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Department of Health and Human Services
Office of Public Health and Science
Attn: Brenda Destro
Hubert Humphrey Building Room 728E
200 Independence Avenue SW
Washington, D.C.

RE: RIN 0991-AB48 "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law"

On behalf of the National Health Law Program and the undersigned organizations and health professionals, we are submitting these comments to the federal Department of Health and Human Services in opposition to the proposed regulation entitled "Ensuring that Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law."

The regulations as proposed would introduce broad, poorly defined, and confusing language to the existing law that protects the right of health care providers to refuse to participate in a health care service to which they have moral or religious objections. There are already ample statutory protections for health care providers who object to providing certain services based on their religious or moral beliefs. Existing law seeks to establish a delicate balance between protecting health care providers and meeting the needs of patients. The proposed regulations cite no evidence that further explication is needed other than the "concern" of the Department. Yet, HHS is offering a complex set of regulations to implement three different statutes[1] that were enacted over the span of more than thirty years, muddying the waters of refusal clauses, and if implemented, severely impacting health outcomes.

Most important, the regulations fail to account for the significant burden on patients, a burden that will fall disproportionately and most harshly on low-income women, that will be imposed by implementation of the proposed regulations.

While the proposed regulations purport to provide clarity and guidance in implementing existing federal conscience clauses that protect individuals and institutions, in reality they are vague and confusing, and create 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 undermining the ability of health facilities to provide required information, counseling,

[1] Church Amendment 42 U.S.C. § 300a et seq; Public Health Service Act 42 U.S.C. § 238n; Weldon Amendment Consolidated Appropriations Act, 2008, P.L. No. 110-161, Div. G § 508(d), 121 Stat. 1844, 2209 (Dec. 26, 2007).

referrals, and health care services in an orderly and efficient manner. The end result could be poorer health outcomes and higher costs for delivering quality care.

**The regulations fail to define important terms and may cause greater confusion not clarity**

Pertinent terms such as "discrimination" and "abortion" are not defined in the regulations, leaving important questions open to individual interpretation, and potentially creating chaos for patients and health systems.

The regulations are unclear as to whether "abortion" includes birth control, in particular emergency contraception. While a California court in *Brownfield v. Daniel Freeman Marina Hospital*[2] found that EC is not an abortifacient, Secretary Michael Leavitt suggested that the term remained ambiguous in the regulations so that individuals or institutions were able to define it for themselves. When asked about whether the regulations' definition of abortion included birth control, as had an earlier draft, Secretary Leavitt said, "This regulation does not seek to resolve any ambiguity in that area. It focuses on abortion and focuses on physicians' conscience in relation to that."[3] Failing to define the term abortion raises important questions about which health services an entity can refuse to provide. Can an insurer refuse to cover contraception in violation of a state's contraceptive equity statute? Can a state refuse to certify a hospital as a Sexual Assault Center if it refuses to provide emergency contraception as required by state law?

Other questions remain about how the regulations intersect with other federal laws. The regulations interfere with the delivery of emergency services. Is the removal of a life-threatening ectopic pregnancy an abortion for which a health worker can refuse to admit the patient? How will the regulations intersect with EMTALA requirements in emergency miscarriages?

The failure to define the term "discrimination" is equally distressing. Title VII already requires that employers accommodate employees' religious beliefs to the extent there is no undue hardship on the employer. The regulations make no reference to Title VII and leave the question of what constitutes "discrimination" unexplained. Can a health entity require that a worker notify it in advance about objections? Can the entity reassign someone who refuses to assist in certain services? By failing to define "discrimination," the regulations could leave employers vulnerable to liability, and supervisors unable to proceed in the orderly delivery of health care services, and women's health at risk.

**The regulations are overly broad, confusing, and have the potential to create instability in health care delivery**

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. The regulations suggest that virtually any worker, paid or volunteer, in a health care, wellness, or research setting can refuse to "assist in the performance" of a health care services or in a health care program. By describing a worker who washes the instruments after a procedure as an example of what it

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[2] Brownfield v. Daniel Freeman Marina Hospital, 256 Cal. Rptr. 240 (1989).

[3] ROB STEIN, *Protections Set for Antiabortion Health Workers*, Washington Post August 22, 2008.

means to "assist in the performance," the regulations fail to offer any useful guidance to employers. If workers in very tangential positions (such as admitting, billing, or custodial) are able to refuse to do their jobs based on personal beliefs, they will undermine the ability of any health system or entity to plan, to properly staff, and to deliver quality care. Employers and medical staff may be stymied in their ability to establish protocols, policies and procedures under these vague and broad definitions. In addition, stretching the interpretation and definition of a "health care service" itself as "participation in any activity with a reasonable connection to the objectionable procedure including referrals, training, and other arrangements for offending procedures" and "an activity related in any way to providing medicine, health care, or any other service related to health or wellness" 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 a particular patient. Can a technician refuse to participate in dialysis for an alcoholic? Can someone opposed to blood transfusions refuse to change a patient's hospital gown? Can a health provider refuse to treat a patient who is gay or lesbian? Or refuse to provide prenatal care to a woman the worker thinks already has too many children?

The regulations as written are subject to misuse and abuse by creating a health care environment that invites large numbers of workers and health professionals to refuse to participate in the orderly delivery of health care services.

**The regulations fail to address the significant health impact of broadly construed refusals**

The regulations assert boldly that, "This regulation does not limit patient access to health care," yet offer no substantiation of that claim. Data in this area is limited, however, the Department has the responsibility to provide evidence that such broad-based refusals do not undermine patient care.

