregnancy loss was denied care for ten days at a religiously affiliated hospital outside Chicago, Illinois.[15] In New Jersey, a transgender man was denied gender affirming surgery at a religiously affiliated hospital which refused to provide him a hysterectomy.[16] Another patient in Arkansas endured a number of dangerous pregnancy complications and could not risk becoming pregnant again. She requested a sterilization procedure at the time of her Cesarean delivery, but her Catholic hospital provider refused to give her the procedure.[17] Another woman was sent home by a religiously affiliated hospital with two Tylenol after her water broke at 18 weeks of pregnancy. Although she returned to the hospital twice in the following days, the hospital did not give her full information about her condition and treatment options.[18]

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[13] *See, e.g., supra* note 3.
[14] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 6 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[15] *See* Julia Kaye, et al., *Health Care* Denied, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.
[16] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 29 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.
[17] *See The Patient Should Come First: Refusals to Provide Reproductive Health Care*, NAT'L WOMEN'S L. CTR. (2017), https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/05/Refusals-FS.pdf; Sandhya Somashekhar, *A Pregnant Woman Wanted her Tubes Tied. Her Catholic Hospital Said No.*, WASH. POST (Sept. 13, 2015), https://www.washingtonpost.com/national/a-pregnant-woman-wanted-her-tubes-tied-her-catholic-hospital-said-no/2015/09/13/bd2038ca-57ef-11e5-8bb1-b488d231bba2_story.html?utm_term=.8c022b364b75.
[18] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 27 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

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b. Refusals of Care are Especially Dangerous for Those Already Facing Barriers to Care

Refusals of care based on personal beliefs already make it difficult for many individuals to access health care and have real consequences for those denied the care they need because of a provider or hospital's religious beliefs. When women and families are uninsured, locked into managed care plans that do not meet their needs, or when they cannot afford to pay out of pocket for services or travel to another location, refusals bar access to necessary care.[19] This is especially true for immigrant patients who often lack access to transportation and may have to travel great distances to get the care they need.[20] In rural areas there may be no other sources of health and life preserving medical care.[21] In developing countries where many health systems are weak, health care options and supplies are often unavailable.[22] When these individuals encounter refusals of care, they may have nowhere else to go.

This reality is especially troubling because individuals who already face multiple and intersecting forms of discrimination may be more likely to encounter refusals. For example, new research shows that women of color in many states disproportionately receive their care at Catholic hospitals. In nineteen states, women of color are more likely than white women to give birth in Catholic hospitals.[23] These hospitals as well as many Catholic-affiliated hospitals must follow the Ethical and Religious Directives (ERDs) which provides guidance on a wide range of hospital matters, including reproductive health care and can keep providers from offering the standard of care.[24] Providers in one 2008 study disclosed that they could not provide the standard of care for managing miscarriages at Catholic hospitals, and as a result, women were delayed care or transferred to other facilities at great risk to their health.[25] The reach of this type of

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[19] In 2016, an estimated 11 percent of women between the ages of 19 to 64 were uninsured. Single mothers, women of color, and low-income women are more likely to be uninsured. *Women's Health Insurance* Coverage, KAISER FAMILY FOUND. 1, 3 (Oct. 31, 2017), http://files.kff.org/attachment/fact-sheet-womens-health-insurance-coverage.

[20] Athena Tapales et al., *The Sexual and Reproductive Health of Foreign-Born Women in the United States*, CONTRACEPTION 8, 16 (2018), http://www.contraceptionjournal.org/article/S0010-7824(18)30065-9/pdf; Nat'l Latina Inst. For Reproductive Health & Ctr. For Reproductive Rights, *Nuestra Voz, Nuestra Salud, Nuestro Texas: the Fight for Women's Reproductive Health in the Rio Grande Valley* 1, 7 (2013), http://www.nuestrotexas.org/pdf/NT-spread.pdf.

