MINUTES

MONTANA HOUSE OF REPRESENTATIVES 53rd LEGISLATURE - REGULAR SESSION

COMMITTEE ON HUMAN SERVICES & AGING

Call to Order: By CHAIRMAN BILL BOHARSKI, on March 10, 1993, at 3:00 p.m.

ROLL CALL

Members Present:

Rep. Bill Boharski, Chairman (R)

Rep. Bruce Simon, Vice Chairman (R)

Rep. Stella Jean Hansen, Vice Chair (D)

Rep. Beverly Barnhart (D)

Rep. Ellen Bergman (R)

Rep. John Bohlinger (R)

Rep. Tim Dowell (D)

Rep. Duane Grimes (R)

Rep. Brad Molnar (R)

Rep. Tom Nelson (R)

Rep. Sheila Rice (D)

Rep. Angela Russell (D)

Rep. Tim Sayles (R)

Rep. Liz Smith (R)

Rep. Carolyn Squires (D)

Rep. Bill Strizich (D)

Members Excused: None

Members Absent: None

Staff Present: David Niss, Legislative Council

Alyce Rice, Committee Secretary

Please Note: These are summary minutes. Testimony and

discussion are paraphrased and condensed.

Committee Business Summary:

Hearing: SB 166, SB 118

Executive Action: None

HEARING ON SB 166

Opening Statement by Sponsor:

SEN. TOM TOWE, Senate District 46, Billings, said that two years ago SB 166 had been a very controversial bill. Legislation was passed with a termination date. The occupational therapists and physical therapists were told to get together, solve their turf

battle, work out their disagreements, and present the bill at the next legislative session. The occupational therapists and physical therapists have now come to an agreement on the bill.

Proponents' Testimony:

Connie Grenz, Occupational Therapist, Montana Occupational Therapy Association, Helena. Written testimony. EXHIBIT 1.

Carrie Gajdosik, Physical Therapist, Vice President and Legislative Chair, Montana Physical Therapy Association, said the physical and occupational therapists have worked very hard to create a document that is agreeable to both professions. Ms. Gajdosik urged the committee to support SB 166.

Gail Wheatley, Physical Therapist, President, Montana Chapter American Physical Therapy Association. Written testimony. EXHIBIT 2.

Opponents' Testimony:

None

Informational Testimony:

None

Questions From Committee Members and Responses:

REP. SIMON said the occupational therapists and physical therapists need to be complimented for the work that has been done to come to an agreement on the bill.

Closing by Sponsor:

SEN. TOWE closed.

HEARING ON SB 118

Opening Statement by Sponsor:

SEN. TOWE, Senate District 46, Billings, said SB 118 fills a void that presently exists the law. Personal care facilities cannot be licensed because licenses for this type of facility are non-existent. This legislation will authorize the Department of Health and Environmental Sciences to issue licenses to adult foster care homes. The department also suggested licensing larger homes with more than five residents. At the present time, residents who need temporary skilled nursing care must go to a facility that has skilled nursing care. This legislation allows a nurse to provide skilled nursing care at homes with more than five residents. The concept of caring for people in a home setting is very important to the elderly and will cost less money

than a nursing home.

Proponents' Testimony:

Eunice Ash, Elderly Care Home, Billings, said care for the elderly is very important. Ms. Ash's personal care home was started in 1987 and business continues to multiply. The home has 87 beds, and for the first time since opening, two of the beds are empty. The residents of the home don't receive Medicare or Medicaid, so they must pay for their care with their own money. As a result, the home has saved the state thousands of dollars. There are five to seven care-givers in the personal care facility. There is always 24 hour care. It is obvious that the personal care given to the residents has added to their physical and psychological feelings of well being. Personal care homes need to be licensed. Ms. Ash urged the committee support HB 218.

Mike Craig, Chief, Licensure Bureau, Department of Health and Environmental Sciences, said we are witnessing a phenomena in health care for personal care homes. Currently, if a people are nonambulatory, incontinent, or chemically or medically restrained, they cannot reside in a personal care home. Craig said he has been required to move many individuals out of personal care homes. People have accused him of signing death warrants. There have been deaths attributed to the department. The department can continue to ignore unlicensed facilities that are proliferating, or the legislature can pass SB 118. The legislation doesn't answer all the issues, but it is a start. Ms. Ash has four homes in Billings; each are in violation of state laws. The department has made a conscious decision not to close her down until it sees what happens with this legislation. SB 118 gives the department the ability to go into the personal care homes to help legitimize them, and assure the State of Montana that services are being provided in a safe environment.

Rose Hughes, Executive Director, Montana Health Care Association, Helena, presented amendments to SB 118. Written testimony. EXHIBIT 3.

Betty Asplin, Elderly Care Home, Laurel, said she has owned and operated unlicensed personal care homes for ten years. The committee should visit the homes before making a decision on the passage of the bill. It's a trauma for the elderly to move from a home they have lived in all their lives, into an elderly care facility. The elderly should have the right to choose where they will live. Ms. Asplin presented a letter from the son of a resident that depicts what happens when the state inspects the elderly homes. EXHIBIT 4.

Norma Larson, Elderly Care Home, Laurel, said she cares for three residents in a small home for the elderly. Ms. Larson said she asked the state for a copy of the regulations for elderly homes when she started business a year ago and still hasn't received them. The elderly health care business is one of the fastest

growing industries in the United States. The elderly population is increasing by leaps and bounds. At least fifty percent of the people who reside in institutionalized nursing homes, do not need to be there. The elderly need to have the chance to choose between institutionalized nursing homes and small personal care homes.

Linda Aves, Laurel. Written testimony. EXHIBIT 5.

Doug Blakley, State Ombudsman, Governor's Office On Aging. Written testimony. EXHIBIT 6.

Opponents' Testimony:

None

Informational Testimony:

None

Questions From Committee Members and Responses:

REP. SQUIRES asked Mike Craig how often health care facilities are inspected. Mr. Craig said the department is required to inspect these facilities within one to three years.

