

**Senate Counsel, Research,
and Fiscal Analysis**

G-17 STATE CAPITOL
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Senate

State of Minnesota

**S.F. No. 3169 - Flue Vaccinations
(Delete-Everything Amendment)**

Author: Senator David J. Tomassoni

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) *KAC*

Date: April 4, 2006

S.F. No. 3169 states that annual mass flu vaccination clinics for individuals who are not in a high-risk priority group must be delayed until November 1 of each year, unless the Commissioner of Health has determined that there will be a sufficient supply of the vaccine and has posted a notice of this determination on the Department's Web site. **S.F. No. 3169** does not apply to live attenuated influenza vaccine.

KC:ph

Senators Tomassoni and Bakk introduced-

S.F. No. 3169: Referred to the Committee on Health and Family Security.

A bill for an act

1.2 relating to health; requiring the delay of annual mass flu vaccination clinics in
1.3 the event of a flu vaccine shortage; imposing penalties; proposing coding for new
1.4 law in Minnesota Statutes, chapter 144.

1.5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.6 Section 1. [144.063] ANNUAL FLU VACCINATIONS DURING A SHORTAGE.

1.7 Subdivision 1. Delayed vaccination. Annual mass flu vaccination clinics for
1.8 individuals who are not in a high-risk priority group according to the guidelines established
1.9 by the National Advisory Committee on Immunization Practices shall be delayed until
1.10 November 1 of each year, unless the commissioner of health has determined that there
1.11 will be a sufficient supply of the vaccine and has posted a notice of this determination
1.12 on the Department of Health's Web site.

1.13 Subd. 2. Penalties. The commissioner of health may impose a fine of up to \$1,000
1.14 upon a person found in violation of this section. The commissioner may impose a fine of
1.15 up to \$10,000 upon a person who intentionally or repeatedly violates this section.

1.16 EFFECTIVE DATE. This section is effective the day following final enactment.

1.1 Senator moves to amend S.F. No. 3169 as follows:

1.2 Delete everything after the enacting clause and insert:

1.3 "Section 1. [144.063] ANNUAL FLU VACCINATIONS DURING A
1.4 SHORTAGE.

1.5 Annual mass flu vaccination clinics for individuals who are not in a high-risk priority
1.6 group according to the guidelines established by the National Advisory Committee
1.7 on Immunization Practices shall be delayed until November 1 of each year, unless the
1.8 commissioner of health has determined that there will be a sufficient supply of the vaccine
1.9 and has posted a notice of this determination on the Department of Health's Web site. This
1.10 section does not apply to live attenuated influenza vaccine.

1.11 EFFECTIVE DATE. This section is effective the day following final enactment."

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**S.F. No. 3292 - Nursing Home Moratorium Exception in
Cass County (the A-1 Delete-Everything Amendment)**

Author: Senator Dallas Sams

Prepared by: David Giel, Senate Research (296-7178)



Date: April 3, 2006

S.F. No. 3292 authorizes a nursing home moratorium exception to build a nursing home of up to 80 beds on the Ah-Gwah-Ching campus using bed licenses transferred from the state-owned facility. The operating rate for the new facility must be determined under existing rules and law. The property payment rate is set at \$35 per day for the first three years, with that amount subsequently adjusted annually for inflation as long as the facility has a contract under the alternative payment system.

DG:rdr

Senators Sams, Koering, Ruud, Higgins and Solon introduced—
S.F. No. 3292: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; providing an exception to the nursing home moratorium for a replacement facility in Cass County; amending Minnesota Statutes 2004, section 144A.071, subdivision 4a.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 144A.071, subdivision 4a, is amended to read:

Subd. 4a. **Exceptions for replacement beds.** It is in the best interest of the state to ensure that nursing homes and boarding care homes continue to meet the physical plant licensing and certification requirements by permitting certain construction projects. Facilities should be maintained in condition to satisfy the physical and emotional needs of residents while allowing the state to maintain control over nursing home expenditure growth.

The commissioner of health in coordination with the commissioner of human services, may approve the renovation, replacement, upgrading, or relocation of a nursing home or boarding care home, under the following conditions:

(a) to license or certify beds in a new facility constructed to replace a facility or to make repairs in an existing facility that was destroyed or damaged after June 30, 1987, by fire, lightning, or other hazard provided:

(i) destruction was not caused by the intentional act of or at the direction of a controlling person of the facility;

(ii) at the time the facility was destroyed or damaged the controlling persons of the facility maintained insurance coverage for the type of hazard that occurred in an amount that a reasonable person would conclude was adequate;

2.1 (iii) the net proceeds from an insurance settlement for the damages caused by the
2.2 hazard are applied to the cost of the new facility or repairs;

2.3 (iv) the new facility is constructed on the same site as the destroyed facility or on
2.4 another site subject to the restrictions in section 144A.073, subdivision 5;

2.5 (v) the number of licensed and certified beds in the new facility does not exceed the
2.6 number of licensed and certified beds in the destroyed facility; and

2.7 (vi) the commissioner determines that the replacement beds are needed to prevent an
2.8 inadequate supply of beds.

2.9 Project construction costs incurred for repairs authorized under this clause shall not be
2.10 considered in the dollar threshold amount defined in subdivision 2;

2.11 (b) to license or certify beds that are moved from one location to another within a
2.12 nursing home facility, provided the total costs of remodeling performed in conjunction
2.13 with the relocation of beds does not exceed \$1,000,000;

2.14 (c) to license or certify beds in a project recommended for approval under section
2.15 144A.073;

2.16 (d) to license or certify beds that are moved from an existing state nursing home to
2.17 a different state facility, provided there is no net increase in the number of state nursing
2.18 home beds;

2.19 (e) to certify and license as nursing home beds boarding care beds in a certified
2.20 boarding care facility if the beds meet the standards for nursing home licensure, or in a
2.21 facility that was granted an exception to the moratorium under section 144A.073, and if
2.22 the cost of any remodeling of the facility does not exceed \$1,000,000. If boarding care
2.23 beds are licensed as nursing home beds, the number of boarding care beds in the facility
2.24 must not increase beyond the number remaining at the time of the upgrade in licensure.
2.25 The provisions contained in section 144A.073 regarding the upgrading of the facilities
2.26 do not apply to facilities that satisfy these requirements;

2.27 (f) to license and certify up to 40 beds transferred from an existing facility owned and
2.28 operated by the Amherst H. Wilder Foundation in the city of St. Paul to a new unit at the
2.29 same location as the existing facility that will serve persons with Alzheimer's disease and
2.30 other related disorders. The transfer of beds may occur gradually or in stages, provided
2.31 the total number of beds transferred does not exceed 40. At the time of licensure and
2.32 certification of a bed or beds in the new unit, the commissioner of health shall delicense
2.33 and decertify the same number of beds in the existing facility. As a condition of receiving
2.34 a license or certification under this clause, the facility must make a written commitment
2.35 to the commissioner of human services that it will not seek to receive an increase in its
2.36 property-related payment rate as a result of the transfers allowed under this paragraph;

3.1 (g) to license and certify nursing home beds to replace currently licensed and certified
3.2 boarding care beds which may be located either in a remodeled or renovated boarding care
3.3 or nursing home facility or in a remodeled, renovated, newly constructed, or replacement
3.4 nursing home facility within the identifiable complex of health care facilities in which the
3.5 currently licensed boarding care beds are presently located, provided that the number of
3.6 boarding care beds in the facility or complex are decreased by the number to be licensed
3.7 as nursing home beds and further provided that, if the total costs of new construction,
3.8 replacement, remodeling, or renovation exceed ten percent of the appraised value of
3.9 the facility or \$200,000, whichever is less, the facility makes a written commitment to
3.10 the commissioner of human services that it will not seek to receive an increase in its
3.11 property-related payment rate by reason of the new construction, replacement, remodeling,
3.12 or renovation. The provisions contained in section 144A.073 regarding the upgrading of
3.13 facilities do not apply to facilities that satisfy these requirements;

3.14 (h) to license as a nursing home and certify as a nursing facility a facility that is
3.15 licensed as a boarding care facility but not certified under the medical assistance program,
3.16 but only if the commissioner of human services certifies to the commissioner of health that
3.17 licensing the facility as a nursing home and certifying the facility as a nursing facility will
3.18 result in a net annual savings to the state general fund of \$200,000 or more;

3.19 (i) to certify, after September 30, 1992, and prior to July 1, 1993, existing nursing
3.20 home beds in a facility that was licensed and in operation prior to January 1, 1992;

3.21 (j) to license and certify new nursing home beds to replace beds in a facility acquired
3.22 by the Minneapolis Community Development Agency as part of redevelopment activities
3.23 in a city of the first class, provided the new facility is located within three miles of the site
3.24 of the old facility. Operating and property costs for the new facility must be determined
3.25 and allowed under section 256B.431 or 256B.434;

3.26 (k) to license and certify up to 20 new nursing home beds in a community-operated
3.27 hospital and attached convalescent and nursing care facility with 40 beds on April 21,
3.28 1991, that suspended operation of the hospital in April 1986. The commissioner of human
3.29 services shall provide the facility with the same per diem property-related payment rate
3.30 for each additional licensed and certified bed as it will receive for its existing 40 beds;

3.31 (l) to license or certify beds in renovation, replacement, or upgrading projects as
3.32 defined in section 144A.073, subdivision 1, so long as the cumulative total costs of the
3.33 facility's remodeling projects do not exceed \$1,000,000;

3.34 (m) to license and certify beds that are moved from one location to another for the
3.35 purposes of converting up to five four-bed wards to single or double occupancy rooms

4.1 in a nursing home that, as of January 1, 1993, was county-owned and had a licensed
4.2 capacity of 115 beds;

4.3 (n) to allow a facility that on April 16, 1993, was a 106-bed licensed and certified
4.4 nursing facility located in Minneapolis to layaway all of its licensed and certified nursing
4.5 home beds. These beds may be relicensed and recertified in a newly-constructed teaching
4.6 nursing home facility affiliated with a teaching hospital upon approval by the legislature.
4.7 The proposal must be developed in consultation with the interagency committee on
4.8 long-term care planning. The beds on layaway status shall have the same status as
4.9 voluntarily delicensed and decertified beds, except that beds on layaway status remain
4.10 subject to the surcharge in section 256.9657. This layaway provision expires July 1, 1998;

4.11 (o) to allow a project which will be completed in conjunction with an approved
4.12 moratorium exception project for a nursing home in southern Cass County and which is
4.13 directly related to that portion of the facility that must be repaired, renovated, or replaced,
4.14 to correct an emergency plumbing problem for which a state correction order has been
4.15 issued and which must be corrected by August 31, 1993;

4.16 (p) to allow a facility that on April 16, 1993, was a 368-bed licensed and certified
4.17 nursing facility located in Minneapolis to layaway, upon 30 days prior written notice to
4.18 the commissioner, up to 30 of the facility's licensed and certified beds by converting
4.19 three-bed wards to single or double occupancy. Beds on layaway status shall have the
4.20 same status as voluntarily delicensed and decertified beds except that beds on layaway
4.21 status remain subject to the surcharge in section 256.9657, remain subject to the license
4.22 application and renewal fees under section 144A.07 and shall be subject to a \$100 per bed
4.23 reactivation fee. In addition, at any time within three years of the effective date of the
4.24 layaway, the beds on layaway status may be:

4.25 (1) relicensed and recertified upon relocation and reactivation of some or all of
4.26 the beds to an existing licensed and certified facility or facilities located in Pine River,
4.27 Brainerd, or International Falls; provided that the total project construction costs related to
4.28 the relocation of beds from layaway status for any facility receiving relocated beds may
4.29 not exceed the dollar threshold provided in subdivision 2 unless the construction project
4.30 has been approved through the moratorium exception process under section 144A.073;

4.31 (2) relicensed and recertified, upon reactivation of some or all of the beds within the
4.32 facility which placed the beds in layaway status, if the commissioner has determined a
4.33 need for the reactivation of the beds on layaway status.

4.34 The property-related payment rate of a facility placing beds on layaway status
4.35 must be adjusted by the incremental change in its rental per diem after recalculating the
4.36 rental per diem as provided in section 256B.431, subdivision 3a, paragraph (c). The

5.1 property-related payment rate for a facility relicensing and recertifying beds from layaway
5.2 status must be adjusted by the incremental change in its rental per diem after recalculating
5.3 its rental per diem using the number of beds after the relicensing to establish the facility's
5.4 capacity day divisor, which shall be effective the first day of the month following the
5.5 month in which the relicensing and recertification became effective. Any beds remaining
5.6 on layaway status more than three years after the date the layaway status became effective
5.7 must be removed from layaway status and immediately delicensed and decertified;

5.8 (q) to license and certify beds in a renovation and remodeling project to convert 12
5.9 four-bed wards into 24 two-bed rooms, expand space, and add improvements in a nursing
5.10 home that, as of January 1, 1994, met the following conditions: the nursing home was
5.11 located in Ramsey County; had a licensed capacity of 154 beds; and had been ranked
5.12 among the top 15 applicants by the 1993 moratorium exceptions advisory review panel.
5.13 The total project construction cost estimate for this project must not exceed the cost
5.14 estimate submitted in connection with the 1993 moratorium exception process;

5.15 (r) to license and certify up to 117 beds that are relocated from a licensed and
5.16 certified 138-bed nursing facility located in St. Paul to a hospital with 130 licensed
5.17 hospital beds located in South St. Paul, provided that the nursing facility and hospital are
5.18 owned by the same or a related organization and that prior to the date the relocation is
5.19 completed the hospital ceases operation of its inpatient hospital services at that hospital.
5.20 After relocation, the nursing facility's status under section 256B.431, subdivision 2j, shall
5.21 be the same as it was prior to relocation. The nursing facility's property-related payment
5.22 rate resulting from the project authorized in this paragraph shall become effective no
5.23 earlier than April 1, 1996. For purposes of calculating the incremental change in the
5.24 facility's rental per diem resulting from this project, the allowable appraised value of
5.25 the nursing facility portion of the existing health care facility physical plant prior to the
5.26 renovation and relocation may not exceed \$2,490,000;

5.27 (s) to license and certify two beds in a facility to replace beds that were voluntarily
5.28 delicensed and decertified on June 28, 1991;

5.29 (t) to allow 16 licensed and certified beds located on July 1, 1994, in a 142-bed
5.30 nursing home and 21-bed boarding care home facility in Minneapolis, notwithstanding
5.31 the licensure and certification after July 1, 1995, of the Minneapolis facility as a 147-bed
5.32 nursing home facility after completion of a construction project approved in 1993 under
5.33 section 144A.073, to be laid away upon 30 days' prior written notice to the commissioner.
4 Beds on layaway status shall have the same status as voluntarily delicensed or decertified
5.35 beds except that they shall remain subject to the surcharge in section 256.9657. The
5.36 16 beds on layaway status may be relicensed as nursing home beds and recertified at

6.1 any time within five years of the effective date of the layaway upon relocation of some
6.2 or all of the beds to a licensed and certified facility located in Watertown, provided that
6.3 the total project construction costs related to the relocation of beds from layaway status
6.4 for the Watertown facility may not exceed the dollar threshold provided in subdivision
6.5 2 unless the construction project has been approved through the moratorium exception
6.6 process under section 144A.073.

