For Immediate Release

September 25, 2008

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CLINTON, MURRAY LEAD SENATORS IN LETTER URGING HHS SECRETARY TO HALT PROPOSED HHS RULE

As Public Comment Period Deadline Nears, 28 Senators Express Their Opposition to Shortsighted Rule in Letter to Secretary Leavitt

WASHINGTON, DC – Senators Hillary Rodham Clinton (D-NY) and Patty Murray (D-WA) today led a group of 28 Senators in submitting a letter to Secretary of Health and Human Services (HHS) Michael O. Leavitt to underscore their serious concerns about a proposed HHS regulation that would undermine women's health. The proposed HHS rule would require any health care entity that receives federal financing to certify in writing that none of its employees are required to assist in any way with medical services they find objectionable. Tonight at midnight marks the deadline for this proposed rule's public comment period.

"The proposed rule is damaging to the health care needs of women, their families, and all Americans, and will only serve to cause havoc, not clarity, among employers and employees in the health care field. Again, we urge you to halt all efforts in moving forward with this rule," the Senators wrote today.

In a face-to-face meeting with Secretary Leavitt on Tuesday, Senators Murray and Clinton pressed Secretary Leavitt on how the vague language in the rule would enable providers to deny access to contraception and questioned Secretary Leavitt on what HHS will do to protect access to critical healthcare and family planning services. The Senators left the meeting still concerned that the rule as currently written would undermine patients' access to care and information about their health care options.

In addition to Senators Clinton and Murray, today's letter to Secretary Leavitt was signed by Senators Akaka, Baucus, Biden, Boxer, Brown, Cantwell, Cardin, Dodd, Durbin, Feinstein, Harkin, Kerry, Klobuchar, Lautenberg, Leahy, Levin, Lincoln, McCaskill, Menendez, Mikulski, Obama, Sanders, Schumer, Stabenow, Tester, and Whitehouse.

The full text of the letter follows:

September 25, 2008

The Honorable Michael O. Leavitt

Secretary

United States Department of Health and Human Services

200 Independence Avenue, SW

Washington, D.C. 20201

Re: RIN 0991-AB48

Dear Mr. Secretary:

We are writing to strongly object to a rule proposed on August 26, 2008 by the Department of Health and Human Services (HHS) that will significantly undermine patients' access to vital health services and information. The ill-conceived and unnecessary proposed rule puts politics and ideology before quality health care. It would expand the ability of health providers to withhold treatment, counseling, or medical information based on their religious or moral beliefs without regard for the needs of the patient. The proposed rule broadens the scope and reach of existing federal refusal laws beyond Congressional intent. If issued, it may leave the door open for health care providers, including insurance plans and hospitals, to deny access to most forms of birth control, while creating confusion and uncertainty about the rights and obligations of patients, doctors, and health care institutions – not merely in the area of reproductive health but throughout the U.S. health care system. Because the proposed rule is damaging to the health care needs of women, their families, and all Americans, we urge you to halt all efforts to move it forward.

Background

In the proposed rule, HHS purports to educate recipients of Department funds about their legal obligations under three statutes – 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*, PL 110-161, Div. G, 508d). These laws give individuals and institutions the ability to refuse to provide, or prohibit requiring the performance or participation in, health services or research activities contrary to his or her religious beliefs or moral convictions.

While HHS claims to be issuing the rule to clarify existing law, its expansive language and ambiguity will likely have the opposite effect. Rather than clarify the law, the proposed rule will lead to confusion for health care providers, state and local governments, and research institutions – which will undoubtedly struggle with the uncertain interaction between this proposed regulation and existing state and federal laws that address these issues.

This proposed rule is a solution in search of a problem. The American Board of Obstetrics and Gynecology (ABOG) recently issued a public statement vehemently denying charges by HHS that ABOG has required physicians to violate their conscience rights by providing or referring patients for abortion – erroneous charges that HHS used as a basis for issuing this unnecessary rule. ABOG has also called on HHS to hold a

hearing to reveal, among other things, actual cases of misconduct that the rule is intended to address which, to date, HHS has failed to provide to the public.

The Proposed Rule Fails to Clarify that Birth Control is Not a Target

Under a previously-leaked draft of this rule in mid-July, HHS defined the term "abortion" to include commonly used FDA-approved methods of birth control. Rather than allay concerns over this language by including a definition of abortion consistent with the consensus of the medical community and existing federal policy, the proposed rule drops the abortion definition entirely. When asked to clarify that the regulation does not apply to birth control, HHS Secretary Leavitt stated: "This regulation does not seek to resolve any ambiguity in that area."

The potential implications of this ambiguity are far-reaching. Like the leaked draft, the proposed rule leaves the door open for insurance plans, hospitals, and other entities to define abortion in any way they choose – including in ways that would include common forms of birth control. As a result, women could be denied access to birth control services, including counseling and information, even if there are other protections in place.

For example, if adopted, the proposed rule could undermine a state's ability to enforce its own law requiring insurance plans that cover other prescription drugs to also cover birth control. It could create confusion for states administering Medicaid and the Title X programs because of existing program requirements ensuring access to contraceptive counseling and services; and it could create an opening for hospitals to refuse to comply with state laws requiring that sexual assault survivors be offered emergency contraception. In short, the proposal may well complicate the administration of longstanding and vital federal family planning programs, as well as state laws adopted to protect access to contraception.