REP. BOHLINGER asked SEN. TOWE if he had reviewed the amendments offered by the Montana Health Care Association (MHCA). SEN. TOWE said he had and is vigorously opposed to amendment number five, the certificate of need. Bureaucracy can kill the best of programs. MHCA proposes to delete lines 11 through 23, page 2, which says in effect, the legislature recognizes that the quality of care given in these homes may be preferable under many circumstances, because of staff ratio, and the home atmosphere avoids an institutionalized atmosphere and associated problems. The legislature recognizes that these homes can be less expensive than nursing homes. The language is appropriate and accurate and should remain in the bill. The association would replace it with "Therefore, the legislature wishes to recognize that the use of private homes or residences in which a homelike atmosphere is preserved is an appropriate setting for individuals whose care needs can be met in such facilities and who choose this type of setting." He urged the committee to reject amendments five and two. The rest of the amendments are acceptable.

REP. BOHLINGER asked Mike Craig if the department believed a certificate of need is necessary for personal home care facilities. Mr. Craig said the department has come to an internal conclusion that a certificate of need is not necessary in personal care facilities because the market has already been established.

REP. SMITH asked Ms. Ash what she charges residents to stay in her homes. Ms. Ash said she charges \$1,200 a month. Nursing

homes charge \$2,200.

CHAIRMAN BOHARSKI said he was aware that Social and Rehabilitation Services (SRS) was turned down on the waiver for personal care facilities. CHAIRMAN BOHARSKI asked Nancy Ellery, SRS, if there will be an impact on Medicaid due to new definitions in the bill. Ms. Ellery said the waiver request was turned down because the department couldn't prove the cost effectiveness of personal care facilities. Category B in the bill will allow the department to resubmit the application. She clarified that residents of personal care facilities do continue to receive Medicaid but it doesn't pay for the cost of the facility. If HB 118 passes, the department intends to request that facility costs be covered under Medicaid.

Closing by Sponsor:

SEN. TOWE said SB 118 is very important because it allows people who don't need to go to skilled nursing homes live in a personal care setting at less cost.

ADJOURNMENT

Adjournment: The hearing adjourned at 5:05 p.m.

WILLIAM BOHARSKI, Chair

UME Beharsk

ALYCE RICE, Secretary

WB/ar

HOUSE OF REPRESENTATIVES

HUMAN SERVICES AND AGING COMMITTEE

ROLL CALL

DATE 3-10-93

NAME	PRESENT	ABSENT	EXCUSED
REP. BILL BOHARSKI, CHAIRMAN	~		
REP. BRUCE SIMON, VICE CHAIRMAN	V		
REP. STELLA JEAN HANSEN, V. CHAIR			
REP. BEVERLY BARNHART	V		
REP. ELLEN BERGMAN	/		
REP. JOHN BOHLINGER			
REP. TIM DOWELL	/		
REP. DUANE GRIMES	V		
REP. BRAD MOLNAR	V		
- REP. TOM NELSON	~		
REP. SHEILA RICE		``.	
REP. ANGELA RUSSELL	V		
REP. TIM SAYLES	~		
REP. LIZ SMITH	V		
REP. CAROLYN SQUIRES	/		
REP. BILL STRIZICH			

My name is Connie Grenz. I am an occupational therapist. I work here in Helena. I specialize in infants, and feeding and swallowing abnormalities. I presently serve as Member-at-Large on the executive board of the Montana Occupational Therapy Association.

In 1985 the occupational therapists requested and were granted professional licensure to protect the consumer from unqualified persons. That was the beginning of my relationships with legislators, lawyers, and the MT Physical Therapy Association. The Montana chapter of the APTA challenged the legality of the licensure law to allow SRS/Medicaid to reimburse OTs for "modalities." SRS/Medicaid has been reimbursing OTs for the use of modalities for over 25 years. In 1990 an attorney general's review was requested and on Jan. 11, 1991 Mark Racicott finalized his interpretation specifically stating "Occupational Therapists are not permitted by Montana law to employ heat, cold, air, light, water, electricity, or sound as therapeutic agents."

Fortunately the Board of Occupational Therapists and the Department of Commerce Lawyers had already drafted language for legislation to clarify the use of physical agent modalities by occupational therapists. Representatives of the Montana Chapter of the Physical Therapy Association strongly objected to the use of such broad language. Admitting that this was a "turf" battle they made efforts to significantly restrict the practice of occupational therapy. Occupational therapists have worked within that restricted scope of practice for two (2) years. The Occupational Therapy Licensure Board has worked diligently to ensure educated therapists not overstep these limitations.

For the past two years a select group of occupational and physical therapists have worked to prepare language to present to you today which will adequately define the use of physical agent modalities by occupational therapists.

I believe that the majority of occupational and physical therapists in this state work as a team sharing knowledge and developing treatment plans to best provide for their patients. I know that there are many areas of overlap innately a part of our treatment approaches, and that usually we recognize our individual abilities and limitations with high professional ethics. There are 160 licensed occupational therapists and 350 licensed physical therapists and still great areas of Montana where persons are unable to receive either service within 100 or 200 miles.

EXHIBIT 1 DATE 3/10/93 SB 166

DATE 3-10-93



MONTANA CHAPTERSB_/66

OF THE

AMERICAN PHYSICAL THERAPY ASSOCIATION

March 10, 1993

TO: Members of the Health and Human Services Committee

FROM: Gail Wheatley, P.T.

President, Montana Chapter APTA

re: SB 166 - Occupational Therapy Practice Act

On behalf of the members of this physical therapy organization in Montana, I would like to fully support and endorse the amended bill as you have it in front of you. Those of you who were here two years ago realize that this has been a Herculean effort since then and we have produced a document which is agreeable to both organizations.

