Ontario

Ministry of Health and Long-Term Care

Inspection Report under the Long-Term Care Homes Act, 2007

Ministère de la Santé et des Soins de longue durée

Rapport d'inspection sous la Loi de 2007 sur les foyers de soins de longue durée

Long-Term Care Homes Division
Long-Term Care Inspections Branch

Division des foyers de soins de longue durée
Inspection de soins de longue durée

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Report Date(s) / Date(s) du apport	Inspection No / No de l'inspection	Log # / No de registre	Type of Inspection / Genre d'inspection
Apr 4, 2018	2018_625133_0004	015805-17	Follow up

Licensee/Titulaire de permis

Hilltop Manor Nursing Home Limited
1005 St. Lawrence Street P.O. Box 430 MERRICKVILLE ON K0G 1N0

Long-Term Care Home/Foyer de soins de longue durée

Hilltop Manor Nursing Home (Merrickville)
1005 St Lawrence Street P.O. Box 430 MERRICKVILLE ON K0G 1N0

Name of Inspector(s)/Nom de l'inspecteur ou des inspecteurs

JESSICA LAPENSEE (133)

Inspection Summary/Résumé de l'inspection

The purpose of this inspection was to conduct a Follow up inspection.

This inspection was conducted on the following date(s): March 6, 7, 8, 9, 2018

This Follow Up inspection was in relation to compliance order #001, issued on July 18, 2017 as a result of inspection ##2017_582548_0012, with a compliance date of October 16, 2017. The compliance order was related to the use of bed rails. The compliance order was not complied as a result of this Follow Up inspection. The licensee will be served with a subsequent compliance order.

During the course of the inspection, the inspector(s) spoke with the Administrator, the Director of Care, the Assistant Director of Care, the Director of Environmental Services, the Physiotherapist, the Director of Activation, registered and non registered nursing staff, housekeeping staff, and residents.

During the course of the inspection, the Inspector reviewed documentation related to the assessment of resident's in relation to bed rail use, reviewed components of identified residents' health care records, observed identified residents in bed, observed identified residents' bed systems.

The following Inspection Protocols were used during this inspection:
Safe and Secure Home

During the course of this inspection, Non-Compliances were issued.
- **1 WN(s)**
- **0 VPC(s)**
- **1 CO(s)**
- **0 DR(s)**
- **0 WAO(s)**

NON-COMPLIANCE / NON - RESPECT DES EXIGENCES	
Legend WN – Written Notification VPC – Voluntary Plan of Correction DR – Director Referral CO – Compliance Order WAO – Work and Activity Order	Legendé WN – Avis écrit VPC – Plan de redressement volontaire DR – Aiguillage au directeur CO – Ordre de conformité WAO – Ordres : travaux et activités
Non-compliance with requirements under the Long-Term Care Homes Act, 2007 (LTCHA) was found. (a requirement under the LTCHA includes the requirements contained in the items listed in the definition of "requirement under this Act" in subsection 2(1) of the LTCHA). The following constitutes written notification of non-compliance under paragraph 1 of section 152 of the LTCHA.	Le non-respect des exigences de la Loi de 2007 sur les foyers de soins de longue durée (LFSLD) a été constaté. (une exigence de la loi comprend les exigences qui font partie des éléments énumérés dans la définition de « exigence prévue par la présente loi », au paragraphe 2(1) de la LFSLD. Ce qui suit constitue un avis écrit de non-respect aux termes du paragraphe 1 de l'article 152 de la LFSLD.

WN #1: The Licensee has failed to comply with O.Reg 79/10, s. 15. Bed rails

Specifically failed to comply with the following:

s. 15. (1) Every licensee of a long-term care home shall ensure that where bed rails are used,
(a) the resident is assessed and his or her bed system is evaluated in accordance with evidence-based practices and, if there are none, in accordance with prevailing practices, to minimize risk to the resident; O. Reg. 79/10, s. 15 (1).
(b) steps are taken to prevent resident entrapment, taking into consideration all potential zones of entrapment; and O. Reg. 79/10, s. 15 (1).
(c) other safety issues related to the use of bed rails are addressed, including height and latch reliability. O. Reg. 79/10, s. 15 (1).

Findings/Faits saillants :

1. The licensee has failed to comply with compliance order (CO) #001 from inspection #2017_582548_0012 served on July 18, 2017 with a compliance date of October 16, 2017.