6.7 The property-related payment rate of the facility placing beds on layaway status
6.8 must be adjusted by the incremental change in its rental per diem after recalculating the
6.9 rental per diem as provided in section 256B.431, subdivision 3a, paragraph (c). The
6.10 property-related payment rate for the facility relicensing and recertifying beds from
6.11 layaway status must be adjusted by the incremental change in its rental per diem after
6.12 recalculating its rental per diem using the number of beds after the relicensing to establish
6.13 the facility's capacity day divisor, which shall be effective the first day of the month
6.14 following the month in which the relicensing and recertification became effective. Any
6.15 beds remaining on layaway status more than five years after the date the layaway status
6.16 became effective must be removed from layaway status and immediately delicensed
6.17 and decertified;

6.18 (u) to license and certify beds that are moved within an existing area of a facility or
6.19 to a newly constructed addition which is built for the purpose of eliminating three- and
6.20 four-bed rooms and adding space for dining, lounge areas, bathing rooms, and ancillary
6.21 service areas in a nursing home that, as of January 1, 1995, was located in Fridley and had
6.22 a licensed capacity of 129 beds;

6.23 (v) to relocate 36 beds in Crow Wing County and four beds from Hennepin County
6.24 to a 160-bed facility in Crow Wing County, provided all the affected beds are under
6.25 common ownership;

6.26 (w) to license and certify a total replacement project of up to 49 beds located in
6.27 Norman County that are relocated from a nursing home destroyed by flood and whose
6.28 residents were relocated to other nursing homes. The operating cost payment rates for
6.29 the new nursing facility shall be determined based on the interim and settle-up payment
6.30 provisions of Minnesota Rules, part 9549.0057, and the reimbursement provisions of
6.31 section 256B.431, except that subdivision 26, paragraphs (a) and (b), shall not apply until
6.32 the second rate year after the settle-up cost report is filed. Property-related reimbursement
6.33 rates shall be determined under section 256B.431, taking into account any federal or state
6.34 flood-related loans or grants provided to the facility;

6.35 (x) to license and certify a total replacement project of up to 129 beds located
6.36 in Polk County that are relocated from a nursing home destroyed by flood and whose

7.1 residents were relocated to other nursing homes. The operating cost payment rates for
7.2 the new nursing facility shall be determined based on the interim and settle-up payment
7.3 provisions of Minnesota Rules, part 9549.0057, and the reimbursement provisions of
7.4 section 256B.431, except that subdivision 26, paragraphs (a) and (b), shall not apply until
7.5 the second rate year after the settle-up cost report is filed. Property-related reimbursement
7.6 rates shall be determined under section 256B.431, taking into account any federal or state
7.7 flood-related loans or grants provided to the facility;

7.8 (y) to license and certify beds in a renovation and remodeling project to convert 13
7.9 three-bed wards into 13 two-bed rooms and 13 single-bed rooms, expand space, and
7.10 add improvements in a nursing home that, as of January 1, 1994, met the following
7.11 conditions: the nursing home was located in Ramsey County, was not owned by a hospital
7.12 corporation, had a licensed capacity of 64 beds, and had been ranked among the top 15
7.13 applicants by the 1993 moratorium exceptions advisory review panel. The total project
7.14 construction cost estimate for this project must not exceed the cost estimate submitted in
7.15 connection with the 1993 moratorium exception process;

7.16 (z) to license and certify up to 150 nursing home beds to replace an existing 285
7.17 bed nursing facility located in St. Paul. The replacement project shall include both the
7.18 renovation of existing buildings and the construction of new facilities at the existing
7.19 site. The reduction in the licensed capacity of the existing facility shall occur during the
7.20 construction project as beds are taken out of service due to the construction process. Prior
7.21 to the start of the construction process, the facility shall provide written information to the
7.22 commissioner of health describing the process for bed reduction, plans for the relocation
7.23 of residents, and the estimated construction schedule. The relocation of residents shall be
7.24 in accordance with the provisions of law and rule;

7.25 (aa) to allow the commissioner of human services to license an additional 36 beds to
7.26 provide residential services for the physically handicapped under Minnesota Rules, parts
7.27 9570.2000 to 9570.3400, in a 198-bed nursing home located in Red Wing, provided that
7.28 the total number of licensed and certified beds at the facility does not increase;

7.29 (bb) to license and certify a new facility in St. Louis county with 44 beds constructed
7.30 to replace an existing facility in St. Louis County with 31 beds, which has resident rooms
7.31 on two separate floors and an antiquated elevator that creates safety concerns for residents
7.32 and prevents nonambulatory residents from residing on the second floor. The project shall
7.33 include the elimination of three- and four-bed rooms;

4 (cc) to license and certify four beds in a 16-bed certified boarding care home in
7.35 Minneapolis to replace beds that were voluntarily delicensed and decertified on or
7.36 before March 31, 1992. The licensure and certification is conditional upon the facility

8.1 periodically assessing and adjusting its resident mix and other factors which may
8.2 contribute to a potential institution for mental disease declaration. The commissioner of
8.3 human services shall retain the authority to audit the facility at any time and shall require
8.4 the facility to comply with any requirements necessary to prevent an institution for mental
8.5 disease declaration, including delicensure and decertification of beds, if necessary;

8.6 (dd) to license and certify 72 beds in an existing facility in Mille Lacs County with
8.7 80 beds as part of a renovation project. The renovation must include construction of
8.8 an addition to accommodate ten residents with beginning and midstage dementia in a
8.9 self-contained living unit; creation of three resident households where dining, activities,
8.10 and support spaces are located near resident living quarters; designation of four beds
8.11 for rehabilitation in a self-contained area; designation of 30 private rooms; and other
8.12 improvements;

8.13 (ee) to license and certify beds in a facility that has undergone replacement or
8.14 remodeling as part of a planned closure under section 256B.437;

8.15 (ff) to license and certify a total replacement project of up to 124 beds located
8.16 in Wilkin County that are in need of relocation from a nursing home significantly
8.17 damaged by flood. The operating cost payment rates for the new nursing facility shall
8.18 be determined based on the interim and settle-up payment provisions of Minnesota
8.19 Rules, part 9549.0057, and the reimbursement provisions of section 256B.431, except
8.20 that section 256B.431, subdivision 26, paragraphs (a) and (b), shall not apply until the
8.21 second rate year after the settle-up cost report is filed. Property-related reimbursement
8.22 rates shall be determined under section 256B.431, taking into account any federal or state
8.23 flood-related loans or grants provided to the facility;

8.24 (gg) to allow the commissioner of human services to license an additional nine beds
8.25 to provide residential services for the physically handicapped under Minnesota Rules,
8.26 parts 9570.2000 to 9570.3400, in a 240-bed nursing home located in Duluth, provided that
8.27 the total number of licensed and certified beds at the facility does not increase;

8.28 (hh) to license and certify up to 120 new nursing facility beds to replace beds in a
8.29 facility in Anoka County, which was licensed for 98 beds as of July 1, 2000, provided the
8.30 new facility is located within four miles of the existing facility and is in Anoka County.
8.31 Operating and property rates shall be determined and allowed under section 256B.431 and
8.32 Minnesota Rules, parts 9549.0010 to 9549.0080, or section 256B.434 or 256B.435. The
8.33 provisions of section 256B.431, subdivision 26, paragraphs (a) and (b), do not apply until
8.34 the second rate year following settle-up; ~~or~~

8.35 (ii) to transfer up to 98 beds of a 129-licensed bed facility located in Anoka County
8.36 that, as of March 25, 2001, is in the active process of closing, to a 122-licensed bed

9.1 nonprofit nursing facility located in the city of Columbia Heights or its affiliate. The
9.2 transfer is effective when the receiving facility notifies the commissioner in writing of the
9.3 number of beds accepted. The commissioner shall place all transferred beds on layaway
9.4 status held in the name of the receiving facility. The layaway adjustment provisions of
9.5 section 256B.431, subdivision 30, do not apply to this layaway. The receiving facility
9.6 may only remove the beds from layaway for recertification and relicensure at the receiving
9.7 facility's current site, or at a newly constructed facility located in Anoka County. The
9.8 receiving facility must receive statutory authorization before removing these beds from
9.9 layaway status; or

9.10 (jj) to license and certify up to 150 beds transferred from an existing, state-owned
9.11 nursing facility in Cass County to a new replacement facility in Cass County located
9.12 within five miles of the existing facility. The property and operating payment rates for
9.13 the replacement facility shall be determined as follows:

9.14 (1) The commissioner shall set the property rate at \$35.00 per patient day.

9.15 (2) During the initial 36-month operating period, the commissioner shall determine
9.16 an operating rate based on a negotiated, assumed occupancy for each 12-month period,
9.17 with a retrospective settle-up, based on costs submitted by the provider.

9.18 (3) After the initial 36-month operating period, the commissioner shall determine
9.19 the operating payment rate based on actual allowable costs annualized for a 12-month
9.20 period, with the annualized property payment costs divided by an assumed occupancy
9.21 of 95 percent.

1.1 Senator moves to amend S.F. No. 3292 as follows:

Delete everything after the enacting clause and insert:

1.3 "Section 1. Minnesota Statutes 2004, section 144A.071, subdivision 4c, is amended
1.4 to read:

1.5 Subd. 4c. **Exceptions for replacement beds after June 30, 2003.** (a) The
1.6 commissioner of health, in coordination with the commissioner of human services, may
1.7 approve the renovation, replacement, upgrading, or relocation of a nursing home or
1.8 boarding care home, under the following conditions:

1.9 (1) to license and certify an 80-bed city-owned facility in Nicollet County to be
1.10 constructed on the site of a new city-owned hospital to replace an existing 85-bed facility
1.11 attached to a hospital that is also being replaced. The threshold allowed for this project
1.12 under section 144A.073 shall be the maximum amount available to pay the additional
1.3 medical assistance costs of the new facility;

1.14 (2) to license and certify 29 beds to be added to an existing 69-bed facility in St.
1.15 Louis County, provided that the 29 beds must be transferred from active or layaway status
1.16 at an existing facility in St. Louis County that had 235 beds on April 1, 2003.

1.17 The licensed capacity at the 235-bed facility must be reduced to 206 beds, but the payment
1.18 rate at that facility shall not be adjusted as a result of this transfer. The operating payment
1.19 rate of the facility adding beds after completion of this project shall be the same as it was
1.20 on the day prior to the day the beds are licensed and certified. This project shall not
1.21 proceed unless it is approved and financed under the provisions of section 144A.073; ~~and~~

1.22 (3) to license and certify a new 60-bed facility in Austin, provided that: (i) 45 of
1.24 the new beds are transferred from a 45-bed facility in Austin under common ownership
1.25 that is closed and 15 of the new beds are transferred from a 182-bed facility in Albert Lea
1.26 under common ownership; (ii) the commissioner of human services is authorized by the
1.27 2004 legislature to negotiate budget-neutral planned nursing facility closures; and (iii)
1.28 money is available from planned closures of facilities under common ownership to make
1.29 implementation of this clause budget-neutral to the state. The bed capacity of the Albert
1.30 Lea facility shall be reduced to 167 beds following the transfer. Of the 60 beds at the
1.31 new facility, 20 beds shall be used for a special care unit for persons with Alzheimer's
1.31 disease or related dementias; and

1.32 (4) to license and certify up to 80 beds transferred from an existing state-owned
1.33 nursing facility in Cass County to a new facility located on the grounds of the
1.34 Ah-Gwah-Ching campus. The operating cost payment rates for the new facility shall be
1.35 determined based on the interim and settle-up payment provisions of Minnesota Rules,
1.36 part 9549.0057, and the reimbursement provisions of section 256B.431. The property

2.1 payment rate for the first three years of operation shall be \$35 per day. For subsequent
2.2 years, the property payment rate of \$35 per day shall be adjusted for inflation as provided
2.3 in section 256B.434, subdivision 4, paragraph (c), as long as the facility has a contract
2.4 under section 256B.434.

2.5 (b) Projects approved under this subdivision shall be treated in a manner equivalent
2.6 to projects approved under subdivision 4a."

2.7 Amend the title accordingly

The Need for a New Long-term Care Facility in Central Cass County

S.F. 3292/H.F. 3486 -- Cass County Nursing Home Moratorium Exception

Cass County has one of the fastest growing rural populations in the State of Minnesota. This is primarily due to its abundant natural resources and scenic beauty which attract people at, or near, retirement age. During the summer months, the county's population reaches 80,000. This rapid population growth is expected to continue at a rate of 38.5% by the year 2030.

Cass County's population is older than the statewide average, with 41% of the population over the age of 45 in 2000 compared to 30% statewide. Residents who are 65 years of age or older represent 18% of the population – in comparison to 12% statewide.

In the year 2000, central Cass County had nearly twice the percentage (24%) of residents age 65 or older in comparison to the northern or southern areas of the County.

The State of Minnesota plans to abandon the Ah-Gwah-Ching long-term care facility by January 1, 2007 and turn the 170 acre campus near Walker over to Cass County and the DNR. The County's long-term vision, as recommended by the Cass County Health Care Task Force, and "planning partnerships" with related State Departments is to locate an integrated medical campus on an 88 acre portion of the property. The probable sequence of development is as follows:

1. 80 Bed Long-term Care Facility
2. Assisted Living
3. Medical Clinic
4. Indian Health Services Satellite Clinic
5. 25-Bed Acute Care Hospital

The cost of an 80 bed long-term care "new facility" is estimated to be \$12 million. Payments on a \$12 million 20 year mortgage (at 6.5%) approximate \$960,000 year. This figure, divided by 27,740 patient days (80 beds multiplied by 365 days multiplied by 95% occupancy) results in a necessary property payment rate of nearly \$35.00 (\$34.60 – an amount that provides no debt service coverage making financing difficult). The new facility will not be subsidized and there is no substantial fund development in place.

With the elimination of the 353 long-term care beds at Ah-Gwah-Ching, two other long-term care facilities remain in Cass County – a 54 bed nursing home in Walker and a 94 bed facility in Pine River. With the addition of an 80 long-term care bed facility in central Cass County, the County would remain under the long-term bed goal of 60 beds per 10,000 population.

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S.F. No. 3318 - Nursing Facility Resident Assessment Schedule and Case Mix Weights

Author: Senator Dallas Sams

Prepared by: David Giel, Senate Research (296-7178)



Date: April 3, 2006

S.F. No. 3318 requires nursing facility case mix classifications to be adjusted after every quarterly resident assessment, rather than every other quarterly assessment as required under current law. It also requires implementation of new case mix weights that were recommended in a time study conducted under 2001 legislation. And it provides nursing facility rate adjustments for facilities that would experience a revenue loss upon implementation of these rate changes.

