KENNEDY CALLS FOR ACTION ON PATIENT SAFETY LEGISLATION

WASHINGTON, DC— Today, Senator Edward M. Kennedy, Chairman of the Health, Education, Labor and Pensions Committee, sent a letter to the Government Accountability Office asking that it investigate why this landmark patient safety legislation, passed by Congress nearly three years ago, has not been fully implemented.

Senator Kennedy said, "American patients deserve the safest and most effective health care possible. It is disgraceful that -- almost three years after Congress enacted bipartisan legislation to improve patient safety -- the Bush Administration has failed to implement it. Today, I am asking the Government Accountability Office to investigate the reasons why the Bush Administration has ignored this landmark patient safety legislation and to urge its full implementation. Continued delay is a serious disservice to millions of patients across the United States, and I implore the Administration to take action immediately."

The text of the letter is below.

January 17, 2008

VIA FACSIMILE & U.S. MAIL

The Honorable David Walker Comptroller General U.S. Government Accountability Office 441 G St., NW Washington, DC 20548

Dear Mr. Walker:

In 1998, the Institute of Medicine issued a landmark report on the quality of medical care, which served as a call to action to improve patient safety. One major response to that report was the bipartisan Patient Safety and Quality Improvement Act (Public Law 109-41), which was signed into law by President George W. Bush almost three years ago, on July 29, 2005. This important legislation was enacted in order to foster a culture of safety by creating Patient Safety Organizations (PSOs) that would collect, aggregate, and analyze confidential patient safety data and information reported by health care providers.

Since enactment of this law, the Department of Health and Human Services (HHS) has been drafting regulations to help implement this significant reform. However, almost three years later, these regulations are still languishing in the review and clearance process. The failure to issue regulations has had a chilling effect on efforts to improve a culture of safety in American medicine, putting the health and safety of patients at risk.

My office has been in constant communication with Secretary Leavitt's office about the progress of the regulations—without a formal response. In an effort to understand the cause of the delay and to prompt action on the regulations, I wrote to Secretary Leavitt on May 4, 2007 and again on October 18, 2007 requesting that his office provide me with a detailed timeline that would outline the next steps that the draft regulations would undergo before they were finalized, and would account for the delays in issuing the regulations. Last week, my office was informed by HHS that Secretary Leavitt will not be providing the requested timeline or an explanation for their egregious delay. For this reason, I request that the GAO initiate an investigation into the cause for the delay at HHS in finalizing these regulations so that this important law can finally be implemented.

My office is not alone in expressing its frustration about the delay in finalizing the regulations for the Patient Safety Act. Last September, the American College of Physicians, the American College of Surgeons, the American Dental Association, the American Hospital Association, the American Medical Association, and the Joint Commission also wrote a letter to Secretary Leavitt urging action. The coalition's letter stated that "Improving patient safety is too important to allow this regulation to be delayed further. We urge you to promptly publish a proposed rule." (emphasis in original).

I continue to be extremely disappointed and troubled by the fact that nearly three years after being signed into law, the regulations are nowhere closer to being finalized and released to the public. I am committed to making sure this important law is fully implemented. Thank you for your attention to this very important matter.

Sincerely,

Edward M. Kennedy Chairman Committee on Health, Education, Labor & Pensions United States Senate