Additional amendments were made on our behalf in the Senate and I urge you to make no changes to the current bill. After the Senate Public Health Committee heard this bill, the Nursing Home Association attempted to present amendments which were rejected by Senator Towe, the bill's sponsor, and would have been adamantly opposed by the OT and PT Associations who have worked so diligently to reach a somewhat precarious agreement.

I apologize for being unable to attend in person today, but we are testifying to maintain our ability as physical therapists to treat injured workers. I'm certain you'll hear much more from us on that issue and I ask for your thoughtful consideration of our concerns in advance.

Please recommend safe passage of this bill on its way through the House. It is now a good document and the Physical Therapy Association speaks as a proponent.



EXHIBIT 3

DATE 3-10-93

SB 5 8 118

36 S. Last Chance Gulch, Suite A · Helena, Montana 59601 Telephone (406) 443-2876 · FAX (406) 443-4614

SENATE BILL 118

PERSONAL CARE FACILITIES

SENATE BILL 118 creates a "Category B" personal care facility which eliminates all of the limitations contained in current law with respect to who can properly be served in this level of care. It, in effect, creates a new category of skilled nursing facility that may not have to meet the requirements for providing skilled nursing facility services.

The "personal care facility" level of care was designed to be a level of care *below* that provided in skilled nursing facilities. The limitations contained in the current personal care law were designed to define that level of care and provide for the safety of individuals cared for in these facilities.

To evaluate this proposed legislation, we should look closely at what types of individuals it proposes be served in this lower level of care. In fact, it allows for the provision of all types of skilled nursing care. Only those requiring acute hospital care are precluded from residing in Category B personal care facilities under this proposal.

EXCLUSIONS/DEFINITIONS IN CURRENT LAW (WHICH ARE ELIMINATED UNDER SB 118:

1. May not be in need of "skilled nursing care".

Section 50-5-101, subsection 27(b) defines "skilled nursing care" as follows:

Senate Bill 118 Page 2 March 10, 1993

(b) "Skilled nursing care" means the provision of nursing care services, health related services, and social services under the supervision of a licensed registered nurse on a 24-hour basis.

Skilled nursing care is the most intensive level of care provided in nursing homes. It is sometimes referred to as "sub-acute" care, since it is the level of care immediately below hospital care (acute care).

Personal care facilities, under their current licensure, may not provide nursing services. However, residents of personal care facilities "...may arrange to have needed care provided by a third party, including a home health agency or an owner, operator, or employee of the facility who is licensed to provide that care, so long as that individual does so under a service agreement separate from that between the resident and the personal care facility." $(ARM\ 16.32.386(a)(c).)$

2. May not be in need of "medical, chemical, or physical restraints".

Health Department rules define "medical restraints" in ARM 16.32.387(3) as follows:

(3) For purposes of this rule, a person is in need of "medical restraints" if he must take medication in order to prevent him from being a danger to himself or others.

Federal *Interpretive Guidelines* define "physical restraints" and "chemical restraints" as follows:

"Chemical restraint" means a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.

"Physical restraints" are any manual method of physical or

DATE 3/10/93

SO 118

Senate Bill 118 Page 3 March 10, 1993

> mechanical device, material or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

> "Physical restraints" include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, and wheelchair safety bars.

Federal *Interpretive Guidelines* also list the following "potential negative outcomes" of restraint use: incontinence, decreased range of motion, and decreased ability to ambulate, symptoms of withdrawal or depression, or reduced social contact.

Restraint use has come under increased scrutiny in recent years because of the dangers and negative outcomes associated with restraints. The trend is to reduce the use of restraints and closely monitor the restraints that are used. This requires well trained professional staff.

3. May not be "nonambulatory or bedridden".

Department of Health rules, at ARM 16.31.387(2) defines ambulatory as follows:

(2) For purposes of this rule, a person is ambulatory if he is capable of self-mobility, either with or without mechanical assistance.

These rules also provide that the facility must be able to accommodate the type of mechanical assistance a resident needs if they are to admit the resident. Residents requiring mechanical assistance must be housed on the ground floor of the facility.

Thus, under current rules, personal care facilities may admit residents in wheelchairs as well as those who use walkers, canes, crutches, or other assistive devices to ambulate. However, because these facilities are not required to have more than one staff member present at all times, residents must be able to evacuate themselves in case of fire or other emergency. Current rules are written to provide this element of safety for the residents of these facilities.

4. May not be "incontinent to the extent that bowel or bladder control is absent".

This provision does not exclude individuals who are sometimes incontinent, or have accidents. Bowel or bladder control must be <u>absent</u>.

It should be noted that the care needs of individuals that meet this strict standard often include catheterization. This requires strict infection control procedures to prevent infections which are often associated with catheterization.

5. May not be "unable to self-administer medications".

Under Montana law, administering medications is considered the practice of nursing. Personal care facilities are not allowed to administer medications in large part because there is no requirement that these facilities employ licensed nurses.

It should be noted that under current law, personal care facility staff is allowed to remind the resident to take his/her medication at the proper time and is required to observe and record this activity on the resident's record. The facility is also required to provide locked storage for all medications.



EXHIBIT _3 DATE 3/10/93

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SENATE BILL 118

PROPOSED AMENDMENTS

1. Amend page 1, lines 22 through 25, and page 2, lines 1 through 3, as follows:

Delete: Lines 22-25 on page 1, and lines 1-3 on page 2.

"The legislature intends that the standards to be adopted under Insert: 50-5-226 and 50-5-227, with respect to Category B personal care facilities, reflect the health care, safety, and professional standards normally associated with providing for the needs of individuals requiring skilled nursing services, who are in need of medical, physical, or chemical restraints, who are nonambulatory or bedridden, who are incontinent to the extent that bowel or bladder control is absent, or are unable to selfadminister medications. These standards shall include, at a minimum, standards that will insure the safe evacuation of individuals from these facilities in case of fire or other emergency; staff qualifications and training; standards related to resident assessment and care planning; standards that will insure the safe and appropriate use of restraints and a restraint reduction program; standards for the prevention and proper treatment of pressure sores associated with nonambulatory and bedridden individuals; standards for the care of individuals with bowel or bladder control absent, including bowel and bladder training programs, catheter care and infection control; and standards related to administration and storage of drugs. It is our intent that Category B personal care facilities not be over-regulated but be properly regulated to provide for the health, welfare and safety of the individuals 'they will serve."

