



September 24, 2008

Department of Health and Human Services
Office of Public Health and Science
Attention: Brenda Destro
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 728E
Washington, DC 20201

Re: RIN 0991-AB48, Provider Conscience Regulation

The Guttmacher Institute is writing in opposition to the above-referenced rule proposed by the Department of Health and Human Services (DHHS) on August 26, 2008, which has the potential to seriously undermine the integrity of the U.S. health care system; create substantial confusion for individual and institutional health care providers, state and local governments, and academic and other research institutions; and, most dangerously, impede individuals' access to critically important health care services that they need and want, and even basic information related thereto.

According to the proposed regulation, DHHS believes there is widespread ignorance of three federal laws, often referred to as the Church Amendments (42 USC 300a-7), the Coats Amendment (42 USC 238n) and the Weldon Amendment (Consolidated Appropriations Act 2008, P.L. 110-161, Div. G, 508d). These provisions allow individuals and institutions under certain circumstances to refuse to provide certain services, explicitly abortions and sterilizations, to which they may object on religious or moral grounds. The stated purpose of the regulation, in response, is to clarify, raise awareness of and require certification of compliance with these laws.

In our view, the regulation is fatally flawed. First, DHHS has provided no evidence that the regulation is needed. Second, DHHS is disingenuous in its assertion that the regulation merely clarifies existing laws; in fact, by redefining key terms, it vastly expands these laws' reach. The regulation conflicts with and undermines a host of other federal and state laws and policies designed to help Americans obtain needed reproductive health information and services. And it contradicts the careful balancing of competing rights and obligations that are both embodied in numerous health professional associations' ethical standards of care and mandated by the long-standing body of civil rights law addressing religious discrimination in the workplace.

For these reasons, as detailed further below, we urge that the regulation be withdrawn.

I. The Department has provided no evidence that the sweeping changes in health care policy and practice it would impose are necessary or justified. The regulation is a solution in search of a problem.

The political and ideological nature of this regulation is apparent in the fact that the “problem” section of the regulation provides no evidence that it is necessary. Only a single example of any tangible problem is offered, a policy by which DHHS claims that the American Board of Obstetrics and Gynecology (ABOG) has forced “health care professionals to choose between their capacity to practice in good standing and their right of conscience.”¹ Yet, this charge—initially made by Secretary Leavitt in a press release in March²—was immediately and forcefully rebutted by ABOG in a letter sent to the Secretary days later.³ ABOG sent another letter to the Secretary in August—after the Secretary repeated this charge in the release announcing this proposed regulation—restating its assurances that the charge is baseless and requesting that DHHS make public any evidence it might have at a formal hearing on the introduced regulation.⁴ The only citation provided for this charge by DHHS is DHHS’ own press release from March.

It is telling, moreover, that in its requests for public comment, DHHS is seeking information about the extent to which Americans know about the federal refusal laws and whether they are properly understood and implemented by public authorities. Gathering such basic information about the extent to which a problem that needs to be solved exists is a responsibility that DHHS should have met before issuing a regulation.

Finally, although DHHS asserts that there is widespread ignorance of the standing right under federal statute to refuse to provide certain health care services, explicitly abortions or sterilizations, it makes no comparable assertion—let alone provides any evidence—that this has resulted in any individual or institutional health care provider actually being forced to provide those services over his or her conscientious objection.

II. The Department asserts that the regulation’s purpose is merely to “clarify” three existing federal conscience laws, but, in fact, the regulation vastly and unaccountably expands those laws’ reach and scope.

The three federal laws at issue have been on the books for years—in one case, for three and a half decades. Over all that time, no administration has felt compelled to promulgate regulations to provide clarity about their meaning. In doing so now, the administration is defining terms and applying the laws in novel and dangerous ways for which there is no evidence of congressional intent. Specifically:

¹ Federal Register, Vol. 73, No. 166, Tuesday, August 26, 2008, page 50276.

² Department of Health and Human Services (DHHS), HHS secretary calls on certification group to protect conscience rights, press release, Mar. 14, 2008, <http://www.hhs.gov/news/press/2008pres/03/20080314a.html>, accessed Sept. 24, 2008.

³ Gant NF, American Board of Obstetrics and Gynecology, letter to Secretary Michael O. Leavitt, March 19, 2008.

⁴ Gant NF, American Board of Obstetrics and Gynecology, letter to Secretary Michael O. Leavitt, Aug. 22, 2008.