[21] Since 2010, eighty-three rural hospitals have closed. *See Rural Hospital Closures: January 2010 – Present*, THE CECIL G. SHEPS CTR FOR HEALTH SERVS. RES. (2018), http://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

[22] *See* Nurith Aizenman, *Health Care Costs Push a Staggering Number of People into Extreme Poverty*, NPR (Dec. 14, 2017), https://www.npr.org/sections/goatsandsoda/2017/12/14/569893722/health-care-costs-push-a-staggering-number-of-people-into-extreme-poverty; *Tracking Universal Health Coverage: 2017 Global Monitoring Report*, WORLD HEALTH ORG. & THE WORLD BANK (2017), http://documents.worldbank.org/curated/en/640121513095868125/pdf/122029-WP-REVISED-PUBLIC.pdf.

[23] *See* Kira Shepherd, et al., *Bearing Faith The Limits of Catholic Health Care for Women of Color*, PUB. RIGHTS PRIVATE CONSCIENCE PROJECT 1, 12 (2018), https://www.law.columbia.edu/sites/default/files/microsites/gender-sexuality/PRPCP/bearingfaith.pdf.

[24] *See id.* at 10-13.

[25] Lori R. Freedman, *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, AM. J. PUB. HEALTH (2008), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2636458/.

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religious refusal of care is growing with the proliferation of both the types of entities using religious beliefs to discriminate and the number of religiously affiliated entities that provide health care and related services.[26]

In addition, in many of the countries where the Department implements global AIDS programs, many of the patients served already face numerous barriers to care, including a broad and harmful refusal provision contained within the statute governing such programs.[27]

c. *In Proposing this Rule, the Agency has Abandoned its Legal Obligations to Adequately Account for Harm to Patients*

By expanding refusals of care the Proposed Rule will exacerbate the barriers to health care services patients need. It is evident that the harm caused by this Proposed Rule will fall hardest on those most in need of care by allowing individuals and health care entities to use their personal beliefs to dictate patient care. The Department should remember, under Executive Order 13563, an agency may only propose regulations where it has made a reasoned determination that the benefits justify the costs and where the regulations are tailored "to impose the least burden on society."[28] The Proposed Rule plainly fails on both counts. Although the Proposed Rule attempts to quantify the costs of compliance, it completely fails to address the costs and burdens to patients who may be denied care and who then may incur and experience even greater social and medical costs.[29]

Moreover, the Establishment Clause of the First Amendment requires the government to adequately account for just these sorts of consequences when considering whether to grant religious exemptions and, in fact, bars granting an exemption when it would detrimentally affect any third party.[30] Because the Proposed Rule would cause substantial harm, including to patients, it would violate the Establishment Clause.[31]

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[26] *See, e.g., Miscarriage of Medicine: the Growth of Catholic Hospitals and the Threat to Reproductive Health Care*, AM. CIVIL LIBERTIES UNION & MERGER WATCH (2013), https://www.aclu.org/files/assets/growth-of-catholic-hospitals-2013.pdf.

[27] *See The Mexico City Policy: An Explainer*, KAISER FAMILY FOUND. (June 1, 2017), https://www.kff.org/global-health-policy/fact-sheet/mexico-city-policy-explainer/.

[28] Improving Regulation and Regulatory Review, Executive Order 13563 (Jan. 18, 2011), https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review.

[29] *See* Rule *supra* note 1, at 94-177.

[30] U.S. Const. amend. I; *Cutter v. Wilkinson*, 554 U.S. 709, 720, 722 (2005) (to comply with the Establishment Clause, courts "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries" and must ensure that the accommodation is "measured so that it does not override other significant interests") (citing *Estate of Thornton v. Caldor*, 472 U.S. 703, 710 (1985)); *see also Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014); *Holt v. Hobbs*, 135 S. Ct. 853, 867 (2015) (Ginsburg, J., concurring).

[31] Respecting religious exercise may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *See Burwell v. Hobby Lobby*, 134 S. Ct. at 2787. When considering

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The Proposed Rule Will Undermine Critical Federal Health Programs, including Title X