Section 1 (144.0724, subdivision 4) amends the resident reimbursement classification statute to require that a nursing facility resident's case mix classification be adjusted following every quarterly assessment, rather than every other quarterly assessment as provided under current law.

Section 2 (256B.438, subdivision 4) makes the same modification in the statute implementing case mix classifications for rate setting purposes.

Section 3 (256B.438, subdivision 8) requires the Department of Human Services (DHS) to implement new case mix weights, based on a time study conducted in response to 2001 legislation, effective October 1, 2006, and requires rate adjustments for facilities estimated to receive a reduction in revenue as a result of implementation of the new case mix weights and the revised resident assessment schedule.

The rate adjustments are determined as follows:

- From October 1, 2006, to June 30, 2007, facilities receive an interim rate adjustment equal to the estimated lost revenue from use of the new weights and new assessment schedule versus use of the current weights and schedule.

- Effective July 1, 2007, DHS shall adjust rates based on data for October 1, 2006, to March 31, 2007, again comparing revenue under the new weights and assessment schedule with expected revenue under the old weights and schedule. This adjustment is available both for facilities that received an interim rate adjustment and for facilities that did not receive the interim adjustment but did experience a loss in revenue due to the new weights and the new assessment schedule.
- For facilities that did receive an interim rate adjustment on October 1, 2006, if the revenue loss determined for the period October 1, 2006, to March 31, 2007, exceeds the interim rate adjustment, those facilities receive a retroactive payment to make up the difference for the period October 1, 2006, to June 30, 2007.

DG:rdr

Senators Sams and Solon introduced--

S.F. No. 3318: Referred to the Committee on Health and Family Security.

A bill for an act

1.2 relating to human services; requiring quarterly resident assessments; modifying
1.3 case mix indices for nursing facility reimbursement; providing certain facilities
1.4 with rate adjustments; amending Minnesota Statutes 2004, sections 144.0724,
1.5 subdivision 4; 256B.438, subdivision 4, by adding a subdivision.

1.6 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

1.7 Section 1. Minnesota Statutes 2004, section 144.0724, subdivision 4, is amended to
1.8 read:

1.9 Subd. 4. **Resident assessment schedule.** (a) A facility must conduct and
1.10 electronically submit to the commissioner of health case mix assessments that conform
1.11 with the assessment schedule defined by Code of Federal Regulations, title 42, section
1.12 483.20, and published by the United States Department of Health and Human Services,
1.13 Centers for Medicare and Medicaid Services, in the Long Term Care Assessment
1.14 Instrument User's Manual, version 2.0, October 1995, and subsequent clarifications made
1.15 in the Long-Term Care Assessment Instrument Questions and Answers, version 2.0,
1.16 August 1996. The commissioner of health may substitute successor manuals or question
1.17 and answer documents published by the United States Department of Health and Human
1.18 Services, Centers for Medicare and Medicaid Services, to replace or supplement the
1.19 current version of the manual or document.

1.20 (b) The assessments used to determine a case mix classification for reimbursement
1.21 include the following:

1.22 (1) a new admission assessment must be completed by day 14 following admission;

1.23 (2) an annual assessment must be completed within 366 days of the last

1.24 comprehensive assessment;

2.1 (3) a significant change assessment must be completed within 14 days of the
2.2 identification of a significant change; and

2.3 (4) ~~the second quarterly assessment following either a new admission assessment, an~~
2.4 ~~annual assessment, or a significant change assessment~~ all quarterly assessments following
2.5 a new admission assessment, a quarterly assessment, an annual assessment, or a significant
2.6 change assessment. Each quarterly assessment must be completed within 92 days of
2.7 the previous assessment.

2.8 **EFFECTIVE DATE.** This section is effective October 1, 2006.

2.9 Sec. 2. Minnesota Statutes 2004, section 256B.438, subdivision 4, is amended to read:

2.10 **Subd. 4. Resident assessment schedule.** (a) Nursing facilities shall conduct and
2.11 submit case mix assessments according to the schedule established by the commissioner
2.12 of health under section 144.0724, subdivisions 4 and 5.

2.13 (b) The resident reimbursement classifications established under section 144.0724,
2.14 subdivision 3, shall be effective the day of admission for new admission assessments. The
2.15 effective date for significant change assessments shall be the assessment reference date.
2.16 The effective date for annual and ~~second~~ all quarterly assessments shall be the first day of
2.17 the month following assessment reference date.

2.18 **EFFECTIVE DATE.** This section is effective October 1, 2006.

2.19 Sec. 3. Minnesota Statutes 2004, section 256B.438, is amended by adding a
2.20 subdivision to read:

2.21 **Subd. 8. New case mix indices.** (a) Effective with rates for the rate year beginning
2.22 October 1, 2006, the commissioner shall implement the case mix indices recommended
2.23 by the time study conducted under Laws 2001, First Special Session chapter 9, article 5,
2.24 section 35, paragraph (e). The commissioner shall implement the new case mix indices
2.25 as follows:

2.26 (1) The September 30, 2005, case mix component of the nursing facility operating
2.27 payment rate shall be multiplied by the new case mix indices to create 36 case mix
2.28 adjusted rates.

2.29 (2) The 36 case mix adjusted rates determined in clause (1), plus the noncase mix
2.30 component, shall be the 36 nursing facility operating payment rates.

2.31 (3) The rate increases authorized by sections 256B.431, subdivision 41, and
2.32 256B.441, subdivision 46, shall be applied to the rates determined under clause (2).

3.1 (b) The commissioner shall adjust the October 1, 2006, operating rates in paragraph
3.2 (a) for nursing facilities estimated to receive a decrease in operating revenue. The rate
interim adjustment is established as follows:

3.4 (1) The commissioner shall use the minimum data set to classify private and medical
3.5 assistance patient days by RUG classification for the rate year ending June 30, 2006,
3.6 according to both the case mix indices and resident assessment schedule to be used on
3.7 September 30, 2006, and the case mix indices and resident assessment schedule to be
3.8 used on October 1, 2006.

3.9 (2) The commissioner shall use the resident days in clause (1) and the nursing
3.10 facility's October 1, 2006, unadjusted operating payment rate to estimate operating
3.11 revenue according to both the case mix indices and resident assessment schedule to be
3.12 used on September 30, 2006, and the case mix indices and resident assessment schedule
to be used on October 1, 2006.

3.14 (3) The estimated operating revenue determined with the case mix indices and
3.15 resident assessment schedule to be used on September 30, 2006, minus the operating
3.16 revenue determined with the case mix indices and resident assessment schedule to be
3.17 used on October 1, 2006, shall equal the decrease in medical assistance and private pay
3.18 operating revenue.

3.19 (4) Facilities with an estimated decrease in clause (3) shall receive an interim rate
3.20 adjustment equal to the value determined in clause (3) divided by the medical assistance
3.21 and private pay resident days in clause (1).

3.22 (5) The interim rate adjustment shall be in effect from October 1, 2006, through
3.23 June 30, 2007, and shall not be part of a facility's operating payment rate after June 30,
3.24 2007. The interim rate adjustment shall be applied to the case mix portion of the facility
3.25 operating rate.

3.26 (6) The commissioner, by August 15, 2006, shall provide nursing facilities which
3.27 the commissioner has estimated will experience a decrease in operating revenue, with
3.28 written notice that specifies the amount of the estimated decrease in operating revenue
3.29 and the amount of the interim rate adjustment. Nursing facilities shall have 30 days to
3.30 decline the interim rate adjustment.

3.31 (c) The commissioner shall adjust the July 1, 2007, operating rates of facilities
3.32 receiving the interim rate adjustments in paragraph (b) and facilities that demonstrate a
3.33 decrease in operating revenue from the implementation of the case mix indices and use of
all quarterly assessments. The adjustment is calculated as follows:

3.35 (1) Facilities that received the interim rate adjustment in paragraph (b) shall report
3.36 to the commissioner the number of medical assistance and private pay resident days

4.1 by RUG classification for the six-month period October 1, 2006, through March 31,
4.2 2007, according to both the case mix indices and resident assessment schedule used on
4.3 September 30, 2006, and the case mix indices and resident assessment schedule used on
4.4 October 1, 2006. A facility not receiving the rate adjustment in paragraph (b) that had a
4.5 decrease in operating revenue resulting from implementation of the new case mix indices
4.6 and the use of quarterly assessments may report to the commissioner the number of
4.7 medical assistance and private pay resident days by RUG classification for the six-month
4.8 period October 1, 2006, through March 31, 2007, according to both the case mix indices
4.9 and resident assessment schedule used on September 30, 2006, and the case mix indices
4.10 and resident assessment schedule used on October 1, 2006. Nursing facilities shall submit
4.11 the required information to the commissioner by May 15, 2007, in the manner specified by
4.12 the commissioner.

4.13 (2) The commissioner shall use the resident days reported in clause (1) and the
4.14 nursing facility's October 1, 2006, unadjusted operating payment rate to determine
4.15 operating revenue under both the case mix indices and resident assessment schedule
4.16 used on September 30, 2006, and the case mix indices and resident assessment schedule
4.17 used on October 1, 2006.

4.18 (3) The operating revenue determined using the case mix indices and resident
4.19 assessment schedule used on September 30, 2006, minus the operating revenue determined
4.20 using the case mix indices and resident assessment schedule used on October 1, 2006,
4.21 shall equal the decrease in operating revenue.

4.22 (4) The July 1, 2007, operating payment rate adjustment shall be the decrease in
4.23 operating revenue determined in clause (3) divided by the total medical assistance and
4.24 private pay days reported in clause (1) for the six-month period October 1, 2006, through
4.25 March 31, 2007. The operating payment rate adjustment shall be applied to the case
4.26 mix portion of the facility operating rate.

4.27 (5) If the amount determined in clause (4) is greater than the amount determined
4.28 under paragraph (b), clause (4), the commissioner shall retroactively pay to nursing
4.29 facilities the difference between the two amounts for all paid medical assistance days
4.30 between October 1, 2006, to June 30, 2007.

4.31 **EFFECTIVE DATE.** This section is effective July 1, 2006.

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**S.F. No. 2890 - Nursing Facility Rate Increase for
Sprinkler Systems or to Meet Life Safety Code Standards**

Author: Senator Linda Berglin

Prepared by: David Giel, Senate Research (296-7178)



Date: April 3, 2006

S.F. No. 2890 provides a nursing facility property payment rate increase effective July 1, 2006, to facilities reimbursed under the alternative payment system for the costs of (1) installing a partial or complete sprinkler system, or (2) complying with the 2000 edition of the Life Safety Code Standards and other applicable standards. A building project completed after 2004 does not need to meet the minimum cost threshold in current law in order to qualify for this rate increase.

DG:rdr

Senator Berglin introduced-

S.F. No. 2890: Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; allowing nursing facilities to receive reimbursement for building projects related to sprinkler systems or compliance with Life Safety Code Standards; amending Minnesota Statutes 2005 Supplement, section 256B.434, subdivision 4.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2005 Supplement, section 256B.434, subdivision 4, is amended to read:

Subd. 4. **Alternate rates for nursing facilities.** (a) For nursing facilities which have their payment rates determined under this section rather than section 256B.431, the commissioner shall establish a rate under this subdivision. The nursing facility must enter into a written contract with the commissioner.

(b) A nursing facility's case mix payment rate for the first rate year of a facility's contract under this section is the payment rate the facility would have received under section 256B.431.

(c) A nursing facility's case mix payment rates for the second and subsequent years of a facility's contract under this section are the previous rate year's contract payment rates plus an inflation adjustment and, for facilities reimbursed under this section or section 256B.431, an adjustment to include the cost of any increase in Health Department licensing fees for the facility taking effect on or after July 1, 2001. The index for the inflation adjustment must be based on the change in the Consumer Price Index-All Items (United States City average) (CPI-U) forecasted by the commissioner of finance's national economic consultant, as forecasted in the fourth quarter of the calendar year preceding the rate year. The inflation adjustment must be based on the 12-month period from the midpoint of the previous rate year to the midpoint of the rate year for which the rate is

2.1 being determined. For the rate years beginning on July 1, 1999, July 1, 2000, July 1, 2001,
2.2 July 1, 2002, July 1, 2003, July 1, 2004, July 1, 2005, July 1, 2006, July 1, 2007, and July
2.3 1, 2008, this paragraph shall apply only to the property-related payment rate, except
2.4 that adjustments to include the cost of any increase in Health Department licensing fees
2.5 taking effect on or after July 1, 2001, shall be provided. Beginning in 2005, adjustment to
2.6 the property payment rate under this section and section 256B.431 shall be effective on
2.7 October 1. In determining the amount of the property-related payment rate adjustment
2.8 under this paragraph, the commissioner shall determine the proportion of the facility's
2.9 rates that are property-related based on the facility's most recent cost report. Beginning
2.10 October 1, 2006, facilities reimbursed under this section shall be allowed to receive a
2.11 property rate adjustment for building projects under section 144A.071, subdivision 2.

2.12 (d) Effective July 1, 2006, facilities reimbursed under this section shall be allowed
2.13 to receive a property rate adjustment for building projects under section 144A.071,
2.14 subdivision 2, and the threshold in section 256B.431, subdivision 16, does not apply if the
2.15 building project was completed on or after January 1, 2005, and:

2.16 (1) was to install a partial or complete sprinkler system; or

2.17 (2) was necessary for the facility to comply with the 2000 edition of the Life Safety
2.18 Code Standards (NFPA 101) and other standards applicable by reference.

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**S.F. No. 3146 - Nursing Facility Planned Closure Rate
Adjustments (the A-1 Delete-Everything Amendment)**

Author: Senator Linda Berglin

Prepared by: David Giel, Senate Research (296-7178)



Date: April 3, 2006

S.F. No. 3146 modifies the process governing nursing facility resident relocations. It also removes the \$2,080 per bed limit on planned closure rate adjustments.

Section 1 (144A.161) modifies nursing facility resident relocation requirements.

Subdivision 1 amends the definition of "local agency" to refer instead to "county social services agency."

Subdivision 1a outlines the scope of the resident relocation language. A facility undertaking a closure, curtailment, reduction, or change in operations and the county social services agency must comply.

Subdivision 2 requires a facility that has given initial notice of its intent to close or modify operations to inform prospective residents prior to admission of its intentions.

Subdivision 3 requires the relocation plan developed by the facility and the county to identify the steps they will take to address the relocation needs of residents who may be difficult to place due to specialized care needs.

Subdivision 4 is technical.

Subdivision 5 modifies and expands the requirement for facilities to provide certain information to the county about each resident to be relocated.

Subdivisions 5a to 5g make technical changes or are unchanged.