Proposed Amendments Page 2 March 10, 1993

Rationale: This amendment clarifies that while it is not the intent of the legislature to over-regulate Category B personal care, it is the intent of the legislature to assure for the residents of these facilities a safe environment and a high quality of health care. It also gives guidance as to the types of regulations envisioned and assures that the care to be provided meets current professional standards for providing the types of care envisioned by this legislation.

2. Amend page 2, lines 10-23, as follows:

Following: "preserved." on line 10

Delete: The remainder of line 10 and all of lines 11-23.

Insert: "Therefore, the legislature wishes to recognize that the use of private homes or residences in which a homelike atmosphere is preserved is an appropriate setting for individuals whose care needs can be met in such facilities and who choose this type of setting."

Rationale: The new language states the legislative intent to allow these types of facilities for individuals who choose them and can receive proper care in them-without making unproven or inaccurate statements about the patient to staff ratios or the cost of these and other facilities. In fact, nursing homes may employ more staff per patient than personal care facilities. Most nursing homes employ 1 full time equivalent for each This reflects the need to have awake staff 24 hours a day and resident. also reflects the range of services provided by nursing homes--social dietary, housekeeping, maintenance, services. activities, administrative, as well as licensed and certified nursing staff. Also, it is difficult to compare the cost of the services, since there are no currently existing personal care facilities which are licensed and meet standards for providing skilled nursing services. "Skilled nursing services," if provided in keeping with today's professional standards is far more expensive than "personal care."

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3. Amend page 15, line 20:

Following: "operating a" "Category A" Insert:

Rationale: The standards for operating a Category A facility should be different from the standards for operating a Category B facility.

4. Amend page 15, line 23:

Following: "facility"

Delete:

"; and (e) standards for operating a Category B personal care Add: facility including the standards referred to in subparagraph (d) as well as standards for resident assessment and care planning, qualifications and training of staff, restraint use and reduction, pressure sore prevention and care, incontinence care, and administration and storage of drugs."

Rationale: This outlines the standards to be adopted by rule with respect to Category B facilities which are allowed to provide skilled nursing care and other services not normally within the scope of "personal care."

5. Amend page 20, lines 7:

Delete:

"or"

Following: "facility"

Add:

"or personal care facility"

The current language in this bill removes personal care facilities from the certificate of need process. Personal care facilities are health care services that should be part of the certificate of need process. This is especially true since this legislation adds "category B" personal care, which is in fact skilled nursing care. Current wisdom is to consider

Proposed Amendments Page 4 March 10, 1993

expansion of certificate of need programs as part of health care reform. CON is looked upon as a health care cost containment program. In addition, the CON issue is one that is expected to be addressed as part of the study to be done under Sen. Franklin's health care reform legislation. Before adding or deleting services from that process, we should wait for the results of the study.



DATE 3/10/93 SB 118

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50-5-101, subsection (27) (b) defines "skilled nursing care":

- (b) "Skilled nursing care" means the provision of nursing care services, health-related services, and social services under the supervision of a licensed registered nurse on a 24-hour basis.
- (c) "Intermediate nursing care" means the provision of nursing care services, health-related services, and social services under the supervision of a licensed nurse to patients not requiring 24-hour nursing care.
- (d) "Intermediate developmental disability care" means the provision of nursing care services, health-related services, and social services for the developmentally disabled, as defined in 53-20-102(4) or persons with related problems.
- (e) "Personal care" means the provision of services and care which do not require nursing skills to residents needing some assistance in performing the activities of daily living.

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Quality Care ADVOCATE

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1224 M Street, N.W., Suite 301 Washington, DC 20005 202/393-2018

Ombudsman Experience

Weak Regulation of Board and Care Is Undermining Nursing Home Reform'

"... Some people seeking nursing home care are unable to receive it for numerous reasons, including: financial inability to pay (e.g., people above the

Medicaid income cap but who cannot afford private-pay rates); long waiting lists for nursing homes and the family is unable to provide athome care; or people with certain conditions which require nursing home care (such as having a history of combative behavior or people with dementia who wander) ... When nursing home beds are not available to these people, they often feel desperate and they look toward other residential options, including homes providing personal care services ...

"Those who advocate on behalf of residents, including those in the nursing home industry who have spent years working towards reform in nursing homes, are seeing much of their efforts undermined as a result of inadequate regulation of personal care homes. For example, in the nursing home context meaningful standards were



Roy Herzbach, Atlanta Ombudsman

set that require nurses aides to have the skills needed to meet resident needs and to improve the quality of care and life for residents. Another example is that the circumstances under which physical and chemical restraints could be used in nursing homes were also significantly limited. Now we see staff at personal care homes with relatively few skills, and we see residents who need nursing home care being restrained in ways that would not be permitted in a nursing home. These are serious steps backward in providing residents with a higher quality of care and life."—From an editorial in *The Ombudsman Newsletter* of the Metropolitan Atlanta Ombudsman Program, 151 Spring St., N.W., Atlanta, GA 30335. (404)586-9800.

Alzheimer's Assoc. Studies Claims About Special Care Unit Services

The Alzheimer's Association is surveying state ombudsmen, nursing home surveyors and families about their experiences with special care units that nursing homes claim provide exceptional services for residents with Alzheimer's disease.

"While we have anecdotes from families about their dissatisfaction with Alzheimer special care units in nursing facilities," said Pam Edens of the association's public policy committee, "we are not certain of the extent of the problems and whether they differ significantly from those about nursing facility care in general."