II A. By redefining “assist in the performance,” the regulation extends the laws’ reach to the provision of information and counseling, potentially allowing health care professionals to withhold precisely what their patients need under the ethical and legal principle of informed consent.

All five provisions comprising the Church Amendments include some variation of the term “assist,” thereby extending protection not only to those health care professionals who perform a given procedure but also to a professional’s assistance in the performance of that procedure. Section 88.2 of this regulation would define “assist in the performance” as participating “in any activity with a reasonable connection” to a given procedure or service. The definition goes on to include several specific examples, including counseling, and it is so broad as to include the provision of even the most basic factual information about the procedure or service.

In its description of the purported problem to be addressed, a previous draft of these regulations, which became public in July, highlighted a finding from a 2007 article in the *New England Journal of Medicine* that 86% of physicians believe they are obligated to provide patients with information on all of their medical options, regardless of a physician’s personal objection.⁵ Presenting this fact as a “problem” implied that this belief stems from ignorance of their legal rights, rather than from a conviction that they are in fact obligated, both legally and under the standards of their profession, to provide all information necessary to obtain a patient’s informed consent.

In formulating the actual proposed regulation, DHHS deleted this finding in its description of the “problem.” Even as it did so, however, it explicitly included the term “counseling” within the definition of “assist in the performance.” This redefinition is unprecedented, and it could have far-reaching implications. Section 88.4(d)(1) is particularly salient here, because it prohibits entities from requiring individuals to assist (read “provide information or counseling”) in the performance of “any part of a health service program or research activity funded by the Department if such service or activity would be contrary to his religious beliefs or moral convictions.”

Unlike most of the provisions included in this regulation, 88.4(d)(1) is not explicitly limited to abortion or sterilization, but rather could be interpreted to apply to a nearly limitless array of health care services. Thus, individuals might rely on it to justify their refusal to provide information or counseling about, for example, Pap tests or STI tests—or cervical cancer or STIs themselves—for teen or unmarried women they believe should be sexually abstinent, or about assisted reproductive technologies to individuals or couples they believe should not be parents because of their marital status, sexual orientation or other characteristics. Indeed, health care professionals might rely on it to justify their refusal to provide information or counseling to *any* patient about services they find religiously or morally objectionable, from vaccination to blood transfusion to end-of-life pain management.

Allowing health care professionals to rely on these federal laws in this manner is not only misguided, it is contrary to the clear intent of Congress when it enacted the relevant section of the Church Amendments in 1974 as part of the National Research Act.⁶ One of the stated

⁵ Curlin FA et al. Religion, conscience, and controversial clinical practices, *New England Journal of Medicine*, 2007, 356(6):593–600.

⁶ P.L. 93-348, July 12, 1974.

primary purposes of that act was to strengthen the institution of informed consent, in response to perceived abuses by medical researchers and practitioners. Given that purpose, it should be clear that Congress did not intend to, simultaneously, undermine informed consent by allowing those same medical researchers and practitioners to refuse to provide relevant information to patients.

II B. By vastly expanding the definition of “workforce,” along with “assist in the performance,” the regulation extends a blanket right to refuse to an unprecedented range of employees only tangentially related, at best, to the provision of health care or the conduct of research.

The definitions included in section 88.2 of this regulation are expansive in other ways. The same definition of “assist in the performance” states that it includes not only counseling, referral and training but also “other arrangements for the procedure, health service, or research activity” and, further, that it applies to any individual who is part of a DHHS-funded entity’s workforce. The definition of “workforce” extends the right to refuse not only to an entity’s employees but also to volunteers and trainees.

Taken together, these definitions extend refusal rights to a host of individuals with at best a tenuous connection to the provision of health care or the performance of research. In the supplementary information discussing the reasoning behind these definitions, DHHS asserts that it is interpreting these terms broadly and, by way of example, states that the regulation would apply to “an employee whose task it is to clean the instruments used in a particular procedure.” By the same logic, the regulation could grant refusal rights to staff members tasked with scheduling appointments, completing and filing insurance forms, or purchasing and inventorying supplies.