When patients are faced with refusals, their health suffers. 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. 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 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.[4] For example, the FDA's own iPledge program that governs the use of the drug Accutane® for severe acne treatment clearly states that women should use two forms of contraception and that "natural family planning" is not an accepted method.[5]

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

[5] U.S. Food & Drug Admin., Accutane® (isotretinoin) Questions and Answers (Oct. 28, 2005)

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. In 2002, 35 percent of all pregnancies were unintended – meaning that they were either unwanted or mistimed.[6] Unintended pregnancy is often a consequence of poverty. 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.[7] The Institute of Medicine associates unintended pregnancy with an increased risk of morbidity for women, insufficient prenatal care, low birthweight babies, an increase in health behaviors during pregnancy that are associated with adverse effects, as well as a negative impact on parenting by both mothers and fathers.[8]

The health services impacted by refusals are most often related to reproductive and sexual health, however, they are also implicated in a wide range of common health treatment and prevention strategies. For example, black women have higher prevalence of heart failure, coronary heart disease, hypertension, and stroke than white women.[9] According to the Centers for Disease Control and the American College of Cardiology, all of these conditions can be exacerbated by pregnancy, resulting in poorer health outcomes for women and their children. Medical practice guidelines and the CDC's Guidelines for Preconception Care recommend that women at risk for pregnancy use contraceptives while bringing their condition under control before they become pregnant.[10]

The health impact of refusal clauses was recently illustrated in the American Journal of Public Health. The authors studied miscarriage management in Catholic hospitals across the country and reported five situations in which pregnant women were put at serious risk when the hospitals refused to allow their physicians to treat them in accordance with the medical standard of care.[11]

Broadly-defined and widely-implemented refusal clauses undermine access to basic health services for all, but particularly harm low income women. The burdens on low-income women can be insurmountable 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. Last, in rural areas there may simply be no other sources of health and life preserving medical care.

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[6] LAWRENCE B. FINER & ELIZABETH K. HENSHAW, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 Perspectives on Sexual and Reproductive Health.; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION *Fertility, Family Planning, and Reproductive Health of U.S. Women: Data From the 2002 National Survey of Family Growth* Series 23, Number 25, DHHS Publication No. (PHS) 2006-1977 (December 2005).

[7] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Healthy People 2010; Chapter 9-6.

[8] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Unintended Pregnancy* (Apr. 4, 2004); http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/index.htm.

[9] HOLLY MEAD, et al., *Racial and Ethnic Disparities in U.S. Health Care: A Chart Book*, The Commonwealth Fund, (2008).

[10] CENTERS FOR DISEASE CONTROL AND PREVENTION, *Recommendations to Improve Preconception Health and Health Care*, 55(RR06);1-23 MMWR.

[11] LORI FREEDMAN, et al., *When There's a Heartbeat: Miscarriage Management in Catholic-Owned Hospitals*, American Journal of Public Health (Aug. 13, 2008).

In 2006, 28% of non-elderly low-income women were uninsured.[12] 39% of all non-elderly Latinas were uninsured, as were 33% of American Indian/Alaskan Native women.[13] These women have limited health care options. They rely on free and low-cost clinics, charity care, or pay for care out of pocket. When they encounter health care refusals, they have nowhere else to go.

These issues are not theoretical or philosophical for the real patients whose health is significantly impacted by refusals to provide information, referrals and care.

**The regulations undermine long-standing ethical and legal principles of informed consent**

Informed consent is at the core of the individual's right to self-determination and to make his or her own decisions about medically appropriate health care. This right is conditional upon two factors: access to relevant and medically accurate information about treatment choices and alternatives; and provider guidance in helping patients make decisions about treatment options based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care. According to the American Medical Association, "The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice."[14]

Informed consent is intended to help balance the imbalance of power in the relationship between health providers and patients, wherein patients authorize specific interventions. Disclosure of medical information is an essential component of the provider-patient relationship, and is embedded in medical and research codes. How will the regulations intersect with federal and state laws on informed consent?

Informed consent is a core ethical as well as legal tenet for physicians 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."[15]

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

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[12] KAISER FAMILY FOUNDATION, *Health Insurance Coverage of Women Ages 18 to 64, by Race/Ethnicity, 2006*, (2008).
[13] KAISER FAMILY FOUNDATION, *Medicaid's Role for Women*, (2007).
[14] American Medical Association, Medical Ethics E-8.08 Informed Consent (Issued March 1981, updated October 4, 2005).
[15] American Medical Association, Medical Ethics E-8.08 Informed Consent (Issued March 1981; updated Oct. 4, 2005).

understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment."[16]

The American Bar Association (ABA) has adopted policy in opposition to refusal clauses that restrict information that patients need to make sound medical decisions, stating "the ABA opposes governmental actions and policies that interfere with patients' abilities to receive from their health care providers, including health care professionals and entities, in a timely manner: (a) all of the relevant and medically accurate information necessary for fully informed health care decision-making; and (b) information with respect to their access to medically accurate care, as defined by the applicable medical standard of care."[17]

**Conclusion**

As the country faces numerous challenges in meeting the health care and public health needs of its residents, these regulations will make the delivery of these services more difficult, more costly, and less efficient. We urge you to withdraw these regulations in consideration of the extreme hardship they will cause for patients and providers. If you will not withdraw the regulations, we request that you modify them as noted above.

Thank you for your consideration.

Sincerely,

National Health Law Program

On behalf of:
Organizations:

California Black Women's Health Project
Maternal and Child Health Access
National Center for Youth Law
National Immigration Law Center
Western Center on Law and Poverty

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[16] American Nurses Association, Code of Ethics for Nurses, Provision 1.4, http://nursingworld.org/ethics/code/protected_nwcoe813.htm.
[17] AMERICAN BAR ASSOCIATION, Policy # 05M104 (2005).

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