The Proposed Rule Fails to Even Mention the Careful Balance Struck by Civil Rights Law

This proposed rule allows any employee of a health care provider to refuse to treat any individual if doing so would violate his or her religious beliefs or moral convictions – without any mention of the needs of the patient. In doing so, the proposed rule fails to address serious questions as to whether its purpose is to upset the careful balance between respecting employees' religious beliefs and employers' ability to provide their patients with access to health care currently maintained in federal law under Title VII of the *Civil Rights Act of 1964*.

Title VII provides a balance between employers' need to accommodate their employees' religious beliefs and practices – including their refusal to participate in specific health care activities to which they have religious objections – with the needs of the people the employer must serve. Under Title VII, employers have a duty to reasonably accommodate an employee or applicant's religious beliefs or practices, unless doing so places an "undue hardship" on the employer's business. This law provides protection for individual belief while still ensuring patients' access to health care services. An extensive guidance just released in July 2008 by the Equal Employment Opportunity Commission (EEOC), the federal agency charged with the enforcement of Title VII and other key employment discrimination laws, discusses in great detail the scope of employers' obligations to accommodate the religious beliefs of their employees.

Because the proposed rule fails to even mention Title VII or the comprehensive EEOC guidance, it will likely cause confusion and uncertainty among employees, employers and patients regarding their rights surrounding these refusals. For example, the rule does not say what steps an institution must take to reasonably accommodate an individual health provider's religious objection, nor whether there are any circumstances at all when the needs of the employer or its clients outweighs such an objection. Instead, it simply includes language prohibiting discrimination in specific circumstances against those who perform or assist with, or who refuse to perform or assist with, certain health services, and ignores the inevitable confusion and potential conflict with other employment protections.

The Proposed Rule Undermines Patients' Access to Information, Counseling, and Referrals

If this proposed rule is implemented, women seeking services at a health care facility that receives direct or indirect funds from HHS may no longer be assured that they will receive information about all of their health care options, including – but not limited to – the option of safe and legal abortion care. The rule allows a broad range of

health care providers and entities to refuse even to counsel patients about options – thus to deny information critical to informed consent.

Additionally, the refusal to counsel patients for services or provide medical information and options could extend to *any medical treatment*, beyond reproductive health care. For example, an oncologist working in a federally-funded prostate cancer treatment program could withhold information from a patient about the option of extracting and freezing sperm before cancer treatment. In this scenario, the oncologist may personally object to assisted reproduction and believe the rule supports his failure to inform the patient about his last chance to have genetically-related children. Indeed, health care professionals might rely on this rule to justify their refusal to provide information or counseling on services from vaccination to blood transfusion to end-of-life pain management. This proposed rule must not stand in the way of the information patients need to make health care decisions for themselves and their families, nor should it undermine providers' legal and ethical requirements to obtain patients' informed consent. As it stands, it threatens to fundamentally undermine the relationship between providers and patients, who will have no way of knowing which services, information, or referrals they may have been denied.

The Proposed Rule Does Not Even Protect Patients in Emergency Situations

The rule fails to address the obligations of individuals and entities in the case of medical emergencies. For example, the federal *Emergency Medical Treatment and Labor Act* (EMTALA) requires hospitals to at least stabilize patients who come to the ER in medical emergencies. Could avoiding "discrimination" against a health care provider be allowed to trump the need to treat a patient in a medical emergency? At best, this failure will cause confusion among providers. At worst, it could place patients in need of emergency medical care in grave harm.

The Proposed Rule Extends Broad Refusal Rights to an Expansive Array of Individuals and Institutions

The proposed rule expands the universe of health care individuals and institutions that may refuse to provide services. It also broadens the scope of what falls under a refusal under the applicable law. For example, the proposed definition of "assist in the performance" states that it includes "counseling, referral, training, and other arrangements

for the procedure, health service, or research activity" and the definition of "workforce" extends the right to refuse not only to an entity's employees but also to volunteers and trainees.

Further, the regulation's definitions of "recipient" and "sub-recipient" would extend the laws' applicability even to "foreign or international organizations (such as agencies of the United Nations)" without any reference or deference to existing federal law governing U.S. foreign policy. This could create confusion among federal agencies about which laws to follow and could lead to unforeseen foreign policy complications.

The Proposed Rule May Impede Biomedical and Behavioral Research

Finally, the proposed rule could have a substantial impact on research activities at federally-funded hospitals and academic, nonprofit and corporate research institutions. In the proposed rule, a broad array of HHS-funded entities, including post-graduate physician training programs, hospitals, laboratories, universities and think tanks, are prohibited from discriminating against any personnel who refuse to perform, or assist in, *any* research activity or service. Without additional guidance about how research institutions should balance the needs of their employees with the needs of their research programs – guidance along the lines of the long established framework provided currently to these institutions under Title VII – this proposed rule could adversely impact a wide range of research efforts, including, among others, federally-funded stem cell research, research involving animal testing, and research intended to help protect U.S. soldiers from biological weapons.

The proposed rule is damaging to the health care needs of women, their families, and all Americans, and will only serve to cause havoc, not clarity, among employers and employees in the health care field. Again, we urge you to halt all efforts in moving forward with this rule.

Sincerely,

Hillary Rodham Clinton Patty Murray

cc:

President George W. Bush

Brenda Destro, Office of Public Health and Science,

Department of Health and Human Services

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