Subdivision 6 requires weekly rather than biweekly status reports from the facility during relocation.

Subdivision 7 is unchanged.

Subdivision 8 places limits on the existing county responsibility to visit residents who are relocated to within 100 miles of the county within 30 days after the relocation. The requirement does not apply to instances when the facility moves to a new location and residents choose to move to that location. The requirement also does not apply to residents admitted after the notice of closure and discharged prior to closure.

Subdivisions 9 to 11 are unchanged.

Section 2 (256B.437, subdivision 3) removes the \$2,080 limit on planned closure rate adjustments negotiated after March 1, 2006. This section also provides that the removal of this limit does not trigger a recalculation of previously negotiated rate adjustments.

DG:rdr

Senator Berglin introduced-

S.F. No. 3146: Referred to the Committee on Health and Family Security.

A bill for an act
relating to human services; removing the limit on certain nursing facility planned
closure rate adjustments; amending Minnesota Statutes 2004, section 256B.437,
subdivision 3.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2004, section 256B.437, subdivision 3, is amended to
read:

Subd. 3. Applications for planned closure of nursing facilities. (a) By August
15, 2001, the commissioner of human services shall implement and announce a program
for closure or partial closure of nursing facilities. Names and identifying information
provided in response to the announcement shall remain private unless approved, according
to the timelines established in the plan. The announcement must specify:

(1) the criteria in subdivision 4 that will be used by the commissioner to approve or
reject applications;

(2) the information that must accompany an application; and

(3) that applications may combine planned closure rate adjustments with moratorium
exception funding, in which case a single application may serve both purposes.

Between August 1, 2001, and June 30, 2003, the commissioner may approve planned
closures of up to 5,140 nursing facility beds, less the number of beds delicensed in
facilities during the same time period without approved closure plans or that have notified
the commissioner of health of their intent to close without an approved closure plan.

Beginning July 1, 2004, the commissioner may negotiate a planned closure rate adjustment
for nursing facilities providing the proposal has no cost to the state. For planned closure
rate adjustments negotiated after March 1, 2006, the limit of \$2,080 in subdivision 6,

2.1 paragraph (a), clause (1), shall not apply. The removal of the limit in subdivision 6,
2.2 paragraph (a), clause (1), shall not constitute an increase to the amount specified in
2.3 subdivision 6, paragraph (a), clause (1), for the purposes of subdivision 6, paragraph (f).

2.4 (b) A facility or facilities reimbursed under section 256B.431 or 256B.434 with a
2.5 closure plan approved by the commissioner under subdivision 5 may assign a planned
2.6 closure rate adjustment to another facility or facilities that are not closing or in the case of
2.7 a partial closure, to the facility undertaking the partial closure. A facility may also elect to
2.8 have a planned closure rate adjustment shared equally by the five nursing facilities with
2.9 the lowest total operating payment rates in the state development region designated under
2.10 section 462.385, in which the facility that is closing is located. The planned closure
2.11 rate adjustment must be calculated under subdivision 6. Facilities that delicense beds
2.12 without a closure plan, or whose closure plan is not approved by the commissioner, are not
2.13 eligible to assign a planned closure rate adjustment under subdivision 6, unless they are
2.14 delicensing five or fewer beds, or less than six percent of their total licensed bed capacity,
2.15 whichever is greater, are located in a county in the top three quartiles of beds per 1,000
2.16 persons aged 65 or older, and have not delicensed beds in the prior three months. Facilities
2.17 meeting these criteria are eligible to assign the amount calculated under subdivision 6 to
2.18 themselves. If a facility is delicensing the greater of six or more beds, or six percent or
2.19 more of its total licensed bed capacity, and does not have an approved closure plan or is
2.20 not eligible for the adjustment under subdivision 6, the commissioner shall calculate the
2.21 amount the facility would have been eligible to assign under subdivision 6, and shall use
2.22 this amount to provide equal rate adjustments to the five nursing facilities with the lowest
2.23 total operating payment rates in the state development region designated under section
2.24 462.385, in which the facility that delicensed beds is located.

2.25 (c) To be considered for approval, an application must include:

2.26 (1) a description of the proposed closure plan, which must include identification of
2.27 the facility or facilities to receive a planned closure rate adjustment;

2.28 (2) the proposed timetable for any proposed closure, including the proposed dates
2.29 for announcement to residents, commencement of closure, and completion of closure;

2.30 (3) if available, the proposed relocation plan for current residents of any facility
2.31 designated for closure. If a relocation plan is not available, the application must include a
2.32 statement agreeing to develop a relocation plan designed to comply with section 144A.161;

2.33 (4) a description of the relationship between the nursing facility that is proposed for
2.34 closure and the nursing facility or facilities proposed to receive the planned closure rate
2.35 adjustment. If these facilities are not under common ownership, copies of any contracts,

3.1 purchase agreements, or other documents establishing a relationship or proposed
3.2 relationship must be provided;

3.4 (5) documentation, in a format approved by the commissioner, that all the nursing
3.5 facilities receiving a planned closure rate adjustment under the plan have accepted joint
3.6 and several liability for recovery of overpayments under section 256B.0641, subdivision
3.7 2, for the facilities designated for closure under the plan; and

3.8 (6) an explanation of how the application coordinates with planning efforts under
3.9 subdivision 2. If the planning group does not support a level of nursing facility closures
3.10 that the commissioner considers to be reasonable, the commissioner may approve a
3.11 planned closure proposal without its support.

3.12 (d) The application must address the criteria listed in subdivision 4.

EFFECTIVE DATE. This section is effective retroactively from March 1, 2006.

1.1 Senator moves to amend S.F. No. 3146 as follows:

Delete everything after the enacting clause and insert:

1.3 "Section 1. Minnesota Statutes 2004, section 144A.161, is amended to read:

1.4 **144A.161 NURSING FACILITY HOME AND BOARD AND CARE HOME**
1.5 **RESIDENT RELOCATION.**

1.6 Subdivision 1. **Definitions.** The definitions in this subdivision apply to subdivisions
1.7 2 to 10.

1.8 (a) "Closure" means the cessation of operations of a facility and the delicensure and
1.9 decertification of all beds within the facility.

1.10 (b) "Curtailement," "reduction," or "change" refers to any change in operations which
1.11 would result in or encourage the relocation of residents.

1.12 (c) "Facility" means a nursing home licensed pursuant to this chapter, or a certified
1.13 boarding care home licensed pursuant to sections 144.50 to 144.56.

1.14 (d) "Licensee" means the owner of the facility or the owner's designee or the
1.15 commissioner of health for a facility in receivership.

1.16 (e) "~~Local agency~~" "County social services agency" means the county or multicounty
1.17 social service agency authorized under sections 393.01 and 393.07, as the agency
1.18 responsible for providing social services for the county in which the nursing home is
1.19 located.

1.20 (f) "Plan" means a process developed under subdivision 3, paragraph (b), for the
1.21 closure, curtailment, reduction, or change in operations in a facility and the subsequent
1.22 relocation of residents.

(g) "Relocation" means the discharge of a resident and movement of the resident to
1.24 another facility or living arrangement as a result of the closing, curtailment, reduction, or
1.25 change in operations of a nursing home or boarding care home.

1.26 Subd. 1a. Scope. A facility undertaking a closure, curtailment, reduction, or change
1.27 in operations and the county social services agency must comply with the requirements
1.28 of this section.

1.29 Subd. 2. **Initial notice from licensee.** (a) A licensee shall notify the following
1.30 parties in writing when there is an intent to close or curtail, reduce, or change operations
1.31 which would result in or encourage the relocation of residents:

- 1.32 (1) the commissioner of health;
- (2) the commissioner of human services;
- 1.34 (3) the ~~local~~ county social services agency;
- 1.35 (4) the Office of the Ombudsman for Older Minnesotans; and

2.1 (5) the Office of the Ombudsman for Mental Health and Mental Retardation.

2.2 (b) The written notice shall include the names, telephone numbers, facsimile
2.3 numbers, and e-mail addresses of the persons in the facility responsible for coordinating
2.4 the licensee's efforts in the planning process, and the number of residents potentially
2.5 affected by the closure or curtailment, reduction, or change in operations.

2.6 (c) After providing written notice under this section, and prior to admission, the
2.7 facility must fully inform prospective residents and their families of the intent to close
2.8 curtail, reduce, or change operations, and of the relocation plan.

2.9 Subd. 3. **Planning process.** (a) The ~~local~~ county social services agency shall,
2.10 within five working days of receiving initial notice of the licensee's intent to close or
2.11 curtail, reduce, or change operations, provide the licensee and all parties identified in
2.12 subdivision 2, paragraph (a), with the names, telephone numbers, facsimile numbers, and
2.13 e-mail addresses of those persons responsible for coordinating ~~local~~ county social services
2.14 agency efforts in the planning process.

2.15 (b) Within ten working days of receipt of the notice under paragraph (a), the ~~local~~
2.16 county social services agency and licensee shall meet to develop the relocation plan.
2.17 The ~~local~~ county social services agency shall inform the Departments of Health and
2.18 Human Services, the Office of the Ombudsman for Older Minnesotans, and the Office
2.19 of the Ombudsman for Mental Health and Mental Retardation of the date, time, and
2.20 location of the meeting so that their representatives may attend. The relocation plan
2.21 must be completed within 45 days of receipt of the initial notice. However, the plan may
2.22 be finalized on an earlier schedule agreed to by all parties. To the extent practicable,
2.23 consistent with requirements to protect the safety and health of residents, the commissioner
2.24 may authorize the planning process under this subdivision to occur concurrent with the
2.25 60-day notice required under subdivision 5a. The plan shall:

2.26 (1) identify the expected date of closure, curtailment, reduction, or change in
2.27 operations;

2.28 (2) outline the process for public notification of the closure, curtailment, reduction,
2.29 or change in operations;

2.30 (3) identify efforts that will be made to include other stakeholders in the relocation
2.31 process;

2.32 (4) outline the process to ensure 60-day advance written notice to residents, family
2.33 members, and designated representatives;

2.34 (5) present an aggregate description of the resident population remaining to be
2.35 relocated and the population's needs;

2.36 (6) outline the individual resident assessment process to be utilized;

3.1 (7) identify an inventory of available relocation options, including home and
 3.2 community-based services;

3.3 (8) identify a timeline for submission of the list identified in subdivision 5c,
 3.4 paragraph (b); ~~and~~

3.5 (9) identify a schedule for the timely completion of each element of the plan; and

3.6 (10) identify the steps the licensee and the county social services agency will take to
 3.7 address the relocation needs of individual residents who may be difficult to place due to
 3.8 specialized care needs such as behavioral health problems.

3.9 (c) All parties to the plan shall refrain from any public notification of the intent to
 3.10 close or curtail, reduce, or change operations until a relocation plan has been established.
 3.11 If the planning process occurs concurrently with the 60-day notice period, this requirement
 3.12 does not apply once 60-day notice is given.

3.13 **Subd. 4. Responsibilities of licensee for resident relocations.** The licensee shall
 3.14 provide for the safe, orderly, and appropriate relocation of residents. The licensee and
 3.15 facility staff shall cooperate with representatives from the ~~local~~ county social services
 3.16 agency, the Department of Health, the Department of Human Services, the Office of
 3.17 Ombudsman for Older Minnesotans, and ombudsman for mental health and mental
 3.18 retardation in planning for and implementing the relocation of residents.

3.19 **Subd. 5. Licensee responsibilities prior to relocation.** (a) The licensee shall
 3.20 establish an interdisciplinary team responsible for coordinating and implementing the
 3.21 plan. The interdisciplinary team shall include representatives from the ~~local~~ county social
 3.22 services agency, the Office of Ombudsman for Older Minnesotans, facility staff that
 provide direct care services to the residents, and facility administration.

3.24 (b) The licensee shall provide a ~~list~~ summary document to the ~~local~~ county social
 3.25 services agency that includes the following information on each resident to be relocated:

3.26 (1) name;

3.27 (2) date of birth;

3.28 (3) Social Security number;

3.29 (4) payment source and medical assistance identification number, if applicable;

3.30 (5) county of financial responsibility;

3.31 (6) date of admission to the facility;

3.32 ~~(5)~~ (7) all diagnoses; and

(8) the name of and contact information for the resident's physician;

3.34 ~~(6)~~ (9) the name and contact information for the resident's family or other designated
 3.35 representative;

3.36 (10) the names of and contact information for any case managers, if known; and

4.1 (11) information on the resident’s status related to commitment and probation.

4.2 (c) The licensee shall consult with the ~~local~~ county social services agency on the
4.3 availability and development of available resources and on the resident relocation process.

4.4 Subd. 5a. **Licensee responsibilities to provide notice.** At least 60 days before the
4.5 proposed date of closing, curtailment, reduction, or change in operations as agreed to in
4.6 the plan, the licensee shall send a written notice of closure or curtailment, reduction, or
4.7 change in operations to each resident being relocated, the resident’s family member or
4.8 designated representative, and the resident’s attending physician. The notice must include
4.9 the following:

4.10 (1) the date of the proposed closure, curtailment, reduction, or change in operations;

4.11 (2) the name, address, telephone number, facsimile number, and e-mail address
4.12 of the individual or individuals in the facility responsible for providing assistance and
4.13 information;

4.14 (3) notification of upcoming meetings for residents, families and designated
4.15 representatives, and resident and family councils to discuss the relocation of residents;

4.16 (4) the name, address, and telephone number of the ~~local~~ county social services
4.17 agency contact person; and

4.18 (5) the name, address, and telephone number of the Office of Ombudsman for Older
4.19 Minnesotans and the ombudsman for mental health and mental retardation.

4.20 The notice must comply with all applicable state and federal requirements for notice
4.21 of transfer or discharge of nursing home residents.

4.22 Subd. 5b. **Licensee responsibility regarding medical information.** The licensee
4.23 shall request the attending physician provide or arrange for the release of medical
4.24 information needed to update resident medical records and prepare all required forms
4.25 and discharge summaries.

4.26 Subd. 5c. **Licensee responsibility regarding placement information.** (a) The
4.27 licensee shall provide sufficient preparation to residents to ensure safe, orderly, and
4.28 appropriate discharge and relocation. The licensee shall assist residents in finding
4.29 placements that respond to personal preferences, such as desired geographic location.

4.30 (b) The licensee shall prepare a resource list with several relocation options for each
4.31 resident. The list must contain the following information for each relocation option,
4.32 when applicable:

4.33 (1) the name, address, and telephone and facsimile numbers of each facility with
4.34 appropriate, available beds or services;

4.35 (2) the certification level of the available beds;

5.1 (3) the types of services available; and
5.2 (4) the name, address, and telephone and facsimile numbers of appropriate available
5.3 home and community-based placements, services, and settings or other options for
5.4 individuals with special needs.