Moreover, the regulation places no conditions whatsoever on these refusal rights. If that interpretation were to hold sway, all sorts of illogical scenarios could be possible. In terms of the provision of health care, family planning clinics or state family planning programs could be forced to hire employees unwilling to provide, discuss or even schedule appointments for contraception. Hospitals could be forced to hire personnel refusing to honor their patients’ end-of-life directives. Pharmacies could be forced to hire clerks refusing to ring up purchases for AIDS medication. Further, health care entities could be hindered in their efforts to ensure that patients are served regardless of their marital status, sexual orientation, age or HIV status—and thus complying with federal or state antidiscrimination laws and employer’s own antidiscrimination policies.

Similarly extreme scenarios could affect research institutions. Research laboratories could be forced to hire staff members opposed to conducting, or in any way supporting, the very research conducted there, including research involving animal testing, vaccination, human embryonic stem cells, sexually transmitted infections, contraception, in vitro fertilization, protection from biological weapons or anything else to which some Americans may object. The Guttmacher Institute itself, because it sometimes receives grants from the National Institutes of Health to conduct behavioral research, would also be impacted, and arguably could be faced with personnel refusing, for example, to perform accounting, administrative or copyediting duties related to such research.

The Department has provided no evidence that Congress intended such a sweeping interpretation of its actions. Nor has it shown that courts or other executive bodies have ever contemplated such a broad interpretation.

II C. By applying the laws to all DHHS-funded research activity, the regulation goes well beyond the scope of legislation concerned specifically with biomedical and behavioral research.

Parts C2 and D of the Church Amendments, as noted above, were passed in 1974 as part of the National Research Act, a law concerned with the ethical conduct of biomedical and behavioral research. Part C2 of the Church Amendments, in fact, is explicitly limited to biomedical and behavioral research.

It appears from section 88.3 of the proposed regulation that the Department does not view Church Part D as limited to such research, or even to health care–related research. And from the list of entities included in Table 1 of the regulation, it appears that DHHS envisions every recipient of a DHHS grant—regardless of the grant’s purpose—to be subject to the regulation and its certification requirements. (The number of grant awards included on that table, 76,000, is equal to the number awarded by the entire Department for FY 2007.⁷)

Such an interpretation of this long-standing law would make it applicable to a vast array of social science research with little or no relation to the issues addressed by the National Research Act. This could include, for example, evaluations of the effectiveness and cost-effectiveness of DHHS programs, including the evaluation research necessary for DHHS to participate in the Office of Management and Budget’s Program Assessment Rating Tool. It could include economic projections used to responsibly manage public money, infrastructure assessments to help the nation prepare for terrorism, epidemics and natural disasters, and tracking systems to monitor the health of American citizens and the performance of doctors, nursing homes and hospitals. The Guttmacher Institute itself could be affected by virtue of its receipt of DHHS funds to monitor the amount of public dollars spent on family planning services or the number of clients served by family planning clinics and even for its basic, statistical analyses of government data that allows the Institute to calculate the number of unintended pregnancies occurring in the United States.

If recipients of such grants were considered subject to this provision of the Church Amendments, it would extend to these entities all of the issues raised above (under II B) regarding the broad definitions of “assist” and “workplace.” In effect, it could undermine the ability of academic and other research institutions to fulfill nearly any research contract with DHHS and, thereby, undermine DHHS’ ability to effectively use the private sector to obtain the research it needs to effectively run its programs.

⁷ DHHS: grant awards by operating division, creation date not available, <http://taggs.hhs.gov/AnnualReport/FY2007/overview/grantawards.cfm>, accessed Sept. 24, 2008.

II D. By applying the laws to foreign and international organizations, the regulation could constrain U.S. foreign policy and foreign aid and potentially conflicts with the policies of other sovereign nations.

The proposed regulation would inappropriately expand the original scope and intent of the laws to potentially include international, foreign and multilateral organizations. Section 88.2 of the regulation defines “recipient” and “sub-recipient” as including “foreign or international organizations (such as agencies of the United Nations) . . . at the discretion of the Department awarding agency.” In doing so, the regulation does not make any reference or give any deference to existing federal law governing U.S. foreign policy, nor to the agencies entrusted to set this policy. This could create confusion among federal agencies about which laws to follow, generate conflict with policies promulgated by the Departments of State and Defense and the U.S. Agency for International Development, and lead to unforeseen foreign policy complications.