Preliminary findings, including the ombudsman survey, are expected to be completed by December. For more information, contact Deborah Beitler at the Alzheimer's Association, 919 N. Michigan Ave., Suite 1000, Chicago, IL 60611. (312)335-5746.

Guidelines for Care

In July the Alzheimer's Association published Guidelines for Dignity: Goals of Specialized Alzheimer/Dementia Care in Residential Settings. The 40-page book is \$5 and can be purchased through local Alzheimer's Association chapters. If there is no chapter in your community, you can order from the association at 919 North Michigan Ave., Suite 1000, Chicago, IL 60611-1676.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food and Drug Administration Rockville MD 20857

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FDA SAFETY ALERT:

Potential Hazards With Restraint Devices

July 15, 1992

To Hospital Administrators, Directors of Nursing, and Directors of Emergency Room Services:

The Food and Drug Administration (FDA) is warning healthcare providers of the potential hazards associated with the use of physical patient restraint devices, such as safety vests, lap and wheelchair belts, and body holders.

We are issuing this warning because reports of deaths and injuries related to the use of these devices have increased over the last year. It is probable that still many restraint related deaths and injuries go unreported. The reports received by FDA encompass all restraint types, patient populations, and types of facilities. The FDA estimates there may be at least 100 deaths or injuries annually associated with the use of restraints, many deaths occurring when the patient is trying to get out of the restraint or while attempting purposeful behavior such as going to the bathroom.

Many of the incidents (fractures, burns, strangulations) seem to be the result of incorrect use of these devices, including inappropriate patient selection, incorrect restraint selection, errors in correctly applying the devices, and inadequate monitoring of patients when restrained. We have consulted with facilities, users, clinicians, and manufacturers to determine what factors may be contributing to hazards with physical restraints. We have also reviewed related regulations such as OBRA'87 and the HCFA Guidelines. The following FDA recommendations are designed to emphasize and complement the HCFA Guidelines and to help decrease the incidence of deaths and injuries with these devices.

- Assess the cause for which the restraint is being considered, develop
 alternatives to restraint use, and implement these alternatives before applying
 restraints.
- Allow the use of restraints ONLY under the supervision of a licensed healthcare provider and for a strictly defined period of time.
- Define and communicate a clear institutional policy on the use of restraints (alternatives to restraint use, appropriate conditions for restraint use, length of wear time, etc.). This written policy should also be available for any patient/resident or any family member.
- Obtain informed consent from patient/resident or guardian prior to use. Patients have the right to be free from restraints. However, if it is determined that a restraint is necessary, explain the reason for the device to the patient/resident and guardian to prevent misinterpretation and to ensure cooperation.
- Display instructions for use in a highly visible location and interpret in foreign languages as necessary.
- Provide in-service training for staff as regularly as possible which should include a return demonstration of proper application of restraints.

- Prior to use, read and follow the manufacturers directions for use:
 - select the type of restraint that is appropriate to the patient's condition.
 - use the correct size.
 - note the "front" and "back" of the restraint and apply correctly.
 - secure restraints designed for use in bed to the bed springs or frame, NEVER to the mattress or the bed rails. If the bed is adjustable, secure restraints to parts of the bed that would move with the patient (not constrict the patient).
 - tie knots with appropriate hitches so that they may be released quickly.
- Emphasize good nursing, rehabilitative, and patient care practices:
 - observe patients in restraints frequently.
 - remove the restraints at least every two hours, and more often if necessary, and allow for activities of daily living.
 - carefully apply the device and adjust properly so that it maintains body alignment and ensures patient comfort.
 - continue assessment even after a restraint is used and discontinue use as soon as feasible. Restraint use should be considered a temporary solution to a situation.
- Clearly document in the patient's record the medical reason for use of the restraint, the type selected, and the length of time for treatment.
- Follow local and State laws regarding the use of protective restraint devices.

Currently, manufacturers of physical patient restraints are being notified of regulatory changes with respect to restraint manufacturing and labeling. Improved device labeling will be required, including the label "prescription only", and should appear on newly marketed devices late 1992. Accompanying graphics, and visual aids will also be encouraged. These improvements should provide facilities with additional instructions and bridge some language barriers.

The Safe Medical Devices Act of 1990, effective November 28, 1991, requires that all hospitals, nursing homes, and acute care facilities report deaths and injuries related to the use of any medical device to the FDA. Discuss with your staff and management your procedures for reporting any death or injury related to patient restraints.

On the attached page are important messages for patients/residents and family members, which you may copy and distribute (using your own letterhead or address stamp, if you wish).

If you have additional questions about the physical patient restraint issue, contact Carol Herman, Office of Training and Assistance (HFZ-250), Center for Devices and Radiological Health, Food and Drug Administration, Rockville, Maryland 20857.

Sincerely your

James S. Benson

Director

Center for Devices and Radiological Health

EXHIBIT.	3		
DATE 3	10	93	
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IMPORTANT TIPS FOR THE USE OF PATIENT RESTRAINTS

Physical patient restraints can be useful in protecting the patients/residents from falls and from wandering or straying. However, restraints are not the only solution to these difficulties, and in some cases may be more dangerous. The following are important tips that can make you more aware of when and how restraints should be used. It will also help you identify problems which could have serious consequences if not responded to.

PATIENT RIGHTS

Patients/residents have the right to be free from restraints. Restraint use should not be a first choice solution. Before allowing yourself or a loved one to be restrained, be sure to understand the reason for the restraint use, request a limited time frame for restraint use, and be sure that all other solutions to the problem have been exhausted.

FACILITY POLICY

All health care facilities must have a written policy on use of patient restraints. Ask to see this document and be sure that you understand and are comfortable with the policy set forth by your facility.

