



Arizona Hospital and Healthcare Association

June 6, 2008

Mr. Rufus Arther
Hospital Community and Community Care Operations
CMS, Region IX
90 Seventh Street, Suite 5-300
San Francisco, CA 94103-6706

Dear Mr. Arther:

Thank you for taking the time to speak with representatives of the Arizona hospital community and myself last week. We appreciate the time you and your staff took to listen to our concerns about the Hospital Restraint/Seclusion Death Report Worksheet. As discussed last week, it is the intention of Arizona's hospitals to comply with all Medicare regulations relating to Conditions of Participation. We view the Centers of Medicare and Medicaid Services (CMS) and Region IX as a partner in our efforts to provide the best quality care to all the patients we serve.

Having said this, the Revised Hospital Restraint/Seclusion Death Report Worksheet is extremely problematic for hospitals. First, the Worksheet is inconsistent with federal regulations that only require hospitals to report deaths to CMS. Reports must be made of all deaths that occur while a patient is in restraint or seclusion; each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; and each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or seclusion contributed to a patient's death. The regulations require only the reporting of the death and documentation of the date and time the death was reported to CMS. Reporting detailed information in the Worksheet is not required by the law.

Moreover, the vast majority of deaths involve critically ill ICU patients with poor prognoses, significant trauma injuries or life threatening illness who are ventilator-dependent and/or expire following failed resuscitation efforts. These patients may have been ventilator dependent for extended days, weeks or even months. It is also common ICU practice for patients on a ventilator to be in a drug induced coma using intravenous moderate sedation. In these cases, either physical and/or chemical restraints are required to assure that patients are expending as little movement/energy as possible and do not pull out lines or potentially harm themselves during periods of agitation or ICU delirium. Levels of sedation are continuously adjusted as patients are attempted to be weaned from the ventilator and or show signs of improvement.

Frequently, patients may be extubated for a trial period and reintubated if necessary. Every effort is made to attempt to have the patient safe and unrestrained when able.

At large tertiary hospitals, it is not unusual to have twenty to thirty ICU deaths a month. These deaths are routinely investigated through a mortality review. As far as the Arizona Hospital and Healthcare Association is aware, restraints have not been found to be the cause of, or to have contributed in any way to, patient deaths in our ICUs.

Completing the detailed Worksheet for every patient death who meets the restraint guidelines for CMS reporting has been found to be an excessive burden for our hospitals and an immense time demand on Quality Management resources. It requires intensive review of restraint and medication details. Information regarding restraints is maintained in various locations both in paper records and electronic documents, and reviewing orders, restraint records, vital signs, patient assessment, progress records necessary to respond to questions on the Worksheet is time-intensive.

Hospitals are at a loss to understand how this information will assist CMS in determining the appropriateness of restraint use in intensive care environments. It does not warrant the tremendous amount of time required to complete this level of investigation for a death known not to be caused by restraint. Hospitals are already experiencing extreme nursing shortages and this activity takes scarce resources away from other important quality monitoring tasks.

In closing, we support CMS' effort to eliminate deaths caused by restraints and believe the Worksheet is appropriate for deaths where a restraint may have directly or indirectly caused or contributed to a patient's death. Furthermore, we understand CMS' desire to review data to assess the potential impact of the use of restraints. However, we find the current Worksheet problematic in this regard. We welcome the opportunity to work with CMS Region IX and/or the Central Office in developing alternative processes that minimize the administrative burden to hospitals while enabling CMS to assess and analyze data necessary to prevent unintended deaths due to the use of restraints or seclusion.

Please feel free to contact me at 602-445-4300 or djohnston@azhha.org if you have any questions or would like to talk further.

Sincerely,

Debbie Johnston
Director, Regulatory Affairs and Policy