STATE OF WISCONSIN
Department of Health and Family Services
Division of Children and Family Services
Division of Disability and Elder Services
Division of Health Care Financing

DCFS Memo Series 2005 - 05
DDES Memo Series 2005 - 08
DHCF Memo Series 2005 - 01
June 20, 2005

RE: USE OF VAIL BEDS FOR CHILDREN AND ADULTS WITH DEVELOPMENTAL DISABILITIES

To: Area Administrators/Human Services Area Coordinators
Bureau Directors
County Departments of Community Programs Directors
County Departments of Developmental Disabilities Services Directors
County Departments of Human Services Directors
County Departments of Social Services Directors
Section Chiefs
Tribal Chairpersons/Human Services Facilitators

From: Burnie Bridge, Administrator
Division of Children and Family Services

Mark Moody, Administrator
Division of Health Care Financing

Sinikka Santala, Administrator
Division of Disability and Elder Services

Attached to his memo are materials related to a recent announcement of the U.S. Food and Drug Administration (FDA) related to concerns regarding the use of beds manufactured by Vail Products, Inc., located in Toledo, Ohio. The announcement relates to the Vail 500, 1000, and 2000 Enclosed Bed Systems. The FDA has determined that the use of these beds poses a public health risk because patients can become entrapped and suffocate, resulting in severe neurological damage or death. The FDA is aware of approximately 30 entrapments resulting from use of these beds, resulting in at least seven (7) deaths. The FDA has advised consumers to stop using these bed systems. If continued use is the only option, Vail Products recommends users follow certain safety precautions.

The FDA has ordered the U.S. Marshall's Service to seize unsold stocks of these beds. DDES and DHCF have already taken action to stop MA card and waiver payments for these devices. However, we are aware that some individuals who are served by counties or are under DHFS guardianship continue to be restrained in Vail beds in both licensed facilities and in private homes.

All county and Department approvals of these beds pursuant to s. HFS 94.10, Adm. Code, must be re-reviewed in light of the FDA findings and action. As to continued use, we are alerting interested parties to this federal action and will monitor the situation. All proper care and attention should be paid to the concerns raised by the FDA. All county and Department approvals must include the required safety measures.

It is critical, and it is our expectation, that agency directors disseminate this information to supervisors and direct service caseworkers.

We will provide additional information as any further actions are taken.

REGIONAL OFFICE CONTACT: Area Administrator

MEMO WEB SITE: https://dcf.wisconsin.gov/cwportal/policy

Attachments FDA Preliminary Public Health Notification:
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062025.htm