Requiring compliance with these laws and certification of compliance from international grantees could also create a severe burden on implementers, particularly those who work with local sub-grantees in other countries. It is unclear how DHHS could feasibly require multilateral organizations such as the World Health Organization and the Global Fund to Fight AIDS, Tuberculosis and Malaria to certify to and monitor enforcement of these regulations for their agencies, sub-agencies and multitudes of grant recipients and sub-recipients. Indeed, such a requirement could force agencies of the United Nations out of DHHS programs altogether, including the President’s Emergency Plan for AIDS Relief.

These regulations may also directly conflict with the laws and policies of other countries where recipients are implementing programs, putting such implementers in an untenable situation. For example, such other countries’ policies may require health care providers to provide referrals in cases of conscientious objection, a requirement that would be unenforceable under these regulations. The regulations would undermine the ability of U.S.-funded organizations to carry out health programs and services throughout the world.

III. At its heart, the regulation is an attack on the ability of American women and men to obtain reproductive health services they need and want, and undermines critical federal and state safeguards that protect access to this care.

Considering the lack of evidence that this regulation is necessary and the expansive manner in which DHHS has interpreted long-standing federal law, it seems clear that other motivations are at play. DHHS’ own language—in the proposed regulation and in the July draft—indicates that it expects the regulation to impact the provision of abortion and contraception services. Specifically:

III A. The regulation undermines the limited but vital requirements related to the provision of abortion-related information and services under Title X and Medicaid.

Although federal statutes bar federal funding of abortion in the vast majority of circumstances, they include several important abortion-related *requirements* in federally funded programs. For example, the laws, regulations and guidelines governing the Title X family planning program require that for clients found to be pregnant, grantees must provide nondirective counseling on

all of a woman’s legal options, including abortion, and referral upon request.^{8, 9, 10} And Medicaid requires a state’s program to cover all medically necessary abortions allowed under the Hyde Amendment—currently, those in cases of rape, incest or endangerment to a woman’s life.¹¹

The proposed regulation does not reference either of these requirements. If DHHS wished to uphold, rather than undermine, them, it would have included in this regulation an explicit statement that they stand, regardless of the regulation and the laws it is interpreting. Without such a statement, the regulation may embolden Title X grantees (which are often state health agencies) or state Medicaid agencies to ignore the requirements set by Congress.

Specifically, the regulation could be interpreted to provide that a state cannot be forced to fund abortions in cases of life, rape and incest—even though federal Medicaid statute, as interpreted by both DHHS and federal courts,^{12,13,14,15} requires states to provide funding in these circumstances. This would make it even more difficult for already-disadvantaged, low-income Americans to obtain the abortion services they need, adding to situations that are already immensely difficult for women on a personal level and dangerous to their physical and/or emotional health.

In relation to Title X, the regulation could allow grantees to ignore the federal requirement to provide nondirective counseling on all of a pregnant woman’s options. If DHHS is going to undercut this important, long-standing requirement, it has an obligation to indicate how it will ensure that every Title X client will be able to receive the counseling and referrals to which they are entitled if individual providers and whole programs, even states, are allowed to refuse.

III B. By failing to acknowledge federal precedent and medical consensus about when pregnancy begins, the regulation undermines federal and state policies promoting access to contraception.

The July draft of these regulations directly addressed the question of what is included under the term abortion. By defining the term “abortion” to include any action that prevents the implantation of a fertilized egg, that draft would have effectively included the birth control pill, other hormonal contraceptives and the intrauterine device. (Although preventing implantation is not their primary mode of action, these methods may sometimes act post-fertilization.)

Defining abortion in this manner would have been contrary to long-standing federal precedent and to the consensus of the medical community as to when pregnancy begins and what

⁸ P.L. 110–161, Dec. 26, 2007.

⁹ 42 CFR 59.5.

¹⁰ DHHS, Program Guidelines for Project Grants for Family Planning Services, Washington, DC: U.S. Government Printing Office, 2001, pp. 18 & 24–25.

¹¹ Richardson SK, Medicaid Bureau, Health Care Financing Administration, DHHS, Letter to State Medicaid Directors, Dec. 28, 1993.

¹² *Dalton v. Little Rock Family Planning Services*, 516 U.S. 474, 116 S. Ct. 1063, 134 L. Ed. 2d 115 (1996).

¹³ *Hern v. Beye*, 57 F.3d 906 (10th Cir. 1995).

¹⁴ *Edwards v. Hope Medical Group for Women*, 512 U.S. 1301, 115 S. Ct. 1, 129 L. Ed. 2d 903 (1994).