The Proposed Rule would seemingly allow health care entities to receive grants and contracts under HHS-funded programs or other federal health programs, such as Title X, the only domestic family planning program, while refusing to provide key services required by those programs.[32] For instance, Congress has specifically required that under the Title X program, providers must offer non-directive pregnancy options counseling[33] and current regulations require that pregnant women receive "referral[s] upon request" for prenatal care and delivery, adoption, and/or pregnancy termination.[34] Under the Proposed Rule, the Department would seemingly allow entities to apply for and receive federal funds while exempting them from the core legal and programmatic duties upon which such funds are generally conditioned.[35] The Proposed Rule creates uncertainty about whether Title X grantees may ensure that the subrecipients they contract with to provide Title X services actually provide the services the program was designed and funded by Congress to deliver. Such actions are particularly concerning in the context of federally supported health programs, such as Title X, which are meant to provide access to basic health services and information for low-income populations.[36] When it comes to Title X, the Proposed Rule would not only sanction conduct at odds with pre-existing legal requirements, but could also undermine the program's fundamental objectives. Every year millions of low-income, including under-insured, and uninsured individuals, rely on Title X clinics to access services they otherwise might not be able to afford.[37]

The Proposed Rule Will Carry Severe Consequences for Providers and Undermine the Provider-Patient Relationship

Existing refusals of care based on personal beliefs already undermine open communication between providers and patients, interfere with providers' ability to provide care according to medical standards, and ignore the reality that many providers want to provide comprehensive care. Hospital systems across the country use religious beliefs to prevent their employees from

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whether the birth control coverage requirement was the least restrictive means in Hobby Lobby, the Court considered that the accommodation offered by the government ensured that affected employees "have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing coverage." *See id.* at 2759. In other words, the effect of the accommodation on women would be "precisely zero." *Id.* at 2760.

[32] *See* Rule *supra* note 1, at 180-181, 183. *See also Title X Family Planning*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2018), https://www.hhs.gov/opa/title-x-family-planning/index.html; *Title X an Introduction to the Nation's Family Planning Program*, NAT'L FAMILY PLANNING & REPRODUCTIVE HEALTH ASSOC. (2017) (*hereinafter* NFPRHA), https://www.nationalfamilyplanning.org/file/Title-X-101-November-2017-final.pdf.

[33] *See, e.g.*, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135 (2017).

[34] *See* What Requirements Must be Met by a Family Planning Project?, 42 C.F.R. § 59.5(a)(5) (2000).

[35] *See, e.g.*, Rule *supra* note 1, at 180-185.

[36] *See* NFPRHA *supra* note 34.

[37] *See id.*

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treating patients regardless of the professional, ethical, or moral convictions of these providers.[38] The Proposed Rule would exacerbate these problems by emboldening health care entities and institutions, including foreign and international organizations, to bind the hands of providers and attempt to limit the types of care they can provide.

The Proposed Rule threatens informed consent, a necessary principle of patient-centered decision-making intended to help balance the power dynamics between health providers and patients and ensure patient-centered decision-making.[39] Informed consent requires providers disclose relevant and medically accurate information about treatment choices and alternatives so that patients can competently and voluntarily make decisions about their medical treatment or refuse treatment altogether.[40] By allowing providers, including hospital and health care institutions, to refuse to provide patients with information, the Proposed Rule makes it impossible for patients to have full information regarding treatment options. While the Department claims the Proposed Rule improves communication between patients and providers, in truth it will deter open, honest conversations that are vital to ensuring that a patient can control their medical circumstances.[41]

The Proposed Rule also disregards standards of care established by the medical community by allowing providers to opt out of providing medical care. Medical practice guidelines and standards of care establish the boundaries of medical services that patients can expect to receive and that providers should be expected to deliver. Yet, the Proposed Rule seeks to allow providers and institutions to ignore the standards of care, particularly surrounding reproductive and sexual health. Information, counseling, referral and provision of contraceptive and abortion services are part of the standard of care for a range of common medical conditions including heart disease, diabetes, epilepsy, lupus, obesity, and cancer.[42] Individuals seeking reproductive health care, regardless of their reasons for needing these services, should be treated with dignity and respect. Allowing providers to flout established medical guidelines and deny medically accurate,

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[38] *See* Julia Kaye, et al., *Health Care Denied*, AM. CIVIL LIBERTIES UNION 1, 12 (2016), https://www.aclu.org/sites/default/files/field_document/healthcaredenied.pdf.

[39] *See* TOM BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (4th ed. 1994); CHARLES LIDZ ET AL., INFORMED CONSENT: A STUDY OF DECISIONMAKING IN PSYCHIATRY (1984).