The licensee was ordered to:

1. Develop and implement a documented interdisciplinary team assessment process for all residents with one or more bed rails in use, and for all residents for which the use of one or more bed rails are being considered. The process shall include an individual resident assessment and shall specifically include all factors, elements and conditions as outlined in the prevailing practices document "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings" (FDA, 2003). As well, the process shall consider the general guidance outlined within the Treatment Programs/Care Plans section of the FDA 2003 clinical guidance document.

2. Ensure the interdisciplinary team assessment process identifies potential nursing/medical and environmental interventions or changes, which may serve as an alternative to bed rail use and the alternatives are trialed if appropriate and dependent on the resident's assessment, during a specified observation period prior to the application of any bed rails or prior to the removal from the use of any bed rails.

3. Ensure the interdisciplinary team clearly documents the final results of the assessment/reassessment, including the risk-benefit analysis and ensuing

recommendation.

4. Update the written plan of care based on each resident's assessment/reassessment by the interdisciplinary team. Include all required information as specified in the FDA 2003 clinical guidance document.

5. Assess risk for entrapment of all resident beds-in-use by clearly documenting an inventory of each bed make and model and corresponding mattress, evaluating each bed system entrapment dimensional criteria for the four entrapment zones and all corrective actions.

6. Develop and deliver education to all staff who have involvement with the use of bed rails in the home with regards to the Ontario Regulation 79/10,s. 15 (1) (a), related to the assessment of the resident in accordance with the FDA 2003 clinical guidance document to minimize risk to the resident.

The licensee completed steps 2, 4, 5 and 6 in CO #001

The licensee failed to complete step 1 in CO #001 for resident #002 regarding the development and implementation of a documented interdisciplinary team assessment process, including all factors, elements and conditions outlined in the prevailing practices document.

The licensee failed to complete step 3 in CO #001 for residents #001, #002 and #003 regarding documentation of the risk-benefit assessment. It is noted that the documentation of the risk benefit assessment is a condition outlined in the prevailing practices document. As such, step 1 and step 3 are interrelated.

Background:

In August, 2012, the acting Director of the Performance Improvement and Compliance Branch, with the Ministry of Health and Long Term Care, issued a memo to all Long Term Care Home Administrators about the risk of bed-related entrapment. The memo directed that the Health Canada guidance document titled "Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards" (HC guidance document) was to be used by all homes as a best practice document. The HC guidance document characterizes, where bed rails are used, the body parts at risk for life threatening entrapment, identifies the locations of hospital bed openings that are

potential entrapment areas, recommends dimensional limits for the gaps in some of the potential entrapment areas, and prescribes test tools and methods to measure and assess gaps in some of the potential entrapment zones. The HC guidance document includes the titles of two additional companion documents by the Food and Drug Administration (FDA) in the United States. The companion documents referred to in the HC Guidance Document are identified as useful resources and outline prevailing practices related to the use of bed rails. Prevailing practices are predominant, generally accepted and widespread practices that are used as a basis for clinical decision-making. One of the companion documents is titled "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings (U.S., FDA, 2003). The 2003 FDA clinical guidance document provides necessary guidance in establishing a clinical assessment where bed rails are used. In the 2003 FDA clinical guidance document, it is specified that any decision to use or to discontinue use of bed rails should be made within the context of an individualized resident assessment using an interdisciplinary team. Numerous factors are to be considered and are specified. The process is to result in a documented risk benefit assessment in the resident's health care record. The decision to use or to discontinue use of bed rails is to be made by the interdisciplinary team; and the effectiveness of the bed rails is to be reviewed regularly.

The 2003 FDA clinical guidance document includes several specific references related to a risk benefit assessment. It is indicated that evaluation is needed to assess the relative risk of using the bed rail compared with not using it for an individual resident (page 3). It is indicated that the resident's chart should include a risk benefit assessment that identifies why other care interventions are not appropriate or not effective if previously attempted and determined not to be the treatment of choice for the resident (page 4). It is indicated that the decision to use bed rails should be based on a comprehensive assessment and identification of the resident's needs, which include comparing the potential for injury or death associated with the use or non-use of bed rails and the benefits for an individual resident (page 5). Finally, it is indicated that if clinical and environmental interventions have proven to be unsuccessful in meeting the resident's assessed needs or a determination has been made that the risk of bed rail use is lower than that of other interventions or of not using them, bed rails may be indicated for use, and documentation of the risk benefit assessment should be in the resident's health care record (page 7).