¹⁵ *Planned Parenthood Affiliates of Michigan v. Engler*, 73 F.3d 634 (6th Cir. 1996).

constitutes the prevention, rather than the termination, of pregnancy.¹⁶ For example, the federal regulations designed to implement the Hyde Amendment say that although funding is not available for abortions, it is available for “drugs or devices to prevent implantation of the fertilized ovum.”¹⁷ Similarly, since the 1970s, DHHS has had an official definition of pregnancy for purposes of establishing safeguards when federally funded research involves pregnant women. The most recent overhaul of these rules, promulgated in 2001 by this administration, says that pregnancy “encompasses the period of time from implantation until delivery.”¹⁸

In his official blog on August 7, Secretary Leavitt denied that his intent was to define contraceptives as abortion.¹⁹ Yet, the regulation as proposed does not make this explicit. It does not include a medically accurate definition of abortion; indeed, it sidesteps the issue entirely by unaccountably including no definition of the term at all. This ambiguity, which can only be interpreted as intentional, leaves a door open for the numerous antiabortion activists who conflate most modern contraceptives with abortion and who assert a refusal right to provide or assist in the provision of those services. Secretary Leavitt himself has acknowledged that such efforts will continue.²⁰

This could have far-reaching consequences. In describing the purported problems to be solved by this regulation, the July draft pointed to state laws and policies mandating that insurance plans cover prescription contraceptive drugs and devices if they cover other prescription drugs; requiring emergency rooms to provide information about and access to emergency contraceptives for victims of sexual assault; requiring pharmacies to ensure customers’ access to lawfully prescribed drugs, including contraceptives; and allowing officials to intervene in hospital mergers to ensure communities’ continued access to its current range of health care services.

These supposed problems—dozens of laws passed by duly elected legislators in most of the states in this country—are not mentioned in the introduced version of this regulation. Nevertheless, these laws may be undermined by insurers, hospitals, pharmacies and other health care institutions that choose to define contraceptives to be abortifacients, citing section 88.4 of this regulation as justification. This seems especially likely in the case of emergency contraception—a method that is wrongly thought by many Americans to be an abortifacient, both because it is taken after intercourse and is still sometimes confused with mifepristone.

Similarly, federal law and regulations require that health care institutions receiving certain DHHS grants—including those under Title X²¹ and Section 330²² of the Public Health Service Act (grants for family planning clinics and community health centers, respectively)—provide clients under those programs with family planning services. This regulation would undermine these requirements, emboldening institutions to accept federal funds under these programs but

¹⁶ Gold RB, The implications of defining when a woman is pregnant, *The Guttmacher Report on Public Policy*, 2005, 8(2):7–10.

¹⁷ 42 CFR 441.207.

¹⁸ 45 CFR 46.202.

¹⁹ Leavitt M, Physician conscience, Secretary Mike Leavitt’s Blog, Aug. 7, 2008, http://secretarysblog.hhs.gov/my_weblog/2008/08/physician-consc.html, accessed Aug. 9, 2008.

²⁰ Simon S, Rules let health workers deny abortions, *The Wall Street Journal*, Aug. 22, 2008, A3.

²¹ 42 USC 300.

²² 42 USC 254(c).

refuse to provide contraceptive services and supplies that they claim to be abortifacients. Title X statute, regulation and guidance, for example, all require that grantees provide a “broad range” of contraceptive methods,^{23,24,25} something that would be impossible for a grantee that refused to provide any hormonal methods.

Furthermore, state agencies are required under federal law to include coverage for family planning services for most enrollees under Medicaid. Because section 88.2 of this regulation includes state agencies under its definition of “entity” and “health care entity”—thus granting the agencies refusal rights—those agencies might also attempt to claim federal funds while refusing to comply with Medicaid’s requirement.

III C. The regulation contradicts long-standing requirements to provide emergency care, including care that would result in abortion.

None of the three laws that are to be clarified by this regulation include any explicit exception for emergency care. Nevertheless, other federal and state laws—most notably the Emergency Medical Treatment and Active Labor Act,²⁶ passed in 1986—do require that institutions provide care in an emergency, a requirement that includes no exception for religious or moral objections to the needed service.

If DHHS wished to uphold, rather than undermine, federal and state requirements to provide emergency care, it would have included in this regulation an explicit statement that nothing in the regulation should be read to undermine such requirements.

