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April 9, 2009

Department of Health and Human Services
Office of Public Health and Science
Attn: Rescission Proposal Comments
Hubert Humphrey Building Room 716G
200 Independence Avenue SW
Washington, D.C.

RE: RIN 0991-AB49 Rescission Proposal

On behalf of the National Health Law Program, the California Black Women's Health Project, and Maternal and Child Health Access, we are submitting these comments to the federal Department of Health and Human Services in strong support of the proposal to rescind the 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" (Regulation).

The Regulation should be rescinded because it introduces broad, poorly defined, and confusing language to the existing law that protects the right of health care providers to refuse to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, and because the Regulation fails to account for the significant burdens that broad refusals have on patients - a burden that falls disproportionately and most harshly on low-income women, severely impacting their health outcomes and their ability to give informed consent for medical care. There are already ample statutory protections for health care providers who object to providing certain services based on their religious or moral beliefs through existing law which seeks to establish a delicate balance between protecting health care providers and meeting the needs of patients. This Regulation upsets that balance and puts patient health in jeopardy.

The Regulation 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 undermining the ability of health facilities to provide required information, counseling, referrals, and health care services in an orderly and efficient manner. Moreover, it opens the door to discrimination against marginalized groups including immigrants, people of color and lesbian, gay, bi-sexual and transgender people. If the regulation is not rescinded, the end result could be poorer health outcomes and higher costs for delivering quality care.

The Regulation should be rescinded because it is overly broad, vague, and has the potential to create instability in health care delivery

The Regulation dangerously expands the application of the underlying statutes[1] by offering an extremely broad definition of who can refuse and what they can refuse to do. The Regulation suggests 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 service or in a health care program. 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 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 Regulation also leaves unclear whether a worker can assert a 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 Regulation is 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 Regulation fails to define important terms and may cause greater confusion instead of clarity

The Regulation fails to define critical terms such as "discrimination" and "abortion," leaving important questions open to individual interpretation, and potentially creating chaos for patients and health systems.

The Regulation creates ambiguity instead of clarity as to whether the term "abortion" includes birth control, in particular emergency contraception. While a California court in *Brownfield v. Daniel Freeman Marina Hospital*[2] found that emergency contraception is not an abortifacient, former Secretary Michael Leavitt suggested that the term remained intentionally ambiguous in the Regulation so that individuals or institutions were able to define it for themselves."[3] Failing to define the term abortion leaves unanswered 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

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[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).

[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.

Center if the hospital will not comply with a state law that requires the provision of provide emergency contraception to victims of sexual assualt?

Questions also remain about how the Regulation intersects with other federal laws. For example, the Regulation may allow violations of EMTALA if a worker refuses to admit a patient in an emergency miscarriage or when there is a life-threatening ectopic pregnancy.

The failure to define the term "discrimination" is equally distressing. Title VII already establishes a framework within which employers can accommodate employees' religious beliefs. The Regulation makes no reference to Title VII and leaves the question of what constitutes "discrimination" unexplained. Is it discrimination for a health entity to 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 Regulation could leave employers vulnerable to liability, and supervisors unable to proceed in the orderly delivery of health care services, putting women's health at risk.

The Regulation fails to address the significant health impact of broadly construed refusals

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 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. 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 Food and Drug Administration's 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] The Regulation allows a health care professional to refuse to advise a woman of the need to use an accepted method of contraception in violation of the medical standard of care. It also may allow workers with only a tangential relationship to health care delivery to erect barriers to care through their refusals, for example, by refusing to file an insurance form, refusing to provide written materials, or refusing to ring up a pharmacy sale for contraception.

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

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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)

[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

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, African-American 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 Prevention (CDC) and the American College of Cardiology, 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. In rural areas there may simply be no other sources of health and life preserving medical care.

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

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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).

[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).

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 Regulation undermines 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 correct the imbalance of power in the relationship between health providers and patients, wherein the provider holds the knowledge and information but only the patient can authorize specific interventions. Disclosure of medical information is an essential component of the provider-patient relationship, and is embedded in medical and research codes. The Regulation is in direct conflict 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 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

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[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).

[16] American Nurses Association, Code of Ethics for Nurses, Provision 1.4, http://nursingworld.org/ethics/code/protected_nwcoe813.htm.

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, the Regulation makes the delivery of these services more difficult, more costly, and less efficient. We urge you to rescind the Regulation in consideration of the extreme hardship they will cause for patients and providers.

Thank you for your consideration.

Sincerely,

National Health Law Program
California Black Women's Health Project
Maternal and Child Health Access

[17] AMERICAN BAR ASSOCIATION, Policy # 05M104 (2005).