[40] *See id.*

[41] *See* Rule *supra* note 1, at 150-151.

[42] For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant. AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE § 114-15, S117 (2017), available at http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf. The American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival. AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 232 (7th ed. 2012).

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evidence-based care to patients harms them and impairs their ability to make the health care decision that is right for them.

In addition, the Proposed Rule ignores the many providers with deeply held moral convictions that affirmatively motivate them to provide patients with health care, including abortion, transition-related care, and end-of-life care. Moreover, the Proposed Rule fails to acknowledge the Church Amendments' protection for health care professionals who support or participate in abortion or sterilization services, which OCR has a duty to enforce.[43] No health care professional should face discrimination from their employer because they treated or provided information to a patient seeking an abortion.

The Department is Abdicating its Responsibility to Patients

The Proposed Rule exceeds OCR's authority by abandoning OCR's mission to address health disparities and discrimination that harms patients.[44] Instead, the Proposed Rule appropriates language from civil rights statutes and regulations that were intended to improve access to health care and applies that language to situations for which it was not intended. By taking the language of civil rights laws and regulations out of context, the Proposed Rule creates a regulatory scheme that is not only nonsensical but is affirmatively harmful. For example, the notice and certification of compliance and assurance requirements simply do not make sense when applied to the laws the Proposed Rule seeks to enforce.[45] They will place a significant and burdensome requirement on health care providers and impose unique challenges for those working in other countries by taking resources away from patient care without adding any benefit.

The Department, including OCR, has an important role to play in ensuring equal opportunity to access health care and ending discriminatory practices that contribute to poor health outcomes and health disparities.[46] If finalized, however, the Proposed Rule will represent a radical departure from the Department's mission to combat discrimination, protect patient access to care,

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[43] *See* The Church Amendments, 42 U.S.C. § 300a-7(c) (2018).
[44] *OCR's Mission and Vision*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/ocr/about-us/leadership/mission-and-vision/index.html ("The mission of the Office for Civil Rights is to improve the health and well-being of people across the nation; to ensure that people have equal access to and the opportunity to participate in and receive services from HHS programs without facing unlawful discrimination; and to protect the privacy and security of health information in accordance with applicable law.").
[45] *See* Rule *supra* note 1, at 203-214.
[46] As one of its first official acts in 1967, the Office of Equal Health Opportunity undertook the massive effort of inspecting 3,000 hospitals to ensure they were complying with Title VI's prohibition against discrimination on the basis of race, color, or national origin. 42. U.S.C. § 2000d (1964). After this auspicious start, the Office of Equal Health Opportunity which would eventually become OCR would go on to ensure that health programs and activities it regulated complied with key anti-discrimination laws including Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794 (1973), Title IX of the Education Amendments of 1972, 20 U.S.C. § 1681 (1972), the Age Discrimination Act of 1976, 42 U.S.C. § 6101 (1976), and Section 1557 of the Affordable Care Act, 42 U.S.C. §18116 (2010), among others. Through robust enforcement of these laws, OCR has worked to reduce discrimination in health care.

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and eliminate health disparities. Through robust enforcement of civil rights laws, OCR has worked to reduce discrimination in health care by ending overtly discriminatory practices such as race segregation in health care facilities, segregation of people with disabilities in health care facilities, categorical insurance coverage denials of care for transition-related care, and insurance benefit designs that discriminate against people who are HIV positive, among other things.[47]

Nevertheless, there is still work to be done, and the Proposed Rule seeks to divert limited resources away from ending discrimination. De facto segregation, for example, continues to contribute to poorer health outcomes for Black people. According to one study, over half of the racial disparity in survival for heart attack patients can be attributed to the lower performance of hospitals that serve predominantly people of color.[48] And these disparities do not occur in isolation. Black women, for example, are three to four times more likely than white women to die during or after childbirth.[49] Further, the disparity in maternal mortality is growing rather than decreasing,[50] which in part may be due to the reality that women have long been the subject of discrimination in health care and the resulting health disparities. For example, women's pain is routinely undertreated and often dismissed.[51] And due to gender biases and disparities in research, doctors often offer women less aggressive treatment, or even no treatment, for conditions such as heart disease.[52] Lesbian, gay, bisexual, and transgender individuals also encounter high rates of discrimination in health care.[53] Eight percent of lesbian, gay, bisexual, and queer people and 29 percent of transgender people reported that a doctor or other health care