Related to the home's new resident assessment process regarding bed rail use:

On March 6, 2018, the Director of Care (DOC) #101 informed the Inspector that there had been two different methods, for two different groups of residents. For the 60 residents in the home at the time that the home initially responded to the compliance order, a document titled "Bed Safety Assessment" (BSA) was manually completed by the DOC and signed by the team members present for discussion of the completed document, including the home's Physiotherapist (PT, #106). DOC #101 indicated that the completion of the BSA document included the review of the resident's most recent "Sleep Evaluation/Summary", and the "Activity Admission Assessment", both within the resident's electronic health care record. For residents admitted after the home's initial response to the compliance order, the DOC informed the Inspector that the documented assessment process consisted of the "Initial Physiotherapy Assessment", the "Sleep Evaluation/Summary", the "Activity Admission Assessment", and the "Bed Safety Assessment 2", all within the resident's electronic health care record. DOC #101 indicated that the "Bed Safety Assessment 2" document was completed on the seventh day following a resident's admission, by DOC #101, and this included a review of the two previously noted assessments and the sleep evaluation, with documentation of the final decision. DOC #101 indicated that the final decision is considered a team decision, including PT #106 and the Director of Activation (DA) #107, given the review of their assessments. The DOC indicated that in response to the compliance order, all three quarter rails and half rails were taken out of use. The DOC indicated that the home currently had two identified types of quarter rails in use.

Related to resident #001:

On one day during the inspection, resident #001 was observed on their bed, with an identified type of bed rail on one side of the bed in a specified position and the same type of bed rail on the other side of the bed in a specified position. At the time of observation, resident #001 was lying on their bed in a specified position. Personal Support Worker (PSW) #102 confirmed to the Inspector that bed rails were always in use for resident #001, in the observed positions. Later that day, resident #001 was again observed on their bed, in a similar position. When asked why bed rails were in use for resident #001, PSW #104 indicated that they had seen the resident use the bed rail on one side of the bed in a specified way. PSW #104 indicated that they had never seen the resident use the bed rail on the other side of the bed. PSW #104 indicated that resident #001 goes in and out of their bed independently. During the discussion with PSW #104, the Inspector observed resident #001 quickly get up and out of their bed, on a specified side of the bed, without use of the bed rail on that side of the bed. Resident #001 then mobilized down the hallway with use of their mobility device. PSW #104 indicated that resident

#001 is physically active. Resident #001 was observed on their bed the next day, with the two bed rails in the same positions as observed the previous day. Resident #001 was lying on their bed in a specified position, different than had been observed the previous day. Two days later, resident #001 was observed on their bed, with the two bed rails in the same positions as previously observed. Resident #001 was lying on their bed in a specified position, different than had been previously observed.

Resident #001 was assessed as part of the home's initial response to the compliance order. On March 7, 2018, the Inspector reviewed resident #001's "Bed Safety Assessment" (BSA) document, dated with an identified date in 2017. At the end of the "PT/OT" section, in part 3, it was indicated "Bed rails are CONTRAINDICATED. Further Assessment required". Within the Nursing Assessment section, question #12 was "Were bed rails contraindicated at any time during this nursing assessment?" The answer selected was "Yes". In the "Bed rail Decision" section, answer "b" was selected, which was "Alternative device has been implemented". In the "Documentation" section, a) ii) was selected, which was "Bed rail/s Contraindicated, alternative/assistive device implemented, task and care plan updated". There was further notation related to the type of bedrails and type of bed that were to be in use for resident #001. The Inspector also reviewed the other previously referenced documents associated to the BSA document.

The documents reviewed for resident #001 did not include a documented risk-benefit assessment, as per the FDA 2003 clinical guidance document (see "Background" for further explanatory detail).

On March 7, 2018, the Inspector interviewed DOC #101 about resident #001's assessment. DOC #101 explained what the contraindications were related to. DOC #101 indicated that at the time of the assessment, it was less of a risk to have bed rails in use for resident #001 as opposed to not, despite the noted contraindications, as resident #001 could not turn when in bed without the bed rails. DOC #101 indicated that bed rails were required for resident #001 for bed mobility.

Related to resident #002:

On one of the inspection days, resident #002 was observed lying on their bed, in a specified way, with an identified type of bedrail on one side of their bed in a specified position. It was observed that there was no bed rail affixed to the other side of resident #002's bed. Two days later, resident #002 confirmed to the Inspector that the bed rail was always in the observed position when they were in their bed. Resident #002

indicated that they could use the rail in a specified way. The next day, resident #002 was observed lying on their bed, in the same position as previously observed, with the bed rail in the same position as previously observed.