This regulation, by not including such an explicit statement, may encourage individual and institutional health care providers, including hospital emergency rooms, to refuse to provide certain types of emergency care, such as an abortion necessary to preserve the life a woman. By leaving unclear the interaction of federal refusal laws and federal and state emergency care requirements, it may also leave state governments in the position of not knowing whether they will be punished by the Department for enforcing their own laws requiring emergency care.

IV. The regulation asserts what is essentially an absolute provider and employee right to refuse—one that stands in sharp contrast to the careful balancing of rights, needs and responsibilities under widely shared standards of medical ethics and long-standing federal civil rights law.

In the entire proposed regulation, DHHS has failed to even hint at any ethical or legal limits of conscientious refusal. This absolutist standpoint runs contrary to the ethical standards promulgated by numerous U.S. and international health professional associations, which also take into account providers’ obligations to their patients’ health, well-being and autonomy. It

²³ 42 USC 300.

²⁴ 42 CFR 59.202.

²⁵ DHHS, Program Guidelines for Project Grants for Family Planning Services, Washington, DC: U.S. Government Printing Office, 2001, pp. 2, 13, 24 & 28.

²⁶ 42 USC 1395dd.

also contradicts Title VII of the Civil Rights Act²⁷ and related state laws that take into account the needs and rights of employers. Specifically:

IV A. The regulation conflicts with ethical standards developed by numerous professional associations that make it clear that providers' conscience rights are to be respected and accommodated, but that they also must not be used to obstruct patients' access to the information and care they need.

Secretary Leavitt has specifically criticized a November 2007 ethics committee opinion by the American College of Obstetricians and Gynecologists (ACOG) that comprehensively evaluates the issue of conscientious refusal and asserts that the right to refuse should, ethically, have its limits and must be balanced with other values and duties that physicians accept “by virtue of entering the profession of medicine.”²⁸ The opinion lays out four criteria for gauging this balance, namely, the degree to which refusal imposes the provider’s beliefs on patients’ autonomy, impacts patients’ health and perception of well-being, is based on proper understanding of scientific evidence, and results, intentionally or not, in discrimination and inequality.

Although the ACOG committee opinion is particularly comprehensive, its conclusions parallel those of numerous other associations of health care professionals—including the American Medical Association,²⁹ the American Nurses Association,³⁰ the American Academy of Physician Assistants³¹ and the American Pharmacists Association³²—all of which, too, have endorsed standards of practice that attempt to balance a provider’s conscientious objection and a patient’s access to care. Although not always spelled out in one place, this balancing leads to several clear obligations, including that:

- providers must impart full, accurate and unbiased information so patients can make informed decisions about their health care;
- patients must always have access to services in emergency circumstances;
- providers must not abandon patients but instead patients must be referred to another provider willing and ready to take over care; and
- providers seeking to “step away” must give adequate and timely notice to patients, employers and others who will be affected by their doing so.

²⁷ 42 USC 2000e

²⁸ American College of Obstetricians and Gynecologists Committee on Ethics, The limits of conscientious refusal in reproductive medicine, ACOG committee opinion no. 385, *Obstetrics and Gynecology*, 200, 110:1203–1208.

²⁹ American Medical Association, *Code of Medical Ethics*, E-8.08, Informed Consent, June 2006, http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_6a07.pdf, accessed Sept. 24, 2008.

³⁰ American Nurses Association, *Code of Ethics for Nurses with Interpretive Statements*, 5.4, Preservation of Integrity, 2005, <http://www.nursingworld.org/MainMenuCategories/ThePracticeofProfessionalNursing/EthicsStandards/CodeofEthics/CodeofEthics.aspx>, accessed Sept. 24, 2008.

³¹ American Academy of Physician Assistants, *Guidelines for Ethical Conduct for the Physician Assistant Profession*, 2008, <http://www.aapa.org/manual/22-EthicalConduct.pdf>, accessed Sept. 23, 2008.

³² Policy Committee Report, *Pharmacist Conscience Clause*, American Pharmacists Association, 1998.

More generally, the right to withdraw from services cannot—from an ethical standpoint, even if it is allowed by law—be used as a pretext for blocking or denying patients’ own rights to care. As the ACOG opinion concludes, “the patient’s well-being must be paramount.”