5.5 The list shall be made available to residents and their families or designated
5.6 representatives, and upon request to the Office of Ombudsman for Older Minnesotans,
5.7 the ombudsman for mental health and Mental Retardation, and the ~~local~~ county social
5.8 services agency.

5.9 (c) The Senior LinkAge line may make available via a Web site the name, address,
5.10 and telephone and facsimile numbers of each facility with available beds, the certification
5.11 level of the available beds, the types of services available, and the number of beds that are
5.12 available as updated daily by the listed facilities. The licensee must provide residents,
5.13 their families or designated representatives, the Office of the Ombudsman for Older
5.14 Minnesotans, the Office of the Ombudsman for Mental Health and Mental Retardation,
5.15 and the ~~local~~ county social services agency with the toll-free number and Web site address
5.16 for the Senior LinkAge line.

5.17 **Subd. 5d. Licensee responsibility to meet with residents and families.** Following
5.18 the establishment of the plan, the licensee shall conduct meetings with residents, families
5.19 and designated representatives, and resident and family councils to notify them of the
5.20 process for resident relocation. Representatives from the local county social services
5.21 agency, the Office of Ombudsman for Older Minnesotans, the ombudsman for mental
5.22 health and mental retardation, the commissioner of health, and the commissioner of
human services shall receive advance notice of the meetings.

5.24 **Subd. 5e. Licensee responsibility for site visits.** The licensee shall assist
5.25 residents desiring to make site visits to facilities with available beds or other appropriate
5.26 living options to which the resident may relocate, unless it is medically inadvisable,
5.27 as documented by the attending physician in the resident's care record. The licensee
5.28 shall provide or arrange transportation for site visits to facilities or other living options
5.29 within a 50-mile radius to which the resident may relocate, or within a larger radius if no
5.30 suitable options are available within 50 miles. The licensee shall provide available written
5.31 materials to residents on a potential new facility or living option.

5.32 **Subd. 5f. Licensee responsibility for personal property, personal funds, and**
telephone service. (a) The licensee shall complete an inventory of resident personal
5.34 possessions and provide a copy of the final inventory to the resident and the resident's
5.35 designated representative prior to relocation. The licensee shall be responsible for the

6.1 transfer of the resident's possessions for all relocations within a 50-mile radius of the
6.2 facility, or within a larger radius if no suitable options are available within 50 miles. The
6.3 licensee shall complete the transfer of resident possessions in a timely manner, but no later
6.4 than the date of the actual physical relocation of the resident.

6.5 (b) The licensee shall complete a final accounting of personal funds held in trust
6.6 by the facility and provide a copy of this accounting to the resident and the resident's
6.7 family or the resident's designated representative. The licensee shall be responsible for the
6.8 transfer of all personal funds held in trust by the facility. The licensee shall complete the
6.9 transfer of all personal funds in a timely manner.

6.10 (c) The licensee shall assist residents with the transfer and reconnection of service
6.11 for telephones or, for residents who are deaf or blind, other personal communication
6.12 devices or services. The licensee shall pay the costs associated with reestablishing service
6.13 for telephones or other personal communication devices or services, such as connection
6.14 fees or other one-time charges. The transfer or reconnection of personal communication
6.15 devices or services shall be completed in a timely manner.

6.16 **Subd. 5g. Licensee responsibilities for final notice and records transfer.** (a) The
6.17 licensee shall provide the resident, the resident's family or designated representative,
6.18 and the resident's attending physician final written notice prior to the relocation of the
6.19 resident. The notice must:

6.20 (1) be provided seven days prior to the actual relocation, unless the resident agrees
6.21 to waive the right to advance notice; and

6.22 (2) identify the date of the anticipated relocation and the destination to which the
6.23 resident is being relocated.

6.24 (b) The licensee shall provide the receiving facility or other health, housing, or
6.25 care entity with complete and accurate resident records including information on family
6.26 members, designated representatives, guardians, social service caseworkers, or other
6.27 contact information. These records must also include all information necessary to
6.28 provide appropriate medical care and social services. This includes, but is not limited
6.29 to, information on preadmission screening, Level I and Level II screening, minimum
6.30 data set (MDS), and all other assessments, resident diagnoses, social, behavioral, and
6.31 medication information.

6.32 (c) For residents with special care needs, the licensee shall consult with the receiving
6.33 facility or other placement entity and provide staff training or other preparation as needed
6.34 to assist in providing for the special needs.

6.35 **Subd. 6. Responsibilities of the licensee during relocation.** (a) The licensee
6.36 shall make arrangements or provide for the transportation of residents to the new facility

7.1 or placement within a 50-mile radius, or within a larger radius if no suitable options
 7.2 are available within 50 miles. The licensee shall provide a staff person to accompany
 7.3 the resident during transportation, upon request of the resident, the resident’s family, or
 7.4 designated representative. The discharge and relocation of residents must comply with all
 7.5 applicable state and federal requirements and must be conducted in a safe, orderly, and
 7.6 appropriate manner. The licensee must ensure that there is no disruption in providing
 7.7 meals, medications, or treatments of a resident during the relocation process.

7.8 (b) Beginning the week following development of the initial relocation plan, the
 7.9 licensee shall submit ~~biweekly~~ weekly status reports to the commissioners of health and
 7.10 human services or their designees and to the ~~local~~ county social services agency. The
 7.11 initial status report must identify:

- 7.12 (1) the relocation plan developed;
- (2) the interdisciplinary team members; and
- 7.14 (3) the number of residents to be relocated.
- 7.15 (c) Subsequent status reports must identify:
- 7.16 (1) any modifications to the plan;
- 7.17 (2) any change of interdisciplinary team members;
- 7.18 (3) the number of residents relocated;
- 7.19 (4) the destination to which residents have been relocated;
- 7.20 (5) the number of residents remaining to be relocated; and
- 7.21 (6) issues or problems encountered during the process and resolution of these issues.

7.22 **Subd. 7. Responsibilities of the licensee following relocation.** The licensee shall
 7.23 retain or make arrangements for the retention of all remaining resident records for the
 7.24 period required by law. The licensee shall provide the Department of Health access to
 7.25 these records. The licensee shall notify the Department of Health of the location of any
 7.26 resident records that have not been transferred to the new facility or other health care entity.

7.27 **Subd. 8. Responsibilities of ~~local~~ county social services agency.** (a) The ~~local~~
 7.28 county social services agency shall participate in the meeting as outlined in subdivision 3,
 7.29 paragraph (b), to develop a relocation plan.

7.30 (b) The ~~local~~ county social services agency shall designate a representative to
 7.31 the interdisciplinary team established by the licensee responsible for coordinating the
 7.32 relocation efforts.

7.33 (c) The ~~local~~ county social services agency shall serve as a resource in the relocation
 7.34 process.

8.1 (d) Concurrent with the notice sent to residents from the licensee as provided in
8.2 subdivision 5a, the ~~local~~ county social services agency shall provide written notice to
8.3 residents, family, or designated representatives describing:

8.4 (1) the county's role in the relocation process and in the follow-up to relocations;

8.5 (2) a ~~local~~ county social services agency contact name, address, and telephone
8.6 number; and

8.7 (3) the name, address, and telephone number of the Office of Ombudsman for Older
8.8 Minnesotans and the ombudsman for mental health and mental retardation.

8.9 (e) The ~~local~~ county social services agency designee shall meet with appropriate
8.10 facility staff to coordinate any assistance in the relocation process. This coordination
8.11 shall include participating in group meetings with residents, families, and designated
8.12 representatives to explain the relocation process.

8.13 (f) The ~~local~~ county social services agency shall monitor compliance with all
8.14 components of the plan. If the licensee is not in compliance, the local agency shall notify
8.15 the commissioners of the Departments of Health and Human Services.

8.16 (g) Except as requested by the resident, family member, or designated representative
8.17 and within the parameters of the Vulnerable Adults Act, the local agency may halt a
8.18 relocation that it deems inappropriate or dangerous to the health or safety of a resident. The
8.19 ~~local~~ county social services agency shall pursue remedies to protect the resident during the
8.20 relocation process, including, but not limited to, assisting the resident with filing an appeal
8.21 of transfer or discharge, notification of all appropriate licensing boards and agencies, and
8.22 other remedies available to the county under section 626.557, subdivision 10.

8.23 (h) A member of the ~~local~~ county social services agency staff shall visit residents
8.24 relocated within 100 miles of the county within 30 days after the relocation. ~~Local~~ This
8.25 requirement does not apply to changes in operation where the facility moved to a new
8.26 location and residents chose to move to that new location. The requirement also does not
8.27 apply to residents admitted after the notice of closure and discharged prior to the actual
8.28 closure. County social services agency staff shall interview the resident and family or
8.29 designated representative, observe the resident on site, and review and discuss pertinent
8.30 medical or social records with appropriate facility staff to:

8.31 (1) assess the adjustment of the resident to the new placement;

8.32 (2) recommend services or methods to meet any special needs of the resident; and

8.33 (3) identify residents at risk.

8.34 (i) The ~~local~~ county social services agency may conduct subsequent follow-up visits
8.35 in cases where the adjustment of the resident to the new placement is in question.

9.1 (j) Within 60 days of the completion of the follow-up visits, the ~~local~~ county social
 9.2 services agency shall submit a written summary of the follow-up work to the Departments
 9.3 of Health and Human Services in a manner approved by the commissioners.

9.4 (k) The ~~local~~ county social services agency shall submit to the Departments of Health
 9.5 and Human Services a report of any issues that may require further review or monitoring.

9.6 (l) The ~~local~~ county social services agency shall be responsible for the safe and
 9.7 orderly relocation of residents in cases where an emergent need arises or when the licensee
 9.8 has abrogated its responsibilities under the plan.

9.9 Subd. 9. **Penalties.** Upon the recommendation of the commissioner of health,
 9.10 the commissioner of human services may eliminate a closure rate adjustment under
 9.11 subdivision 10 for violations of this section.

9.12 Subd. 10. **Facility closure rate adjustment.** Upon the request of a closing facility,
 9.13 the commissioner of human services must allow the facility a closure rate adjustment
 9.14 equal to a 50 percent payment rate increase to reimburse relocation costs or other
 9.15 costs related to facility closure. This rate increase is effective on the date the facility's
 9.16 occupancy decreases to 90 percent of capacity days after the written notice of closure is
 9.17 distributed under subdivision 5 and shall remain in effect for a period of up to 60 days.
 9.18 The commissioner shall delay the implementation of rate adjustments under section
 9.19 256B.437, subdivisions 3, paragraph (b), and 6, paragraph (a), to offset the cost of this
 9.20 rate adjustment.

9.21 Subd. 11. **County costs.** The commissioner of human services shall allocate up
 9.22 to \$450 in total state and federal funds per nursing facility bed that is closing, within
 9.23 the limits of the appropriation specified for this purpose, to be used for relocation costs
 9.24 incurred by counties for resident relocation under this section or planned closures under
 9.25 section 256B.437. To be eligible for this allocation, a county in which a nursing facility
 9.26 closes must provide to the commissioner a detailed statement in a form provided by the
 9.27 commissioner of additional costs, not to exceed \$450 in total state and federal funds per
 9.28 bed closed, that are directly incurred related to the county's role in the relocation process.

9.29 Sec. 2. Minnesota Statutes 2004, section 256B.437, subdivision 3, is amended to read:

9.30 Subd. 3. **Applications for planned closure of nursing facilities.** (a) By August
 9.31 15, 2001, the commissioner of human services shall implement and announce a program
 9.32 for closure or partial closure of nursing facilities. Names and identifying information
 9.33 provided in response to the announcement shall remain private unless approved, according
 9.34 to the timelines established in the plan. The announcement must specify:

10.1 (1) the criteria in subdivision 4 that will be used by the commissioner to approve or
10.2 reject applications;

10.3 (2) the information that must accompany an application; and

10.4 (3) that applications may combine planned closure rate adjustments with moratorium
10.5 exception funding, in which case a single application may serve both purposes.

10.6 Between August 1, 2001, and June 30, 2003, the commissioner may approve planned
10.7 closures of up to 5,140 nursing facility beds, less the number of beds delicensed in
10.8 facilities during the same time period without approved closure plans or that have notified
10.9 the commissioner of health of their intent to close without an approved closure plan.

10.10 Beginning July 1, 2004, the commissioner may negotiate a planned closure rate adjustment
10.11 for nursing facilities providing the proposal has no cost to the state. For planned closure
10.12 rate adjustments negotiated after March 1, 2006, the limit of \$2,080 in subdivision 6,
10.13 paragraph (a), clause (1), shall not apply. The removal of the limit in subdivision 6,
10.14 paragraph (a), clause (1), shall not constitute an increase to the amount specified in
10.15 subdivision 6, paragraph (a), clause (1), for the purposes of subdivision 6, paragraph (f).

10.16 (b) A facility or facilities reimbursed under section 256B.431 or 256B.434 with a
10.17 closure plan approved by the commissioner under subdivision 5 may assign a planned
10.18 closure rate adjustment to another facility or facilities that are not closing or in the case of
10.19 a partial closure, to the facility undertaking the partial closure. A facility may also elect to
10.20 have a planned closure rate adjustment shared equally by the five nursing facilities with
10.21 the lowest total operating payment rates in the state development region designated under
10.22 section 462.385, in which the facility that is closing is located. The planned closure
10.23 rate adjustment must be calculated under subdivision 6. Facilities that delicense beds
10.24 without a closure plan, or whose closure plan is not approved by the commissioner, are not
10.25 eligible to assign a planned closure rate adjustment under subdivision 6, unless they are
10.26 delicensing five or fewer beds, or less than six percent of their total licensed bed capacity,
10.27 whichever is greater, are located in a county in the top three quartiles of beds per 1,000
10.28 persons aged 65 or older, and have not delicensed beds in the prior three months. Facilities
10.29 meeting these criteria are eligible to assign the amount calculated under subdivision 6 to
10.30 themselves. If a facility is delicensing the greater of six or more beds, or six percent or
10.31 more of its total licensed bed capacity, and does not have an approved closure plan or is
10.32 not eligible for the adjustment under subdivision 6, the commissioner shall calculate the
10.33 amount the facility would have been eligible to assign under subdivision 6, and shall use
10.34 this amount to provide equal rate adjustments to the five nursing facilities with the lowest
10.35 total operating payment rates in the state development region designated under section
10.36 462.385, in which the facility that delicensed beds is located.