PRESCRIPTION DEVICE

Restraints are prescription devices and may only be used if a physician, or other healthcare professional licensed to prescribe in your State, has specifically ordered a restraint for an individual. The need for the restraint must be well documented in the patient chart and assessment of the need should continue even after the device has been ordered.

PATIENT CRITERIA

Not all patients/residents are appropriate for restraint use. For example, an agitated or seriously confused patient may not be a good candidate for restraints. The use of restraints may only add to this agitation or confusion and place the patient in jeopardy as he/she may try to escape from the device. These medical symptoms combined with the use of a restraint may lead to a serious injury or death.

APPROPRIATE SIZE

It is very important to be sure that the appropriate size of restraint is selected. A restraint that is too small will be uncomfortable for the patient and may cause agitation or constriction of bodily parts. A restraint that is too large or loose, where the patient can slide down or forward, may result in asphyxiation.

GOOD LABELING

Manufacturers of patient restraints are being required to develop better labeling. They are also being encouraged to use graphics in improved labels, sewn directly on the device, to help ensure proper application. Look for these labels and alert a healthcare provider if it appears a device is on incorrectly or a patient is uncomfortable in a restraint.

PROPER USE

For wheelchair use, be sure that the patient is upright and securely seated in the chair before applying the restraint. See device directions for correct application. Incorrect application is more likely to result in the patient sliding forward which may result in asphyxiation. For use in a bed, be sure the restraint is NEVER tied to the bed rails or mattress. The restraint should only be tied to the bed springs. Also, most restraints are not indicated for use with regular beds or regular chairs, including geri-chairs. Consult the manufacturer labeling for correct application of the restraint to any bed or chair.

LENGTH OF WEAR

Any patient/resident in a restraint must be free of that restraint at frequent intervals to ensure good patient health. Long-term immobilization can contribute to various health problems including decubitus ulcers, nerve damage, incontinence, and sensory deprivation. Consult with the facility policy for the maximum length of each period of restraint use. During the time when the patient is free of the restraint, be sure that exercise, such as walking, is available and encouraged.

PATIENT MÓNITORING

Patients/residents must be monitored frequently while wearing a restraint device. As with any other medical device, supervision and monitoring are critical to ensure the safety of the patient.

Ask your facility what alternatives exist or are being developed to reduce the use of restraints. Restraints should never be used as a substitute for nursing care. They are an adjunct to proper care. In many cases, volunteers may be all a facility needs to help keep patients free from restraints. However, if you are aware of the potential dangers of restraint use and know what to look for and what to do if you see a restraint being used incorrectly, it could save a patient from a serious injury or even death.

GUIDANCE TO SURVEYORS	Interpretive Guidelines: \$483.13(a) "Physical or mechanical device, material, "Physical restraints" are any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot	remove easily which restricts freedom of movement or normal access to one's body.	hand mitts, soft ties or vests, and wheelchair safety bars. Also included as	restraints are facility practices which meet the definition of a restraint, such as tucking in a sheet so tightly that a bedbound resident cannot move, bedrails, or chairs	unat prevent tising, or plating a wheelchair-bound resident so close to a wait that the wall prevents the resident from rising. (See also 42 CFR 483.25(h), Accidents, for bed	rails.) Wrist bands or devices on clothing that trigger electronic alarms to warn staff that a resident is leaving a room do not, in and of themselves, restrict freedom of movement and should not be considered as restraints.	"Chemical Restraint" means a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms.	"Discipline" is any action taken by the facility for the purpose of punishing or penalizing residents.	"Convenience" is any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the residents' best interest.	When coupled with appropriate exercise, therapeutic interventions such as pillows, pads, or removable lap trays, are often effective in achieving proper body position, balance and alignment, and preventing contractures without use of restraints. Attention to individual, mental, physical and psychosocial needs, meaningful activity, environmental changes, and appressive nursing resultation or restorative programs	are other examples of less restrictive methods of meeting resident needs. If the restraint is used to enable the resident to attain or maintain his or her highest practicable level of functioning, a facility must have evidence of consultation with appropriate health professionals, such as occupational or physical therapists. This consultation should consider the use of less restrictive therapeutic intervention prior to using restricting as defined in this confession and the numbers.	The use of therapeutic interventions must be justified through the care planning process and demonstrate that these interventions promote the care and services necessary for the resident to attain or maintain the highest practicable well-being.	If the resident chooses to include a physical restraint as part of care and treatment, then the restraining device may be used for specific periods for which the restraint has been determined to be a therapeutic intervention (e.g., a bedrail used by a resident for turning.)	
REGULATION	\$483.13 Resident behavior and facility practices.	(a) Restraints. The resident has	physical or chemical restraints	imposed for purposes of discipline or convenience, and not required	to treat the resident's medical symptoms.	We tag #F221 for deficiencies concerning physical restraints.	Vee tag #F222 for deficiencies concerning chemical							
TAG NUMBER	F220-A		F222											