This regulation does not even acknowledge these standards of practice nor the balance that they seek. It does not contemplate any impact on patients’ health, well-being and right to autonomy. Indeed, it explicitly or implicitly endorses refusal to abide by each of these ethical obligations, allowing refusal related to information, emergency care and referral and remaining silent on the issue of notice.

IV B. The regulation contradicts Title VII of the Civil Rights Act, which carefully balances employees’ rights to be free from religious discrimination in the workplace with the legitimate needs of employers, including their ability to serve their clients.

Currently, claims of religious discrimination in the workplace (health care or otherwise) are governed by an extensive body of laws, regulations and court precedent—most importantly, Title VII of the Civil Rights Act. Title VII includes explicit language that attempts to appropriately balance the religious rights of workers with the practical needs of employers, including their ability to provide needed care to their clients. Specifically, the law requires that an employer reasonably accommodate an employee’s religious practices unless so doing would impose an undue hardship on the employer.³³ Refusal on religious grounds to perform or assist in a given procedure would be considered a religious practice.

The section of the Equal Employment Opportunity Commission’s compliance manual related to religious discrimination and Title VII was updated in July 2008 and includes several helpful examples in the health care field of how this balance should work in practice. Example 34 describes the case of a nurse with a religious objection to assisting with abortions: Her hospital’s offer to transfer her from the labor and delivery unit (where emergency abortions may be performed) to the neonatal intensive care unit (where they are not) would be a reasonable accommodation; the hospital was not obligated to instead allow her to trade assignments with other nurses in the labor and delivery unit, because there were not enough staff members able and willing to trade with her (an undue hardship for the hospital).

Examples 43 and 44, relating to a pharmacist objecting to the provision of contraceptives, are also instructive: The pharmacist’s employer provided a reasonable accommodation to the pharmacist by allowing him to signal a coworker to serve any customers who arrive seeking contraceptives; yet, the employer would not have to allow the objecting pharmacist to simply walk away from a customer or leave a caller indefinitely on hold. Furthermore, this employer’s accommodation may have been a undue hardship for a smaller pharmacy where qualified coworkers would not always be available.

The regulation proposed by DHHS does not acknowledge this body of laws and precedence, nor the measured balance included therein. If DHHS wished to uphold, rather than undermine, the existing standard, it would have included in this regulation an explicit statement deferring to Title VII. Without such a statement, the regulation threatens this careful balance by allowing

³³ U.S. Equal Employment Opportunity Commission, *EEOC Compliance Manual*, Section 12, Religious Discrimination, July 22, 2008, <http://www.eeoc.gov/policy/docs/religion.pdf>, accessed Sept. 24, 2008.

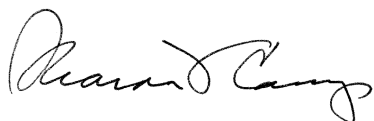
religious practices that create an undue hardship on the employer and in the process impacting patient care.

Extrapolating from the examples provided by the EEOC, if the undue hardship to the employer (and its clients) were not considered and the employee's religious practices were to be accommodated regardless of the consequences, a nurse could be allowed to remain in a position in which her refusal to assist in emergency abortions could—because no other nurses were available—endanger patients' lives. Similarly, a pharmacist could be allowed to refuse to serve customers seeking contraception, even if—because no other pharmacists were available—that meant driving away a pharmacy's customers or (in a one-pharmacy community) denying the community access to contraceptives entirely.

Conclusion

In summary, DHHS has provided no evidence that this regulation is necessary. Moreover, both by what it has included in the regulation (such as its overly broad definitions of many key terms) and by what it has left out entirely (such as any reference to the regulation's interaction with numerous other federal and state policies), DHHS has made clear that it seeking to promote both the conceptual validity and the actual assertion of an unconstrained right of conscientious refusal as broadly as possible. Its single-minded pursuit of its goal, unsupported by evidence of congressional intent and conflicting with a host of other federal and state laws, runs counter to a long history of carefully balancing competing rights and interests. It would undermine the integrity of the entire U.S. health care system, leading to wide-spread confusion and impeding individual access to important health care information and services. Once again, for all of the reasons described in this letter, we urge DHHS to withdraw this regulation.

Sincerely,

A handwritten signature in black ink, appearing to read "Sharon L. Camp". The signature is fluid and cursive, with the first name "Sharon" and last name "Camp" clearly distinguishable.

Sharon L. Camp
President and CEO