



Healthcare Association
of New York State

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**HANYS BLASTS FEDERAL ACTION PROHIBITING USE OF MEDICAL CHECKLISTS
“Absurd” Decision Threatens Life-Saving Improvement Efforts Across the Nation**

ALBANY, N.Y. — Healthcare Association of New York State (HANY) President Daniel Sisto today blasted as “absurd policy and a dangerous threat to patient care” a recent ruling by the federal government to prohibit the use of checklists in certain medical settings. The ruling last month by the federal Office for Human Research Protections (OHRP) effectively shut down a life-saving program directed by Johns Hopkins University that dramatically reduced deadly hospital infections.

The Johns Hopkins University program, which focused on hospitals in Michigan, found that using a simple five-step checklist was tremendously effective in reducing infection rates. The researchers’ findings were compelling: over an 18-month period the rate of intravenous line infections fell by two-thirds and the intensive care infection rate fell from 4% to zero. In all, according to the researchers, the effort in Michigan saved more than 1,500 lives and nearly \$200 million.

The federal agency justified its decision to halt the program stating that the use of the checklists in a medical research setting violated medical research standards because patients did not provide written informed consent specific to the use of a checklist. Informed consent is a critical component of medical research and is necessary to protect research subjects. It is routinely used, for example, when research is conducted on new medicines. The OHRP decision essentially equates the use of a checklist with administering an experimental medication.

“This decision will have a chilling effect on health care research across the nation,” Mr. Sisto said. “Thousands of hospitals nationwide, including a great many here in New York, are engaged in developing and implementing new techniques to reduce infections and improve the quality of care. This absurd determination has the potential to halt many of these efforts and stands in blatant conflict with the national imperative to enhance patient safety.”

Mr. Sisto noted that nearly every hospital in New York State is taking part in a national effort by the Institute for Healthcare Improvement (IHI) to reduce hospital infections. The IHI “5 Million Lives” campaign implements various improvements, including checklists, to prevent common hospital infections. HANY works closely with hospitals across the state to promote and share new knowledge and best practices.

A December 30, 2007 Op-Ed piece in *The New York Times* by a leading national health expert stated that if the government’s ruling is applied more widely, “whole swaths of critical work to ensure safe and effective care would either halt or shrink: efforts by the Centers for Disease Control and Prevention to examine responses to outbreaks of infectious disease; the military’s program to track the care of wounded soldiers; the Five Million Lives campaign, by the nonprofit Institute for Healthcare Improvement, to reduce avoidable complications in 3,700 hospitals nationwide.”

Mr. Sisto added: “In one stroke of a bureaucrat’s pen, we may lose a tool that has proven to be tremendously effective in saving lives. This action is tantamount to the FAA prohibiting the use of checklists in the aviation industry. It’s counter to science and common sense, and incredibly dangerous.”

“This ruling must be reversed immediately.”

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