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May 22, 2006

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Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
Room 5541 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Levinson,

Thank you for your continued efforts to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs. I appreciate the dedication of you and your staff towards these ends.

Ten years ago, Congress passed and President Clinton signed Public Law 104-146 that would require, as a condition of state eligibility for federal Ryan White CARE Act funds, "a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to HIV and should seek testing."

In explaining the provision when offered as an amendment in the U.S. Senate, the author—then-Senator Jesse Helms-- stated that the intent was to ensure that "States are going to have to make a genuine and concerted effort" to ensure that spouses are "promptly notified" of possible HIV exposure by a current or previous spouse (pages S10708 - S10709 of the *Congressional Record* for July 26, 1995). The amendment was overwhelming approved 98 to zero by the U.S. Senate and unanimously by the members of the House/Senate conference of which I was a member.

As a practicing physician who has cared for a number of patients living with HIV/AIDS, I believe that confidential notification is a necessary and effective public health strategy that helps break the chain of transmission by alerting those at risk before they become infected and to ensure lifesaving treatment and secondary prevention to those who have already been infected. This is especially important for spouses who have no reason to suspect that they are at risk and therefore are unlikely to take any precautions to guard them against infection or to seek testing that could diagnose their condition and ensure access to treatment when it is most effective. There have been countless stories of women and men who became unknowingly infected by a partner or spouse who hid his or her status and the spouse only learned of the infection when diagnosed with an AIDS-defining illness, far too late to maximize the benefits of existing medical therapies or prevent perinatal transmission to their children. The 1996 spousal notification law was intended to end tragedies such as these.

But that has not been the case because the law appears to never have been fully enacted.

In a letter dated January 26, 1998, then-Secretary of Health and Human Services Secretary Donna E. Shalala stated that the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) jointly coordinated the implementation of this provision that went into effect April 1, 1997.

According to Secretary Shalala's letter, "examples of program principles and practices that CDC believes would minimally constitute a good-faith effort regarding HIV spousal notification were developed by CDC and HRSA in consultation with health department and community representatives and were provided to the States in their certification packages. These included the following:

"For individuals reported to the State on or after April 1, 1997, as being diagnosed with AIDS (or HIV infection in States requiring HIV-infection reporting by law or regulation), if not already determined by the reporting health care provider, each such individual shall be:

- asked if he or she has, or has had, a spouse (defined by this law as "any individual who is the marriage partner of an HIV-infected patient or who has been the marriage partner of an HIV-infected patient at any time within the 10-year period prior to diagnosis of HIV infection");
- informed that he or she should notify his or her spouse, or former spouses, of the potential exposure to HIV.

"Reasonable efforts must be made to determine if each HIV-infected individual intends to notify his or her spouse of their possible exposure to HIV or agrees to have a qualified health care provider notify them. In situations where the HIV-infected individual reports that he or she intends to notify the spouse, culturally competent counseling and educational services on the following issues should be available:

- how to make the notification;
- how to preserve confidentiality of both the individual and the spouse;
- how HIV infection and transmission can be prevented;
- how the spouse can access testing, other prevention services, and treatment.

"If the HIV infected individual is unable or unwilling to notify his or her spouse, culturally competent services should be available from the provider or the health department to do so."

Secretary Shalala's letter further states, "Unless covered by existing law, policy, or regulation, States should develop policies that address situations involving HIV-infected individuals who do not plan to notify their spouses and who refuse health department assistance."

But the letter notes "CDC and HRSA agreed that appropriate State health agency officials should have the authority to define a 'good faith effort' for their jurisdictions" and that "as of February 1, 1997, CDC and HRSA had determined that all 50 states were essentially in compliance with Public Law 104-146."

In essence, HHS and the agencies abdicated their responsibilities to enforce the law and allowed states to "rubber stamp" their own compliance.

In three follow-up letters between March and June 1998 to Secretary Shalala, I forwarded reported evidence in three separate states—New York, New Jersey and California—that spousal notification was being hindered by state laws and regulations.

On June 25, 1998, Congressman Tom Bliley, the chairman of the U.S. House Committee on Commerce wrote to Secretary Shalala stating that "the Committee is becoming increasingly concerned that States are falling considerably short of complying with" the spousal notification law.