- 11.1 (c) To be considered for approval, an application must include:
- 11.2 (1) a description of the proposed closure plan, which must include identification of
- 11.3 the facility or facilities to receive a planned closure rate adjustment;
- 11.4 (2) the proposed timetable for any proposed closure, including the proposed dates
- 11.5 for announcement to residents, commencement of closure, and completion of closure;
- 11.6 (3) if available, the proposed relocation plan for current residents of any facility
- 11.7 designated for closure. If a relocation plan is not available, the application must include a
- 11.8 statement agreeing to develop a relocation plan designed to comply with section 144A.161;
- 11.9 (4) a description of the relationship between the nursing facility that is proposed for
- 11.10 closure and the nursing facility or facilities proposed to receive the planned closure rate
- 11.11 adjustment. If these facilities are not under common ownership, copies of any contracts,
- 11.12 purchase agreements, or other documents establishing a relationship or proposed
- 3 relationship must be provided;
- 11.14 (5) documentation, in a format approved by the commissioner, that all the nursing
- 11.15 facilities receiving a planned closure rate adjustment under the plan have accepted joint
- 11.16 and several liability for recovery of overpayments under section 256B.0641, subdivision
- 11.17 2, for the facilities designated for closure under the plan; and
- 11.18 (6) an explanation of how the application coordinates with planning efforts under
- 11.19 subdivision 2. If the planning group does not support a level of nursing facility closures
- 11.20 that the commissioner considers to be reasonable, the commissioner may approve a
- 11.21 planned closure proposal without its support.
- 11.22 (d) The application must address the criteria listed in subdivision 4.

EFFECTIVE DATE. This section is effective retroactively from March 1, 2006.

1.1 Senator moves to amend the delete-everything amendment
1.2 (SCS3146A-1) to S.F. No. 3146 as follows:

1.3 Page 9, after line 28, insert:

1.4 "Sec. 2. Minnesota Statutes 2005 Supplement, section 256B.0918, subdivision 1,
1.5 is amended to read:

1.6 Subdivision 1. **Program criteria.** Beginning on or after October 1, 2005, within
1.7 the limits of appropriations specifically available for this purpose, the commissioner shall
1.8 provide funding to qualified provider applicants for employee scholarships for education
1.9 in nursing and other health care fields. Employee scholarships must be for a course of
1.10 study that is expected to lead to career advancement with the provider or in the field
1.11 of long-term care, including home care or care of persons with disabilities, or nursing.
1.12 Providers that secure this funding must use it to award scholarships to employees who
1.13 work an average of at least 20 hours per week for the provider. Executive management
1.14 staff without direct care duties, registered nurses, and therapists are not eligible to receive
1.15 scholarships under this section.

1.16 Sec. 3. Minnesota Statutes 2005 Supplement, section 256B.0918, subdivision 3,
1.17 is amended to read:

1.18 Subd. 3. **Provider selection criteria.** To be considered for scholarship funding,
1.19 the provider shall submit a completed application within the time frame specified by the
1.20 commissioner. In awarding funding, the commissioner shall consider the following:

- 1.21 (1) the size of the provider as measured in annual billing to the medical assistance
1.22 program. To be eligible, a provider must receive at least ~~\$500,000~~ \$300,000 annually
1.23 in medical assistance payments;
- 1.24 (2) the percentage of employees meeting the scholarship program recipient
1.25 requirements;
- 1.26 (3) staff retention rates for paraprofessionals; and
- 1.27 (4) other criteria determined by the commissioner.

1.28 Sec. 4. Minnesota Statutes 2005 Supplement, section 256B.0918, subdivision 4,
1.29 is amended to read:

1.30 Subd. 4. **Funding specifics.** Within the limits of appropriations specifically
1.31 available for this purpose, for the rate period beginning on or after October 1, 2005, to
1.32 September 30, 2007, the commissioner shall provide to each provider listed in subdivision
33 2 and awarded funds under subdivision 3 a medical assistance rate increase to fund
1.34 scholarships up to ~~two-tenths~~ three-tenths percent of the medical assistance reimbursement
1.35 rate. The commissioner shall require providers to repay any portion of funds awarded

2.1 under subdivision 3 that is not used to fund scholarships. If applications exceed available
 2.2 funding, funding shall be targeted to providers that employ a higher percentage of
 2.3 paraprofessional staff or have lower rates of turnover of paraprofessional staff. During
 2.4 the subsequent years of the program, the rate adjustment may be recalculated, at the
 2.5 discretion of the commissioner. In making a recalculation the commissioner may consider
 2.6 the provider's success at granting scholarships based on the amount spent during the
 2.7 previous year and the availability of appropriations to continue the program."

2.8 Page 11, after line 23 insert:

2.9 "Sec. 6. Laws 2005, First Special Session chapter 4, article 9, section 5, subdivision
 2.10 8, is amended to read:

2.11	Subd. 8. Board of Nursing	3,078,000	3,631,000
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2.12 **BASE ADJUSTMENT.** The base for the
 2.13 board of nursing is increased by \$141,000
 2.14 in fiscal year 2008 and by \$216,000 in fiscal
 2.15 year 2009.

2.16 **BOARD OF NURSING**

2.17 **APPROPRIATIONS INCREASE.** Of
 2.18 this appropriation, \$120,000 the first year
 2.19 and \$126,000 the second year are for the
 2.20 increased cost of board operations, excluding
 2.21 salary increases and \$85,000 each year is to
 2.22 hire an advanced practice registered nurse.

2.23 **TRANSFERS FROM SPECIAL**

2.24 **REVENUE FUND.** Of this appropriation,
 2.25 the following transfers shall be made as
 2.26 directed from the state government special
 2.27 revenue fund:

2.28 (a) \$392,000 in fiscal year 2006, \$864,000
 2.29 in fiscal year 2007, \$930,000 in fiscal year
 2.30 2008, and \$930,000 in fiscal year 2009
 2.31 shall be transferred to the general fund
 2.32 and is appropriated to the Department
 2.33 of Human Services to offset the state
 2.34 share of the medical assistance program
 2.35 costs of the long-term care and home and

3.1 community-based care employee scholarship
3.2 program and associated administrative costs.

3.3 At the end of each biennium, any funds
3.4 not expended for the scholarship program
3.5 and associated administrative costs shall
3.6 ~~be transferred to the state government~~
3.7 ~~special revenue fund~~ carried over to the
3.8 next biennium for the same purpose.

3.9 Notwithstanding section 15, this paragraph
3.10 expires June 30, ~~2009~~ 2011.

3.11 (b) \$125,000 the first year and \$200,000 the second year shall be transferred to the health
3.12 professional education loan forgiveness program account for loan forgiveness for nurses
3.13 under Minnesota Statutes, section 144.1501. This appropriation shall become part of base
3.14 level funding for the commissioner for the biennium beginning July 1, 2007, but shall not
3.15 be part of base level funding for the biennium beginning July 1, 2009. Notwithstanding
3.16 section 15, this paragraph expires on June 30, 2009. "

3.17 Renumber the sections in sequence and correct the internal references

3.18 Amend the title accordingly

1.1 Senator moves to amend the delete-everything amendment
1.2 (SCS3146A-1) to S.F. No. 3146 as follows:

Page 11, after line 23, insert:

1.4 "Sec. 3. Minnesota Statutes 2005 Supplement, section 626.557, subdivision 14,
1.5 is amended to read:

1.6 Subd. 14. **Abuse prevention plans.** (a) Each facility, except home health agencies
1.7 and personal care attendant services providers, shall establish and enforce an ongoing
1.8 written abuse prevention plan. The plan shall contain an assessment of the physical plant,
1.9 its environment, and its population identifying factors which may encourage or permit
1.10 abuse, and a statement of specific measures to be taken to minimize the risk of abuse. The
1.11 plan shall comply with any rules governing the plan promulgated by the licensing agency.

1.12 (b) Each facility, including a home health care agency and personal care attendant
1.13 services providers, shall develop an individual abuse prevention plan for each vulnerable
1.14 adult residing there or receiving services from them. The plan shall contain an
1.15 individualized assessment of: (1) the person's susceptibility to abuse by other individuals,
1.16 including other vulnerable adults; (2) the person's risk of abusing other vulnerable adults;
1.17 and (3) statements of the specific measures to be taken to minimize the risk of abuse to
1.18 that person and other vulnerable adults. For the purposes of this paragraph, the term
1.19 "abuse" includes self-abuse.

1.20 (c) If the facility, except home health agencies and personal care attendant services
1.21 providers, knows that the vulnerable adult has committed a violent crime or an act of
1.22 physical aggression toward others, the individual abuse prevention plan must detail the
1.23 measures to be taken to minimize the risk that the vulnerable adult might reasonably be
1.24 expected to pose to visitors to the facility ~~and persons outside the facility~~, if unsupervised.
1.25 Under this section, a facility knows of a vulnerable adult's history of criminal misconduct
1.26 or physical aggression if it receives such information from a law enforcement authority or
1.27 through a medical record prepared by another facility, another health care provider, or the
1.28 facility's ongoing assessments of the vulnerable adult."

1.29 Renumber the sections in sequence and correct the internal references

1.30 Amend the title accordingly

**Senate Counsel, Research,
and Fiscal Analysis**

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State of Minnesota

S.F. No. 2647 - Refusal to Dispense Prescription Drugs or Devices (Delete-Everything Amendment)

Author: Senator Sheila M. Kiscaden

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) *KTC*

Date: March 31, 2006

S.F. No. 2647 prohibits pharmacists from refusing to dispense a prescription drug or device pursuant to a valid prescription or order except under specific circumstances.

Section 1 (151.415) prohibits a pharmacist from refusing to dispense a legend drug or device pursuant to a valid prescription or order, except under specific circumstances.

Subdivision 1, paragraph (a), states that no pharmacist shall refuse to dispense or obstruct a patient in obtaining a legend drug or device that has been legally prescribed or ordered for that patient. States that a violation of this section shall constitute unprofessional conduct by the pharmacist, which may subject the pharmacist to disciplinary action by the Board of Pharmacy.

Paragraph (b) requires a pharmacist to dispense a drug or device pursuant to a lawful prescription or order unless one of these circumstances exists:

(1) based on the pharmacist's professional training and professional judgment dispensing the drug or device would adversely affect the known medical condition of the patient for whom the prescription or order was prescribed;

(2) the drug or device is not in stock. If this is the case then the pharmacist must:

(i) immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner;

(ii) promptly transfer the prescription to another pharmacy known to stock the drug or device that is near enough to the site to ensure the patient has timely access to the drug or device;
or

(iii) return the prescription to the patient and refer the patient to a pharmacy that stocks the prescribed drug or device to ensure that the patient has timely access to the drug or device;
or

(3) the pharmacist refuses to dispense on a sincerely held religious belief, as defined under title VII. If this is the case, the pharmacist may only refuse if the pharmacist's objection can be reasonably accommodated without imposing an undue hardship on the patient or the employer and the pharmacy has established protocols ensuring timely access to the prescribed drug or device. A pharmacy may require employees or potential employees to notify the pharmacy in writing of the categories or types of prescriptions the pharmacist refuses to dispense. In determining whether reasonable accommodations can be made, the following factors may be considered:

(i) whether the proposed accommodation ensures timely access to the drug or device as dictated by the patient's needs or known medical condition;

(ii) the employer's financial costs in implementing the accommodation; and

(iii) the potential impact on the pharmacy's reputation or good will in the community due to failure to timely prescription services.

Subdivision 2 states that this section imposes no duty on a pharmacist to dispense a drug or device without payment, including payment directly by the patient or through a third-party payer or the payment of any required co-payment by the patient.

KC:ph

Senators Kiscaden, Berglin and Solon introduced-

S.F. No. 2647: Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; prohibiting a pharmacist from refusing to dispense a prescription drug or device except under certain circumstances; proposing coding for new law in Minnesota Statutes, chapter 151.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [151.415] PROHIBITION AGAINST REFUSING TO DISPENSE A LEGEND DRUG OR DEVICE.

Subdivision 1. Prohibition. No pharmacist licensed under this chapter shall refuse to dispense a legend drug or device pursuant to a valid prescription or order except under one of the following circumstances:

(1) based on the pharmacist's professional training and judgment, the pharmacist determines that according to standard pharmacy practice, dispensing the drug or device pursuant to the prescription or order would cause a medical problem to the patient for whom the prescription or order was prescribed due to therapeutic duplications, drug-disease contraindications, drug interactions, including serious interactions with other prescription and over-the-counter medications, incorrect dosage or duration of drug treatment, drug allergy interactions, or drug abuse or misuse;

(2) the legend drug or device is not in stock, in which case, the pharmacist must offer the patient the following options and perform the option that is chosen by the patient without delay:

(i) the pharmacist will obtain the drug or device under the pharmacy's standard procedures for expedited ordering of any drug or device not in stock;

2.1 (ii) the pharmacist will locate a pharmacy or other health care facility of the patient's
2.2 choice that has the drug or device in stock and transfer the prescription under its standard
2.3 procedures for transferring prescriptions for drugs or devices; or

2.4 (iii) the unfilled prescription will be returned to the patient and the pharmacist will
2.5 refer the patient to the nearest pharmacy or other health care facility that has the drug or
2.6 device in stock; or

2.7 (3) the pharmacist refuses to dispense a drug or device on ethical, moral, or religious
2.8 grounds but only if reasonable accommodation of the pharmacist's refusal to dispense
2.9 can be made without causing undue hardship to the patient or employer. A pharmacy
2.10 shall require employees and prospective employees to notify the pharmacy in writing of
2.11 the categories or types of prescriptions that the pharmacist refuses to fill due to one of
2.12 these reasons. In determining whether reasonable accommodation can be made without
2.13 imposing an undue hardship on the patient or the employer, the following factors shall
2.14 be considered:

2.15 (i) whether the proposed accommodation would delay the filling of the prescription
2.16 such that the pharmacy is not able to fill the prescription in the equivalent time period as
2.17 the pharmacy would fill other prescriptions of in-stock drugs or devices;

2.18 (ii) the pharmacy's ability to fill the patient's prescription in store;

2.19 (iii) the pharmacy's financial costs in implementing the accommodation; and

2.20 (iv) the negative impact on the pharmacy's reputation or good will in the community
2.21 due to failure to provide timely prescription services.

2.22 Subd. 2. **Payment limitation.** This section imposes no duty on a pharmacist
2.23 to dispense a legend drug or device without payment for the drug or device, including
2.24 payment by the patient or through a third-party payer accepted by the pharmacy or
2.25 payment of any required co-payment owed by the patient.

2.26 Subd. 3. **Penalty.** Any pharmacist who violates this section shall be subject to
2.27 disciplinary action by the Board of Pharmacy according to this chapter.

1.1 Senator moves to amend S.F. No. 2647 as follows:

1.2 Delete everything after the enacting clause and insert:

1.3 "Section 1. [151.415] PROHIBITION AGAINST REFUSING TO DISPENSE A
1.4 LEGEND DRUG OR DEVICE.

1.5 Subdivision 1. Prohibition. (a) No pharmacist shall refuse to dispense or obstruct a
1.6 patient in obtaining a legend drug or device that has been legally prescribed or ordered
1.7 for that patient. A violation of this section constitutes unprofessional conduct by the
1.8 pharmacist and shall subject the pharmacist to disciplinary action by the Board of
1.9 Pharmacy.