Rev. 250

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GUIDANCE TO SURVEYORS	For the resident to make an informed choice about the use of restraints, the facility should explain to the resident potential negative outcomes of restraint use. Potential negative outcomes might include incontinence, decreased range of motion, and decreased ability to ambulate, symptoms of withdrawal or depression, or reduced social contact. 42 CFR 483.20 requires a resident to be comprehensively assessed by an appropriate health professional to determine the resident's specific medical symptoms. Therefore, if a resident is restrained, the assessment must show the presence of a specific medical symptom that would require the use of restraints, those symptoms that are being treated, and how the use of restraints will assist the resident in reaching his or her highest level of physical and psychosocial well-being. This would include considering the least restrictive therapeutic intervention before using restraints as part of treating the resident's medical symptoms. The least restrictive therapeutic intervention is one that provides the resident the maximum amount of freedom of movement.	In the case of a resident who is incapable of making a decision, the surrogate or representative may exercise this right. (See 42 CFR 483.10(a)(3) & (4).) However, the surrogate or representative cannot give the facility permission to use restraints for the sake of discipline or staff convenience or when the restraint is not necessary to treat the resident's medical symptoms. The resident's right to participate in care planning and the right to refuse treatment are addressed at 42 CFR 483.20(d) and 483.10(b), respectively, and include the right to accept or refuse restraints.	Restraints may not be used to permit staff to administer treatment to which the resident has not consented. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has notice that the resident has previously made a valid refusal of the treatment in question.	The decision to apply physical restraints should be based on the assessment of each resident's capabilities, an evaluation of less restrictive alternatives and the ruling out of their use. The plan of care should also contain a schedule or plan of rehabilitative training to enable the progressive removal of restraints or the progressive use of less restrictive means, as appropriate. This systematic approach assures that restraints would not be applied for purposes of discipline or convenience and only to enable treatment of medical symptoms.	Survey Procedures and Probes: \$483.13(a) Determine if the facility follows a systematic process prior to using restraints. For sampled residents observed as physically restrained during the survey or whose clinical record shows the use of physical restraints within 30 days of the survey, determine the	04-92 P-77
REGULATION						!
TAG	F221 F222 Cont.					Rev. 250

GUIDANCE TO SURVEYORS	intended use of the restraint convenience or discipline, or a therapeutic intervention for specified periods to attain and maintain the resident's highest practicable physical, mental or psychosocial well-being. This process should answer these questions:	What Are	Lan the cause(s) be removed, then has the facility attempted to u alternatives in order to avoid a decline in physical functioning associatestraint use? (See Physical Restraints Resident Assessment Protocol (paragraph I.) If these alternatives have been tried and found wanting, does the facil least restrictive restraint for the least amount of time? Does the facil monitor and adjust care to reduce negative outcomes while continually tind and use less restrictive alternatives?	o Did the resident make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained? o Does the facility use the Physical Restraint RAP to evaluate the appropriateness of restraint use? Refer to MDS Sections K. N. E. H. L. and relevant RAPS, and to notes from other health	professionals to determine if restrained residents have maintained their physical, mental, psychosocial and functional status, or if the use of restraints has been associated with increase in falls, urinary or fecal incontinence, pressure sores, loss of muscle tone, loss of independent mobility, increased agitation, loss of balance, symptoms of withdrawal or depression, reduced social contact, or decreased appetite.	If restraint usage is associated with a subsequent decline in functioning, determine if the interdisciplinary team addressed this situation in the plan of care by comparing the resident's functional status before the application of restraints, as documented in assessment (MDS) and care plans, to his/her current observed status. Determine whether these changes are attributable to unavoidable disease progression, versus inappropriate use of restraints. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use, and maintained the resident's strength and mobility?	Where appropriate, cross reference to 42 CFR 483.20, Resident Assessment and 483.25, Quality of Care requirements.
REGULATION				,		•	
TAG	F221 F222 Cont.		-				

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GUIDANCE TO SURVEYORS	Interpretive Guidelines: \$483.13(b) Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.	"Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a come, cause physical harm, or pain or mental anguish.	"Verbal abuse" refers to any use of oral, written or gestured language that includes disparaging and derogatory terms to residents or their families, or within their hearing distance, to describe residents, regardless of their age, ability to comprehend, or disability.	"Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.	"Physical abuse" includes hitting, slapping, pinching, kicking, etc. It also includes controlling behavior through corporal punishment.	"Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.	"Involuntary seclusion" means separation of a resident from other residents or from his or her room against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.	Survey Procedures and Probes: \$483.13(b) Offsite, presurvey review of complaints can focus your on-site review of actual incidents and predisposing factors to abuse or neglect. On-site, if the facility maintains incident/accident reports, during the Entrance Conference ask for these reports for the 3-6 months preceding the survey.	Report and record any instances where you observe an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately.	o [Individual/Group] Do you ever feel that staff are upset or angry with you or other residents? (If yes) What do they do to make you feel that way?
REGULATION	(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.									
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EXHIBIT 4 Lonnie R. Kellogg

DATE 3-10-93

SB_1/8 918 E. 5th

Laurel, MJ 59044

Dear Sirs;

This letter is in response to the state inspection at the Twin (ottage (are (enter and addresses the written remarks concerning my father, Wesley M. Kellogg.

9, Lonnie R. Kellogg residing at 918 E. 5th St., Laurel, MJ., have been selected by a sister, Lynda Groscopp and 2 brothers, (ody Kellogg and David Kellogg to be the responsible party to insure the well being and welfare of our father, Wes Kellogg.

The first issue to be addressed is the locking of the bedroom door. Lois Wicks advised me of this before she took action via a phone call to have my permission to do so. This was needed at that time for two reasons; I.) To stop Wesley from putting on 2 or 3 sets of clothes at one time which have now been removed entirely to eleviate his packing everything up to move out and 2.) to stop his sleeping during daytime hours and being up all night causing commotion and interuptions in the other patients' noutine.

Your remarks indicate this is a violation of his rights. I will tell you what a violation of his rights are: If these standards are not followed, he will be required to go to a nursing home which is the last place dad would even like to be. That is a violation of his rights as an American and a human being to live where he wants. The care that dad receives at Twin (ottage is unsurpassable. He is fed well, kept clean and any time he isn't feeling well, he is taken directly to the laurel Medical (linic for treatment.

A VSOLATION OF RIGHTS? If there is any violation it is on your part for implying the Jwin (ottage (are (enter cannot provide dad adequate care. This violates his right to live where he wants and the rest of the family's right of providing the best care possible for our father. Thank God the state and people like you are not in control as we still have fundamental rights under the constitution to protect us from government intervention such as this.

The second issue is that dad is on too much Haldol. I have checked with his Doctor, lee Richardson and the pharmisist, John Barsnes, who dispenses the prescription and both have said the amount he is taking does not and will not make him drugged. It will slow him down and stabelize his nervous energy which is associated with Alzheimers. As for his appearing drowsy, this does happen for a period of time after he eats. But then who doesn't feel drowsy after eating?

