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November 21, 2006

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Leslie V. Norwalk, Esq.,  
Acting Administrator  
Barry Straube, MD,  
Acting Chief Medical Officer  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Ave., SW  
Washington, D.C. 20201

Dear Ms. Norwalk and Dr. Straube:

I am writing on behalf of the National Association of State Mental Health Program Directors (NASMHPD) to strongly object to any weakening of rules governing seclusion and restraint procedures in hospitals that participate in the Medicare and Medicaid programs. We are concerned that the safeguards established in the Final Interim Rule published in 1999 could be diminished in the final rule expected to be issued by CMS on December 8.

NASMHPD represents the \$27.3 billion public mental health service delivery system serving 6.1 million people annually in all 50 states, 4 territories, and the District of Columbia. It is the only national association to represent state mental health commissioners/directors and their agencies. In addition, NASMHPD has an affiliation with the approximately 220 state psychiatric hospitals.

Members of NASMHPD believe that seclusion and restraint, including “chemical restraints,” are safety interventions of last resort. It is a long-standing goal of NASMHPD to prevent, reduce, and ultimately eliminate the use of seclusion and restraint and to ensure that, when such interventions are necessary, they are administered in as safe and humane manner as possible by appropriately trained personnel. For many years, NASMHPD in partnership with the Substance Abuse and Mental Health Services Administration has trained hospital personnel in policies and practices to reduce seclusion and restraint. There is strong evidence that many treatment facilities have been successful in reducing these potentially harmful practices.

We believe that the so-called “one-hour rule” that requires a physician or other licensed independent professional to see and evaluate the need for restraint or seclusion within one hour after the initiation of an intervention is essential in preventing harm to and even the death of individuals with psychiatric illnesses.

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Because of the significant medical and behavioral risks inherent in the use of seclusion and restraints, it is critically important that only licensed practitioners who are specially trained and qualified to assess and monitor the individual's safety should order these interventions.

While past congressional and regulatory hearings identified controversies and differences of opinion, the requirements have been largely accepted and led to improvements in standards of care. The last opportunity to address these issues was a CMS public hearing held in 2002 after which no action was taken to change the Interim Final Rule (42 CFR 482.13). There is substantial evidence that the existing rule has heightened awareness of the dangers of seclusion and restraint and has led to improved practices in hospitals subject to its requirements. The track record in other settings such as jails illustrates the need for strong protections as required in the patients' rights regulations.

NASMHPD could not support a waiver or carve-out for underserved areas. If a physician or other licensed independent provider is not available to assess whether the patient has been injured and evaluate whether another remedy is available, it is our view that seclusion and restraint is potentially too dangerous to be handled by individuals who do not meet the qualifications outlined in the existing regulation. Those states with underserved areas can make regulatory or statutory changes that allow physician assistants or advanced practice nurses to be included as Independent Licensed Practitioners (LIP), thereby meeting the current CMS Conditions of Participation.

The September 2006 OIG report "Hospital Reporting of Deaths Related to Seclusion and Restraint" makes strong recommendations concerning system failures in reporting and taking corrective action to address potentially harmful conditions. NASMHPD encourages CMS to reassess any changes being proposed in the Interim Final Rule in light of this new documentation. If any changes are made, they should strengthen the reporting and corrective action provisions.

Thank you for considering our views on these issues.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert W. Glover", written in a cursive style.

Robert W. Glover, Ph.D.  
Executive Director

Cc: Eric B. Broderick, D.D.S., M.P.H., A. Kathryn Power, M.Ed., SAMHSA