1.10 (b) Notwithstanding any other provision of law, a pharmacist shall dispense drugs
1.11 and devices pursuant to a lawful order or prescription unless one of the following
1.12 circumstances exists:

1.13 (1) based solely on the pharmacist's professional training and judgment, dispensing
1.14 the drug or device pursuant to the prescription or order would adversely affect the known
1.15 medical condition of the patient for whom the prescription or order was prescribed due
1.16 to therapeutic duplications, drug-disease contraindications, drug interactions, including
1.17 serious interactions with other prescription and over-the-counter medications, incorrect
1.18 dosage or duration of drug treatment, drug allergy interactions, or drug abuse or misuse;

1.19 (2) the legend drug or device is not in stock. If an order or prescription cannot be
1.20 dispensed because the drug or device is not in stock, the pharmacist shall take one of the
1.21 following actions:

1.22 (i) immediately notify the patient and arrange for the drug or device to be delivered
23 to the site or directly to the patient in a timely manner;

1.24 (ii) promptly transfer the prescription to another pharmacy known to stock the drug
1.25 or device that is near enough to the site from which the prescription or order is transferred
1.26 to ensure the patient has timely access to the drug or device; or

1.27 (iii) return the prescription to the patient and refer the patient to a pharmacy that
1.28 stocks the prescribed drug or device to ensure that the patient has timely access to the
1.29 drug or device; or

1.30 (3) the pharmacist refuses on sincerely held religious beliefs as defined in United
1.31 States Code, title 42, section 2000e(j), to dispense a drug or device pursuant to an order
1.32 or prescription. A pharmacist may object to dispensing a drug or device on this basis
1.33 only if the pharmacist's objection can be reasonably accommodated without imposing
1.34 an undue hardship on the patient or the employer and the pharmacy has established
1.35 protocols that ensure that the patient has timely access to the prescribed drug or device
1.36 despite the pharmacist's refusal to dispense the order or prescription. A pharmacy may

2.1 require employees and prospective employees to notify the pharmacy in writing of the
2.2 categories or types of prescriptions that the pharmacist refuses to dispense due to one of
2.3 the above-stated grounds. In determining whether reasonable accommodation can be
2.4 made without imposing an undue hardship on the patient or the employer, the following
2.5 factors may be considered:

2.6 (i) whether the proposed accommodation ensures that the patient has timely access
2.7 to the drug or device as dictated by the patient's needs or known medical condition;

2.8 (ii) the employer's financial costs in implementing the accommodation; and

2.9 (iii) the potential impact on the pharmacy's reputation or good will in the community
2.10 due to failure to provide timely prescription services.

2.11 Subd. 2. Payment limitation. This section imposes no duty on a pharmacist to
2.12 dispense a drug or device pursuant to a prescription or order without payment for the
2.13 drug or device, including payment directly by the patient or through a third-party payer
2.14 accepted by the pharmacist or payment of any required co-payment by the patient. "



CONSCIENCE CLAUSE AND REFUSAL TO FILL PRESCRIPTIONS

PHARMACISTS' professional role is to improve medication use, ensure patients have access to medications and know how to make the best use of those medications. Much of a pharmacist's time is spent interacting with patients offering guidance and healthcare advice, as well as identifying possible drug interactions that could be harmful to a patient's health.

MPHA SUPPORTS LEGISLATION THAT:

- *Allows pharmacists to refuse to dispense prescriptions that are clinically inappropriate or would cause drug related problems according to MN rule 6800.3110.*
- *Allows the pharmacist to step away from dispensing a drug or device they have an ethical, religious or moral objection to.*
- *Requires a policy in place to protect patient access to legally valid prescriptions.*

SYSTEMS CAN BE DEVELOPED WHICH ALLOW PHARMACISTS TO CONSCIENTIOUSLY REFUSE TO DISPENSE MEDICATIONS AND ALSO PROVIDE PATIENTS TIMELY ACCESS TO THEIR PRESCRIPTIONS. FOR EXAMPLE:

- The pharmacy can staff accordingly so other pharmacists may dispense.
- Referring or transferring the prescription to another pharmacy that dispenses or carries the product.
- In order to ensure access is maintained, rural pharmacists can collaborate with other health care providers in their community to see that the patients' needs are served.

The professional role of the pharmacist as the final safety check before a drug is dispensed to a patient must be preserved.

Plan B: Pharmacologic Mechanism of Action and a Moral Dilemma for Pharmacists

By: Laura Norlander, RPh

Plan B (levonorgestrel) is a progestin hormonal product . This product is marketed as an emergency contraceptive. It can work after an egg is fertilized and human life is in its earliest stages of development. Plan B can prevent the transport of this life from the fallopian tube to the uterus and/or change the uterus lining (endometrium) so the tiny human life cannot implant and continue its development.

The issue at hand is that many pharmacists know human life has begun at conception. To purposefully interfere with the fertilized egg's ability to implant in the mother's uterus is an early abortion.

There are pharmacists who want to practice pharmacy to promote life and alleviate suffering within a moral framework. Just as physicians and nurses in Minnesota are not required to participate in or accommodate abortions, so there are pharmacists who do not want to be required to accommodate the use of products that can be chemical abortifacients.

FDA document for Plan B

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 21045

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

JUL 20 1999

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW
Division of Pharmaceutical Evaluation II

NDA **21-045**

Drug/Drug Product: PLAN B, levonorgestrel 0.75 mg oral tablets

Indication: **Emergency Contraceptive**

Date of Application: 1/29/99

Classification: **Priority (3P)**

Sponsor: **Women's Capital Corporation (WCC)**

Reviewer: **Ameeta Parekh, Ph.D.**

SYNOPSIS:

Women's Capital Corporation (WCC) has submitted the NDA 21-045 for levonorgestrel (LNG) 0.75 mg tablets, in response to the FDA's announcement (62 Federal Register, 8610, February 25, 1997) for applications from industry for new products to meet the need of emergency postcoital contraception that may be used to prevent unwanted pregnancies. This oral contraceptive (OC) product is intended to be used as a 2 tablet regimen, with the first 0.75 mg tablet to be taken within 72 hours after unprotected sex and the next 0.75 mg tablet to be taken 12 hours later (PLAN B). LNG has a long history of use in U.S. as a chronic low dose contraceptive, either as a single entity (e.g. implantable Norplant or OC Ovrette) or in combination with estrogens in OC pills.

The Human Pharmacokinetics and Biopharmaceutics section of the NDA provides data from a relative bioavailability study comparing a suspension formulation to the to-be-marketed formulation of Plan B. Sponsor has also provided published literature reports on clinical pharmacokinetics and review articles addressing potential for drug-drug interactions. Well designed studies to assess the influence of hepatic, renal, ethnic differences and age, on pharmacokinetics of LNG have not been evaluated. In-vitro dissolution has been characterized for PLAN B and the sponsor has proposed a method and specification for quality control of the final product.

LNG binds to albumin (50%) and sex hormone binding globulin, SHBG, (47.5%) extensively. The free fraction in plasma is about 2.5% (Fotherby, Clin. Pharmacokin. 28, 3, 1995). After oral administration, LNG is rapidly absorbed and the maximum plasma concentrations (C_{max}) are achieved within 1-2 hours (T_{max}). Reported studies show minimum first pass and high absolute bioavailability. LNG is a low extraction drug with the reported apparent clearance values ranging from 6-7 L/hr. The apparent volume of distribution is in the range of 100 L.

COMMENTS:

The following general comments (1 and 2) have been conveyed to the sponsor via a telephone conference dated 7/15/99:

1. Information on drug interaction potential is generally useful to assure the efficacy of oral contraceptives. Since PLAN B is indicated for acute indication, knowledge of isozymes responsible for its metabolism could be very useful to determine efficacy implications upon coadministration with other drugs. The sponsor should be encouraged to explore this to address specifically, the drug interaction potential for LNG.
2. It is interesting to note that the only Asian female in the study WCC-PK-001 had low AUCs (62511; range 62511-222143 pg*hours/ml) and Cmax (9448; range 6657-38990 pg/ml) values. Note also that the study conducted by He, et al, Contraception, 41, 5, 1990, compared a Chinese pill to Postinor (Hungarian tablet similar to PLAN B) and showed lower relative bioavailability for the Chinese pill (about 25% for AUC and 100% for Cmax). The pregnancy rates, however, were similar for both products. Given that LNG pharmacokinetics are highly variable, it is not clearly evident that lower concentrations in the Asian population (if in fact this holds) may be the cause of higher pregnancy rates. It could be worthwhile exploring further whether ethnicity is an important covariate for pharmacokinetics of LNG and whether higher doses should be explored in the Asian population.
3. The in-vitro dissolution methodology is acceptable. The specifications should be set as Q % in minutes and this has been conveyed to, and agreed to, by the sponsor in a letter dated 7/13/99.

RECOMMENDATIONS:

The Office of Clinical Pharmacology and Biopharmaceutics, DPEII, has reviewed the Section 6 of NDA 21-045 for PLAN B for emergency contraception. The NDA is acceptable from the pharmacokinetics perspective.

ISI 7/20/99
Ameeta Parekh, Ph.D.
Division of Pharmaceutical Evaluation II
Office of Clinical Pharmacology & Biopharmaceutics

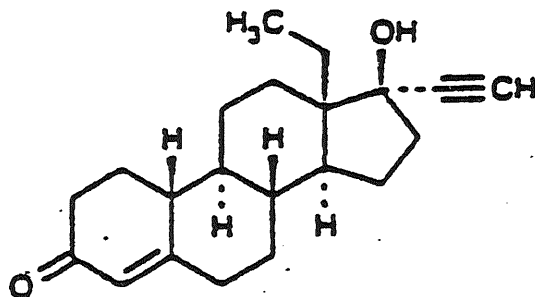
FT Signed by John Hunt ISI 7/20/99.

OCPB Briefing, 7/15/99 (Dr. Mei-Ling Chen, John Hunt, Dr. Ameeta Parekh)
cc: NDA 21-045, HFD-870 (M.Chen, J. Hunt, A.Parekh), HFD-580 (J.Mercier, D.Davis)
CDR (Barbara Murphy)

BACKGROUND:

LNG, the active isomer of dl-norgestrel, is the active ingredient in the 0.75 mg wet granulation tablets. These are manufactured by and packaged as 2 blister packs. PLAN B is distributed by Women's Capital Corporation (WCC) in the U.S.

Structure of Levonorgestrel



USAN: Levonorgestrel

Chemical Name: 18,19-Dinorpregn-4-en-20-yn-3-one, 13-ethyl-17-hydroxy-, (17 α)-(-)-.

Molecular Formula: C₂₁H₂₈O₂

Molecular Weight: 312.45

The Clinical Pharmacology and Biopharmaceutics review is formatted to address the pertinent questions that are generally relevant to this section, as follows:

QUESTIONS:

What is currently available for the indication of emergency contraception (EC) ?
Why is NDA 21-045 a priority application ?

Combinations of ethinyl estradiol (EE, 0.1 or 0.12 mg) and levonorgestrel (LNG, 0.5 or 0.6 mg) are believed to be safe and effective for EC use (1996 Advisory Committee decision). Currently, these combinations are used off label for EC indication in the U.S. Preven™ (4 pills each of LNG 0.25mg and EE 0.05mg combination) was approved in 1998 for U.S. market based on the Advisory Committee decision and meta analysis

submitted for the use of this regimen. Currently, this is the only approved product in U.S. for this indication.

The combination products contain estrogen and progestin. The current NDA is a progestin alone product which, according to the sponsor, has reduced side effects due to the absence of estrogen (nausea, vomiting). The safety and efficacy data for the current NDA is derived from well controlled clinical trials specifically for EC.

Is 0.75 mg LNG approved elsewhere in the world for this indication ?

The LNG 0.75 mg tablets are marketed as Postinor™ by since 1980 and available in 34 countries. This is packaged as 4 or 10 tablets for occasional postcoital contraception.

Do clinical safety and efficacy studies support the approval ?

The NDA contains clinical safety and efficacy data from 2 well controlled randomized clinical studies on levonorgestrel for EC. Supporting data is also provided from 3 additional multicenter studies (with 0.75 mg levonorgestrel) and 32 additional single center studies with various doses.

What is the proposed dose and how was this determined ?

This product (PLAN B) will be used as a 2-tablet regimen with the first tablet taken within 72 hours after unprotected sexual intercourse and the next tablet to be taken 12 hours later. A third dose is recommended if vomiting occurs within 4 hours after either required dose.

The dose in the clinical trials was determined based on data accumulated over 3 decades from several countries. Doses of 0.15 to 0.4 mg have been used as OC within 1 hour of infrequent coital act. Doses as high as 1 mg to be used within 8 hours after intercourse have also been reported. Lower LNG doses have been used within 1-8 hours of unprotected intercourse and associated with disruption of menstrual cycles. It is reported that a 30% pregnancy rate was reduced to 1% when the dose of LNG was increased from 0.15mg to 0.75-1 mg (Landgren, et.al, Contraception, 39,3,1989). The choice of 0.75 mg dose is based on the established safety and efficacy of its use in many countries.

What is the mechanism of action ?

LNG = levonorgestrel

The mechanism whereby LNG prevents pregnancy as an oral or implantable contraceptive is due to its potent progestin activity. Postcoital administration could theoretically prevent pregnancy by interfering with a number of physiological processes including ovulation, sperm transport through cervical mucus and fallopian tubes, release of pituitary gonadotropins, corpus luteum function, fertilization, embryo transport and implantation. It is not effective once the process of implantation has begun.

**Senate Counsel, Research,
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S.F. No. 637 - Physical Therapy (Delete-Everything Amendment)

Author: Senator Yvonne Prettner Solon

Prepared by: Katie Cavanor, Senate Counsel (651/296-3801) KTC

Date: March 31, 2006

S.F. No. 637 modifies the physical therapy licensure statutes.

Section 1 (148.65, subdivision 8) adds the definition of "licensed health care professional."

Section 2 (148.75) permits a physical therapist to continue to treat a patient beyond the initial 30-day period of treatment without an order or referral from a physician, chiropractor, podiatrist, or dentist. This section also allows a physical therapist to treat a patient without referral without first having practiced for a year under a physician's order. This section also removes the requirement that the therapist consult with the patient's health care provider who prescribed the treatment if the treatment is altered. This section also clarifies that a therapist is required to refer a patient to a health care professional if the patient's medical condition, at any time, is beyond the scope of practice of a physical therapist, and that the physical therapist may not be disciplined by the Board if the patient refuses to comply with a referral if the referral is documented in the physical therapy record.

(Currently, after the initial 30 days of treatment, the physical therapist is required to have a referral from a health care professional to continue treating the patient unless there is a previous diagnosis indicating an ongoing condition warranting therapy. If the therapist has not practiced for a year, then the therapist cannot provide treatment without a referral.)

Section 3 (148.76, subdivision 2) makes conforming changes in this section to the changes made in section 2.