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[47] *See, e.g., Serving People with Disabilities in the Most Integrated Setting: Community Living and Olmstead*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/community-living-and-olmstead/index.html; *Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html; *National Origin Discrimination*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/national-origin/index.html; *Health Disparities*, DEP'T OF HEALTH AND HUMAN SERVS. (2018), https://www.hhs.gov/civil-rights/for-individuals/special-topics/health-disparities/index.html.

[48] *See* Skinner et al., *Mortality after Acute Myocardial Infarction in Hospitals that Disproportionately Treat African-Americans*, NAT'L INSTIT. OF HEALTH 1 (2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1626584/pdf/nihms13060.pdf.

[49] *See* Nina Martin, *Black Mothers Keep Dying After Giving Birth. Shalon Irving's Story Explains Why*, NPR (Dec. 2017), https://www.npr.org/2017/12/07/568948782/black-mothers-keep-dying-after-giving-birth-shalon-irvings-story-explains-why.

[50] *See id.*

[51] *See, e.g.*, Diane E. Hoffmann & Anita J. Tarzian, *The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain*, 29:1 J. OF L., MED., & ETHICS 13, 13-27 (2001).

[52] *See, e.g.*, Judith H. Lichtman et al., *Symptom Recognition and Healthcare Experiences of Young Women with Acute Myocardial Infarction*, 10 J. of the Am. Heart Ass'n 1 (2015).

[53] *See, e.g., When Health Care Isn't Caring*, LAMBDA LEGAL 5 (2010), https://www.lambdalegal.org/sites/default/files/publications/downloads/whcic-report_when-health-care-isnt-caring_1.pdf. A survey examining discrimination against LGBTQ people in health care more than half of respondents reported that they have experienced at least one of the following types of discrimination in care: being refused needed care; health care professionals refusing to touch them or using excessive precautions; health care professionals using harsh or abusive language; being blamed for their health care status; or health care professionals being physically rough or abusive.

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provider had refused to see them because of their actual or perceived sexual orientation or gender identity in the year before the survey.[54]

OCR must work to address these disparities, yet the Proposed Rule seeks to prioritize the expansion of existing religious refusal laws beyond their statutory requirements and create new religious exemptions where none had previously existed rather than using already limited resources to protect patient access to health care. The Proposed Rule will harm patient care and is antithetical to OCR's mission—to eliminate discriminatory practices that contribute to persistent health inequality.[55]

The Proposed Rule Conflicts with Other Existing Federal Law

The Proposed Rule generates chaos through its failure to account for existing laws that conflict with the refusals to care it would create.

For example, the Proposed Rule makes no mention of Title VII,[56] the leading federal law barring employment discrimination, or current Equal Employment Opportunity Commission (EEOC) guidance on Title VII.[57] With respect to religion, Title VII requires reasonable accommodation of employees' or applicants' sincerely held religious beliefs, observances, and practices when requested, unless the accommodation would impose an "undue hardship" on an employer.[58] For decades, Title VII has established the legal framework for religious accommodations in the workplace. When a health care worker requests an accommodation, Title VII ensures that employers can consider the effect an accommodation would have on patients, coworkers, public safety, and other legal obligations. The Proposed Rule, however, sets out an entirely different and conflicting standard, leaving health care employers in the impossible position of being subject to and trying to satisfy both. Indeed, when similar regulations were proposed in 2008, EEOC Commissioners and Legal Counsel filed comments that raised similar concerns and stated clearly that Title VII should remain the relevant legal standard.[59]

Furthermore, the language in the Proposed Rule would seem to put health care entities in the position of being forced to hire people who intend to refuse to perform essential elements of a position even though Title VII would not require such an "accommodation." For example, there is no guidance about whether it is impermissible "discrimination" for a Title X-funded health

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[54] *See* Jaime M. Grant et al., *Injustice at Every Turn: a Report of the National Transgender Discrimination Survey*, NAT'L GAY AND LESBIAN TASK FORCE & NAT'L CTR. FOR TRANSGENDER EQUALITY, http://www.thetaskforce.org/static_html/downloads/reports/reports/ntds_full.pdf.
[55] *See supra* note 46.
[56] 42 U.S.C. § 2000e-2 (1964).
[57] *Title VII of the Civil Rights Act of 1964*, U.S. EQUAL EMP'T. OPPORTUNITY COMM'N (2018), https://www.eeoc.gov/laws/statutes/titlevii.cfm.
[58] *See id.*
[59] Letter from EEOC Commissioners and General Counsel (Sept. 24, 2008), *available at* https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html.