On July 9, 1998, Secretary Shalala responded that "The Centers for Disease Control and Prevention (CDC) requires documentation that every state health official has certified that a good faith effort will be made to comply with the provisions of Public Law 104-146" and that "CDC relies on its State partners to ensure that materials submitted to CDC are accurate." As noted previously, CDC allowed states to self-certify their own compliance.

When pushed for additional evidence that spouses were in fact being notified of potential HIV-exposure, Dr. Claire V. Broome, Acting Director of the CDC responded in a letter dated September 17, 1998, that "State and local health departments do not have reporting systems in place that provide information on the number of spouses notified. Similarly, there is no national system for collecting comprehensive data on the number of spouses or other partners of HIV-infected individuals who are notified of their potential exposure to HIV."

On October 1, 1998, I sent a letter to then-Inspector General (IG) June Gibbs Brown to "request that the OIG conduct an investigation to determine if States are indeed conducting federal spousal notification as required under the Ryan White CARE Act Amendments of 1996."

In a letter dated May 28, 1999, the IG stated that "there is little hard data to document the results of States' notification efforts." The IG's final report was released in August 1999, noting that "While States have taken action on their certifications, their efforts do not completely ensure that vulnerable people are always made aware of their

possible exposure to HIV. Based on our findings, additional efforts need to be undertaken to ensure maximum notification while ensuring confidentiality and meeting patients' needs."

Last month, the Government Accountability Office (GAO) released a report analyzing the laws and policies of twelve states that found continuing shortcomings with state compliance of the federal spousal notification law.

According to GAO, "In New York, North Carolina, and Texas, statutory or regulatory provisions require that public health officials or health departments notify partners, including spouses, of their possible exposure to HIV." This is the intent of the federal law.

However, GAO found that "In California, Connecticut, Florida, Kentucky, Missouri, New York, Pennsylvania, and Washington, the provisions permit health care providers, public health officials, or health departments to notify partners, including spouses, of their possible exposure to HIV." This approach falls short of the legal requirement. The law states that HHS shall not make a grant to any State "unless such State takes administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to HIV." The verb in the law is "require," not "permit."

Furthermore, GAO found that "In the remaining 2 states—Massachusetts and Minnesota—public health officials or health departments may notify partners, including spouses, only with the consent of index patient." This is an overt violation of the federal law.

In summary, an analysis of twelve states' laws by GAO sound only three which appear to be complying with the federal condition for CARE Act funding yet all have been certified by CDC as being compliant.

CDC staff dispute the GAO's findings and claim that States are indeed complying with the federal law by making "good faith" efforts to notify spouses of HIV-infected individuals.

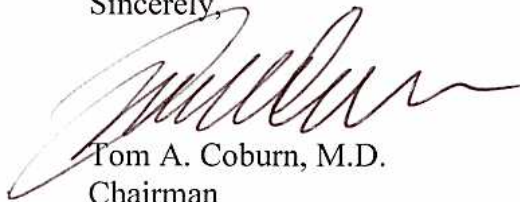
The dubious nature in which States' compliance were certified and the repeated findings by Congress, the HHS OIG, and GAO that States were not complying with the law raise serious and lingering questions.

I request that the OIG conduct a thorough review of any actions the CDC and States took since the OIG issued its findings and recommendations in 1999 and an analysis of all State spousal notification laws to ensure that every State receiving funding under the Ryan White CARE Act is, in fact, complying with this federal law requiring notification of spouses of HIV-infected individuals as a condition of funding.

Additionally, I would request a separate examination of laws, in addition to the spousal notification law, that HHS and its agencies have allowed grantees to interpret and self-certify their own compliance. This practice is very worrisome because it may result in confusion, uncertainty, federal laws not being properly enacted or enforced, or the denial of rights and responsibilities. Lawmakers need to be assured that there is sufficient accountability and transparency of the laws we pass.

If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tom Coburn', written over a light blue horizontal line.

Tom A. Coburn, M.D.

Chairman

Subcommittee on Federal Financial Management,
Government Information, & International Security

cc: Honorable Michael O. Leavitt
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Enclosures