Your inspection should be in the evening when he is up and down 40 times and paces the floor and lets his dog in and out 20 times in a 30 minute period. The use of Haldol is not to supress his actions, only to control them for his well being. I visit dad on a weekly basis and can assure you he is not drugged. Before any increase in medication is prescribed the management of Twin Cottage discusses with me any changes that are to be made.

Alzheimers is a cruel and disheartening disease. It not only effects the patient but friends and family as well. As there is no way to know what an alzheimer patient such as dad is thinking or desires, we can only go by the values and morals that the patient lived by. As I have known dad for over 45 years, I feel that I can express what he would say to you if he were capable; "Keep your nose out of affairs that don't concern you."

I know the (are (enter should be inspected to protect the well being of the patients. However, when an explanation is offered for a situation by a care center it should be taken at face value unless conditions suggest otherwise. In this case there are NO conditions to suggest otherwise. I have investigated into other places for dad to stay and there are none that can compare to the care he is receiving at Iwin (ottage (are Center.

Furthermore, there is no way on God's green earth that a state agency is going to tell my family where and where not we can place our father. We have his best interest at heart and if you think you can change that, you had better back up and take another look because you are headed for one heck of a fight that will not be pleasant for your agency.

Respectfully,

Lonnie R. Kellogg

EXHIBIT 5

DATE 3-10-93

SB 1/8

Regarding - Foster care for the elderly Versus nulsing home care.

Ladies & Kallemen,

My father died 10 days ago, I'm glack he did not have to spend his last year on earth in a nursing home, when my mother was unable to care for dad sie was at her wits end, the did not want to place him in a nursing home. The found out about foster care for the elderly and was lucky enough to find a place for him in a foster home.

Mot only was the foster home more appealing, but the cost was less than half the Nates quoted to here by Several hursing home facilities. Also, the homey atmosphere made her feel less quilty about his move, Many times an elderly apouse has the responsibility of placing his or

her life-long spouse in a home. The guilt alone is quite awesome,

I felt dad was much happier and more comfortable in a foster home than he would have been in an institution. A mursing home is indeed an institution much leke a minimum security prison,

Dad Could visit with his care-giver as she was preparing meals. He Could smell the food as it was cooking. The foster care-giver had a little dog and dad smiled from lar to lar when he played with that dog.

Meals were served in a family setting Dad didn't have to struggle down a long bare hall way to a cafeteria. At healtime his care-giver sort of "tucked him in" and wished him a good night.

EXHIBIT_ 5

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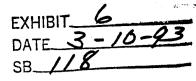
Dad's old friends were not intimidated & were lager to visit him in the foster home. The family was lager to visit him there, too. Olten times we would all sit around thith the other elderly the caregiver and have a real nice visit. Best of all, when we took dad home for the noway he was eager to get back home to his home "the foster home) at the Ind of the day, so we know he was happy there.

When an old person is taken out of his or her efetime home, how cruel we are to put them into institutions when there is a splendid alternative in foster care for the elderly.

Thank you,

Sincerely, Kinda Aves 602 Date

GOVERNOR'S OFFICE ON AGING





MARC RACICOT, GOVERNOR

(406) 444-3111

STATE OF MONTANA:

PO BOX 200801 HELENA, MONTANA 59620-0801

March 10, 1993

TO:

House Committee on Human Services and Aging

FROM:

Doug Blakley, State Ombudsman

RE:

SB 118

As State Long-Term Care Ombudsman, I am responsible for serving as an advocate for residents of long-term care facilities, including nursing homes and personal care homes. Through our local ombudsmen, we currently visit all licensed personal care homes and several adult foster care homes, assisting residents and consumers in resolving concerns and complaints pertaining to care and rights issues. If SB 118 passes, our programs would be responsible for providing advocacy services to the new category of facilities created by this bill.

I have serious concerns about SB 118 because of its implications for the health and safety of residents in the new category B personal care homes. Since the majority of residents in this type of facility have significant impairments in decision making, a greater need exists for requirements which ensures them a safe environment. The major complaints we deal with in personal care home are the inappropriate admission and/or retention of residents and the adequacy of care provided to those who need care beyond assistance with activities of daily living.

The major drawbacks of SB 118 are twofold: expertise of staff to deliver care and qualified oversight of the care. Currently, there are no professional qualifications or training requirements for those operating or working in personal care homes. SB 118 fails to address this basic issue. While the bill has a requirement for annual oversight, on-going oversight is not addressed. This is particularly troubling in light of the fact that SB 118 would allow residents who need skilled nursing care, restraints or bedbound residents in a facility. By definition these would be nursing home level residents.

Thus, I feel the expansion of services in category B homes without addressing the training and oversight issues pose a significant health and safety risks to residents placed in such a facility. The changes in SB 118 would exacerbate the major problems we see in personal care homes rather alleviate them.

HOUSE OF REPRESENTATIVES VISITOR REGISTER

Duman Services	COMMITTEE BILL	NO. <u>SB</u>	118
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Doug Blakley	office on Aging		
Miko Crossing	1 des S		
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PLEASE LEAVE PREPARED TESTIMONY WITH SECRETARY. WITNESS STATEMENT FORMS
ARE AVAILABLE IF YOU CARE TO SUBMIT WRITTEN TESTIMONY.

HOUSE OF REPRESENTATIVES VISITOR REGISTER

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DATE 3/10/93 SPONSOR (S		LL NO. 3E		
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NAME AND ADDRESS	REPRESENTING	SUPPORT	OPPOSE	
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Carrie Dogdinh	MT PT assoc.	/		
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PLEASE LEAVE PREPARED TESTIMONY WITH SECRETARY. WITNESS STATEMENT FORMS ARE AVAILABLE IF YOU CARE TO SUBMIT WRITTEN TESTIMONY.