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center not to hire a counselor or clinician whose essential job functions would include counseling women with positive pregnancy tests because the applicant refuses to provide non-directive options counseling even though the employer would not be required to do so under Title VII.[60] It is not only nonsensical for a health care entity to be forced to hire someone it knows will refuse to fulfill essential job functions, but it would also foster confusion by imposing duties on employers far beyond Title VII and current EEOC guidance.

In addition, the Proposed Rule fails to address treatment of patients facing emergency health situations, including an emergency requiring miscarriage management or abortion, thereby inviting confusion and great danger to patient health. The Emergency Medical Treatment and Active Labor Act ("EMTALA") requires hospitals that have a Medicare provider agreement and an emergency room or department to provide to anyone requesting treatment an appropriate medical screening to determine whether an emergency medical condition exists, and to stabilize the condition or if medically warranted to transfer the person to another facility.[61] Under EMTALA every hospital is required to comply – even those that are religiously affiliated.[62] Because the Proposed Rule does not mention EMTALA or contain an explicit exception for emergencies, some institutions may believe they are not required to comply with EMTALA's requirements. This could result in patients in emergency circumstances not receiving necessary care.

The Proposed Rule Will Make It Harder for States to Protect their Residents

The Proposed Rule will have a chilling effect on the enforcement of and passage of state laws that protect access to health care and prevent discrimination against individuals seeking medical care. The preamble of the Proposed Rule discusses at length state laws that the Department finds objectionable, such as state laws that require anti-abortion counseling centers to provide information about where reproductive health care services can be obtained or whether facilities have licensed medical staff, as well as state laws that require health insurance plans to cover abortion.[63] Moreover, the Proposed Rule invites states to further expand refusals of care by making clear that this expansive rule is a floor, and not a ceiling, for religious exemption laws.[64]

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[60] *See* Rule *supra* note 1, at 180-181.
[61] 42 U.S.C. § 1295dd(a)-(c) (2003).
[62] In order to effectuate the important legislative purpose, institutions claiming a religious or moral objection to treatment must comply with EMTALA, and courts agree. *See, e.g., Shelton v. University of Medicine and Dentistry of New Jersey*, 223 F.3d 220, 228 (3rd Cir. 2000), In In re Baby K, 16 F.3d 590, 597 (4th Cir. 1994); *Nonsen v. Medical Staffing Network, Inc.* 2006 WL 1529664 (W.D. Wis.); *Grant v. Fairview Hosp.*, 2004 WL 326694, 93 Fair Empl. Prac. Cas. (BNA) 685 (D. Minn. 2006); *Brownfield v. Daniel Freeman Marina Hosp.*, 208 Cal. App. 3d 405 (Ca. Ct. App. 1989); *Barris v. County of Los Angeles*, 972 P.2d 966, 972 (Cal. 1999).
[63] *See, e.g.*, Rule, *Supra* note 1, at 3888-89.
[64] *See id.*

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Conclusion

The Proposed Rule will allow religious beliefs to dictate patient care by unlawfully expanding already harmful refusals of care. The Proposed Rule is discriminatory, violates multiple federal statutes and the Constitution, ignores congressional intent, fosters confusion, and harms patients contrary to the Department's stated mission. For all of these reasons, the National Institute for Reproductive Health calls on the Department to withdraw the Proposed Rule in its entirety. If you have any questions, please do not hesitate to contact Rose MacKenzie at rmackenzie@nirhealth.org or 646-520-3519.

Sincerely,

Andrea Miller
President
National Institute for Reproductive Health
& National Institute for Reproductive Health Action Fund