Section 4 repeals Minnesota Rules, parts 5601.0100, subparts 5, 6, 7, and 8 (definitions for licensed health care professional or licensed health care provider, initiation of treatment, previously diagnosed condition, and clinical experience); 5601.1200 (reports); 5601.1800 (initiation of treatment for a condition not previously diagnosed); 5601.1900 (initiation of treatment for a previously diagnosed condition); and 5601.2000 (limitation on practice).

KC:ph

Senators Lourey, Solon, Higgins, Foley and Nienow introduced--
S.F. No. 637: Referred to the Committee on Health and Family Security.

1 A bill for an act

2 relating to health occupations; eliminating the
3 prohibition against providing physical therapy after
4 30 days without a physician's order or without
5 practicing for one year; amending Minnesota Statutes
6 2004, sections 148.75; 148.76, subdivision 2.

7 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

8 Section 1. Minnesota Statutes 2004, section 148.75, is
9 amended to read:

10 148.75 [LICENSES; DENIAL, SUSPENSION, REVOCATION.]

11 (a) The state Board of Physical Therapy may refuse to grant
12 a license to any physical therapist, or may suspend or revoke
13 the license of any physical therapist for any of the following
14 grounds:

15 (1) using drugs or intoxicating liquors to an extent which
16 affects professional competence;

17 (2) conviction of a felony;

18 (3) conviction for violating any state or federal narcotic
19 law;

20 (4) obtaining a license or attempting to obtain a license
21 by fraud or deception;

22 (5) conduct unbecoming a person licensed as a physical
23 therapist or conduct detrimental to the best interests of the
24 public;

25 (6) gross negligence in the practice of physical therapy as
26 a physical therapist;

1 ~~(7) treating human ailments by physical therapy after an~~
2 ~~initial 30-day period of patient admittance to treatment has~~
3 ~~lapsed, except by the order or referral of a person licensed in~~
4 ~~this state in the practice of medicine as defined in section~~
5 ~~147.081, the practice of chiropractic as defined in section~~
6 ~~148.01, the practice of podiatry as defined in section 153.01,~~
7 ~~or the practice of dentistry as defined in section 150A.05 and~~
8 ~~whose license is in good standing, or when a previous diagnosis~~
9 ~~exists indicating an ongoing condition warranting physical~~
10 ~~therapy treatment, subject to periodic review defined by board~~
11 ~~of physical therapy rule,~~

12 ~~(8) treating human ailments, without referral, by physical~~
13 ~~therapy treatment without first having practiced one year under~~
14 ~~a physician's orders as verified by the board's records,~~

15 ~~(9) failing to consult with the patient's health care~~
16 ~~provider who prescribed the physical therapy treatment if the~~
17 ~~treatment is altered by the physical therapist from the original~~
18 ~~written order. ---The provision does not include written orders to~~
19 ~~"evaluate and treat";~~

20 ~~(10) treating human ailments other than by physical therapy~~
21 ~~unless duly licensed or registered to do so under the laws of~~
22 ~~this state;~~

23 ~~(11) (8) inappropriate delegation to a physical therapist~~
24 ~~assistant or inappropriate task assignment to an aide or~~
25 ~~inadequate supervision of either level of supportive personnel;~~

26 ~~(12) (9) practicing as a physical therapist performing~~
27 ~~medical diagnosis, the practice of medicine as defined in~~
28 ~~section 147.081, or the practice of chiropractic as defined in~~
29 ~~section 148.01;~~

30 ~~(13) (10) failing to comply with a reasonable request to~~
31 ~~obtain appropriate clearance for mental or physical conditions~~
32 ~~that would interfere with the ability to practice physical~~
33 ~~therapy, and that may be potentially harmful to patients;~~

34 ~~(14) (11) dividing fees with, or paying or promising to pay~~
35 ~~a commission or part of the fee to, any person who contacts the~~
36 ~~physical therapist for consultation or sends patients to the~~

1 physical therapist for treatment;

2 ~~(15)~~ (12) engaging in an incentive payment arrangement,
3 other than that prohibited by clause ~~(14)~~ (11), that tends to
4 promote physical therapy overuse, that allows the referring
5 person or person who controls the availability of physical
6 therapy services to a client to profit unreasonably as a result
7 of patient treatment;

8 ~~(16)~~ (13) practicing physical therapy and failing to refer
9 to a licensed health care professional a patient whose medical
10 condition at the time of evaluation has been determined by the
11 physical therapist to be beyond the scope of practice of a
12 physical therapist; and

13 ~~(17)~~ (14) failing to report to the board other licensed
14 physical therapists who violate this section.

15 (b) A license to practice as a physical therapist is
16 suspended if (1) a guardian of the physical therapist is
17 appointed by order of a court pursuant to sections 524.5-101 to
18 524.5-502, for reasons other than the minority of the physical
19 therapist; or (2) the physical therapist is committed by order
20 of a court pursuant to chapter 253B. The license remains
21 suspended until the physical therapist is restored to capacity
22 by a court and, upon petition by the physical therapist, the
23 suspension is terminated by the Board of Physical Therapy after
24 a hearing.

25 Sec. 2. Minnesota Statutes 2004, section 148.76,
26 subdivision 2, is amended to read:

27 Subd. 2. [PROHIBITIONS.] No physical therapist may:

28 ~~(1) treat human ailments by physical therapy after an~~
29 ~~initial 30-day period of patient admittance to treatment has~~
30 ~~lapsed, except by the order or referral of a person licensed in~~
31 ~~this state to practice medicine as defined in section 147.001,~~
32 ~~the practice of chiropractic as defined in section 148.01, the~~
33 ~~practice of podiatry as defined in section 153.01, the practice~~
34 ~~of dentistry as defined in section 150A.05, or the practice of~~
35 ~~advanced practice nursing as defined in section 62A.15,~~
36 ~~subdivision 3a, when orders or referrals are made in~~

1 ~~collaboration-with-a-physician,-chiropractor,-pediatrist,-or~~
2 ~~dentist,-and-whose-license-is-in-good-standing,-or-when-a~~
3 ~~previous-diagnosis-exists-indicating-an-ongoing-condition~~
4 ~~warranting-physical-therapy-treatment,-subject-to-periodic~~
5 ~~review-defined-by-Board-of-Physical-Therapy-rule;~~

6 ~~(2)-treat-human-ailments-by-physical-therapy-treatment~~
7 ~~without-first-having-practiced-one-year-under-a-physician's~~
8 ~~orders-as-verified-by-the-board's-records;~~

9 (3) use any chiropractic manipulative technique whose end
10 is the chiropractic adjustment of an abnormal articulation of
11 the body; and

12 (4) (2) treat human ailments other than by physical therapy
13 unless duly licensed or registered to do so under the laws of
14 this state.

SF 637 – PT Open Access Bill

I am Bill Roberts. I am a physician residing in Mahtomedi, MN and I currently practice on the eastside of St Paul at the Phalen Village Clinic where I see patients and teach family medicine residents and medical students. I have been a licensed physician in MN since 1979. I am Board Certified in Family Medicine and Sports Medicine. I was in private practice in White Bear Lake, MN for 22 years and I am currently with UMN DFMCH as an Associate Professor in the Medical School. I am also the Immediate past President ACSM and a previous Medical Director of the HealthEast St Johns Physical Therapy and Fitness Center.

In the spirit of full disclosure, I am married to a PT with 30 years of practice in MN and my daughter is a DPT candidate who will graduate next month from the College of St Catherines.

I am familiar with both the practice and the current training of physical therapists. PTs are competent, safe, and knowledgeable. They work as part of the health care team and collaborate with physicians and others in the field. I trust PTs to evaluate and treat patients within the scope of their license and none of my 28 years of working with PT leads me to believe that open access would be a safety issue for patients or that their training is not adequate for entering practice after graduation. However, open access will be cost effective for patients and increase patient choice.

The main concern for this bill is patient safety and there is data supporting the safety of open access for patients. The medical and chiropractic associations spoke against the bill at the House sub committee hearing, citing examples of potential problems from open access, but presented no data to support their concerns. While the “gee whiz” examples create an emotional reaction, I would suggest that there are plenty of bad outcomes in all the areas of medicine. Everyone here is familiar with the Institute of Medicine report on physician medical errors. Living with a PT, I have witnessed the missed diagnoses by physicians in PT patients picked up in a physical therapy evaluation and reported back to the physician by my wife, a PT. I have also discussed missed physician diagnoses recognized by my daughter who is still in training.

I think decisions like open access should be based on group data and not anecdotes of perceived potential problems. The data that is available regarding open access for physical therapy is favorable and shows no problems with patient safety. Two publications that look at direct access and show no risk to patients are first **Moore et al. *Journal of Orthopedic Sports Phys Therapy*, 2005 titled “Risk determination for patients with direct access to physical therapy in military health care facilities.”** a 40 month data collection with no reported adverse events resulting from the PT’s diagnoses or management, regardless of how patients accessed physical therapy services. And second **Overman et al. *Physical Therapy*, 1988 titled “Physical therapy care for low back pain: Monitored program of first-contact nonphysician care”** *found no adverse outcomes that could be attributed to physical therapist first-contact care.* In addition, a letter from the **Federation of State Boards of Physical Therapy (the umbrella**

organization of 53 physical therapy licensing jurisdictions within the United States) dated January 27, 2006 states "The Federation has found no increase in number or severity of either malpractice or disciplinary cases in jurisdictions that have direct access to physical therapy when compared with those jurisdictions that do not have any form of direct access."

The second area of contention seems to be the 1 year requirement to practice under a physician's orders. Physical therapy as a profession has determined the optimal educational program and clinical training based on their needs as practitioners with the intention that therapists will be able to practice independently upon graduation and passage of national licensure examination. The accreditation standards for PT programs require instruction for independent decision making and the Federation of State Licensing Boards develops and administers national exams that test the PT students on ability and knowledge to practice independently at graduation. PT graduates have demonstrated in studies a higher level of knowledge in managing musculoskeletal conditions than medical students, physician interns and residents, and many physicians other than seasoned orthopedists. I am comfortable that a new PT graduate can evaluate and manage physical therapy problems without a year of physician supervision.

As physicians

Physical therapists are trained and competent to develop a plan of care for patients. Physical therapy standards of practice require a physical therapist to perform a physical therapy evaluation on every patient and determine the best treatment based on that evaluation and the therapist's knowledge of evidence for treatment. Physical therapists have a professional responsibility to provide the most beneficial and efficacious treatment based on their independent evaluation and physical therapists are the experts in physical therapy and musculoskeletal conditions. While American Medical Schools are struggling to beef up or even offer required courses in musculoskeletal medicine by 2010, physical therapy is already there.

I speak in favor of SF 637 to grant open access to physical therapists for the citizens of MN and find no safety risk from searches of the current literature. In response to objections based on potential safety issues, I hark back to the Wendy's commercial that was popular several years ago and ask "Where's the beef?" Open access will be safe and save patients time and money, and it will be safe for the medical system. Physical therapists will remain as they have always been a part of the health care team that promotes health and looks after patient well being. Physical therapists are well trained within their scope of practice to treat muscular skeletal conditions and will refer patients back to their physicians when the patients do not respond to therapy, do not fit the usual physical therapy patterns of care, or fall outside their scope of practice.

Thank you.

Testimony of Jim House, M.D., M.S.
Senate Health and Family Security Committee
April 4, 2006
S.F. 637

Mr. Chair and members, my name is Dr. Jim House. I am an orthopedic surgeon and Professor Emeritus at the University of Minnesota. I am testifying today on behalf of the Minnesota Orthopedic Society and the Minnesota Medical Association.

Let me begin by saying that I have worked with physical therapists for more than 35 years as an orthopedic surgeon. I respect PTs and enjoy working with them as a part of the health care team in the treatment of many musculo-skeletal injuries, countless disorders and disease. I am not here today to protect my own practice or that of a colleague but am concerned about patient welfare.

This bill removes important patient safety mechanisms that are intended to ensure coordination of care between health care providers. First, it eliminates the requirement that patients obtain a physician's referral following the first 30 days of treatment. Second, it scales back the PT training regiment by eliminating the requirement that they practice their first year in coordination with a physician. And finally, the bill removes the requirement that PTs coordinate with a patient's health care provider following a referral if treatment is modified.

First, regarding unlimited direct access, we believe that to allow patients to go directly to physical therapists for an unlimited amount of time, without receiving a medical diagnosis, raises patient safety concerns that have not been addressed.

While physical therapists are well trained within their scope of treating muscular skeletal conditions, they are not trained to perform medical diagnoses or order diagnostic x-rays. In fact, they are prohibited in statute from performing medical diagnoses.

It is important to understand that there are many, many causes of back pain that must be diagnosed in advance of physical therapy treatment. For example, malignancies that spread to the spinal column; kidney tumors and other kidney disease; abdominal problems arising from the pancreas; hip pain; or vascular problems, like abdominal aortic aneurysms, could all present as back pain.

If not seen by a physician, these conditions may be missed and the patient will continue treatment causing dangerous, sometimes life-threatening, delays in diagnoses and proper treatment.

You don't have to simply take my word for it. In 2004, Congress asked the Medicare Payment Advisory Commission to "study the feasibility and advisability of allowing Medicare fee-for-service beneficiaries to have "direct access" to outpatient physical therapy services...." The Commission concluded that physician referral was necessary to ensure appropriate physical therapy services for Medicare beneficiaries. Their report said, "Beneficiaries often have multiple medical conditions and physicians can consider their broad medical care needs."

Even more concerning is the removal of the current requirement that a physical therapist practice their first year under a physician's orders. Licensed practitioners in any number of professional fields are required to practice under supervision as part of the completion of their training. In addition to being a

safeguard for comprehensive training, this first year is critical to establishing systematic coordination between PTs and other health care providers.

Finally, the bill further jeopardizes patient safety and stands in the way of coordination of patient care by removing the requirement that PTs coordinate with the patient's health care provider when treatment is modified from an original referral if one exists.

This coordination is critical, particularly during post operative care and rehabilitation after undergoing a surgical procedure. Post operative care and rehabilitation are some of the most valuable functions of physical therapy, yet it is an absolute necessity that the prescribing surgeon oversee the therapists actions because the surgeon has unique knowledge of what type of surgical techniques and reconstructive devices were used during the operation.

I must ask you, "What is the problem we are trying to solve with this bill?" Current law allows a patient to go directly to physical therapists for up to 30 days. If an injury or ailment is not improving within 30 days, then a physician should see that patient to perform a complete medical diagnosis. Coordination of care is critical – especially for complicated medical conditions.

In conclusion, as a constituent and member of the MMA and the Board of Directors of the Minnesota Orthopedic Society, I respectfully request that you do not remove mechanisms that ensure patient safety and coordination between health care providers. Minnesota has an outstanding reputation for health care and we must maintain high quality care for our citizens.

Thank you for your time. I would be happy to try to answer any questions you may have.