Resident #002 was admitted to the home on an identified date in 2017. It was confirmed by DOC #101 that one bed rail was put into use for resident #002 on the resident's admission day. DOC #101 indicated that this was done following an initial nursing assessment at the time of admission and a conclusion that the resident needed a bed rail for bed mobility. DOC #101 indicated that the team assessment process had occurred after the application of a bed rail for resident #002. DOC #101 indicated that upon completion of the "Bed Safety Assessment 2" document, on resident #002's seventh day in the home, the final decision was that one bed rail should continue to be in use for the resident. As per the FDA 2003 clinical guidance document, any decision regarding bed rail use is to be made within the framework of a prescribed resident assessment, by an interdisciplinary team, resulting in a documented risk benefit assessment.

Resident #002 was assessed, in relation to bed rail use, using the second method implemented by the home. All of the previously described components of the second bed rail related assessment process for resident #002 were reviewed. The documents reviewed for resident #002 did not include a documented risk-benefit assessment, as per the FDA 2003 clinical guidance document (see "Background" for further explanatory detail).

As previously referenced, it was identified by DOC #101 that PT #106 was a part of the interdisciplinary team that assesses residents and approves the use of bed rails. As resident #002 was assessed, in relation to bed rail use, with the second method implemented by the home, the physiotherapy component of the assessment process was the "Initial Physiotherapy Assessment" (IPA). Resident #002's IPA was reviewed. The IPA did not make any reference to bed rails. This was in noted contrast to the "PT/OT" portion of the previously referenced "Bed Safety Assessment" (BAS) document, used for the first group of resident's that were assessed, where a recommendation was made in relation to bed rail use and consideration was given to the use of an alternative devices. On March 7, 2018, PT #106 indicated to the Inspector that they had participated in team decision making about the use of bed rails for the 60 residents that were in the home at the time of the initial response to the compliance order, using the BAS document. The PT indicated that with regards to residents admitted to the home after that time, such as resident #002, they had not been involved in making decisions about bed rail use. PT #106 indicated that they were aware that DOC #101 reviewed the IPA that they

completed for new residents, such as resident #002, when DOC #101 completed the "Bed Safety Assessment 2" document and made a final decision concerning bed rail use. PT #106 confirmed that they were not a part of a team process for approving the use of bed rails for resident #002. As per the FDA 2003 clinical guidance document, the use of bed rails should be approved by the interdisciplinary team.

Related to resident #003:

On one of the inspection days, resident #003 was observed lying on their bed, in a specified position, with an identified type of bed rail on one side of the bed in a specified position. It was observed that there was no bed rail affixed to the other side of resident #003's bed. At the time of observation, PSW #103 confirmed that the bed rail was always in the observed position. PSW #103 indicated that resident #003 used the bed rail in specified ways, and, that the bed rail served a specified purpose related to a specified aspect of the resident's health condition. Three days later, resident #003 was again observed lying on their bed, in the previously observed position, with the bed rail in the previously observed position.

Resident #003 was assessed as part of the home's initial response to the compliance order. On March 7, 2018, the Inspector reviewed resident #003's "Bed Safety Assessment" (BAS) document, dated with an identified date in 2017. Within the Nursing Assessment section, question #12 was "Were bed rails contraindicated at any time during this nursing assessment?" The answer selected was "Yes". In the Documentation section, it was indicated that one identified type of bed rail on a specified side of the bed would be in use for resident #003. The Inspector also reviewed the other previously referenced documents associated to the BAS.

The documents reviewed for resident #003 did not include a documented risk-benefit assessment, as per the FDA 2003 clinical guidance document (see "Background" for further explanatory detail).

On March 8, 2018, the Inspector interviewed the DOC about resident #003's BAS document. DOC #101 explained what the contraindication was in relation to. DOC #101 indicated that at the time of the assessment, the benefit of bed mobility outweighed the risks related to bed rail use for resident #003.

The licensee has failed to comply with O. Reg. 79/10, s. 15 (1) in that the licensee has failed to ensure that where bed rails are used, the resident is assessed in accordance

with prevailing practices, to minimize risk to the resident.

In summary, the severity of the issues identified was determined to be a level 2 as there was potential for actual harm to the residents. The scope of the issues identified was level 3 as they related to three of the three residents reviewed. The home had a compliance history of 4 as there was ongoing non-compliance with O. Reg. 79/10, s. 15 that included:
- voluntary plan of correction (VPC) issued August 20, 2015 (inspection #2015_285126_0030)
- compliance order (CO) #001 issued July 18, 2017 with a compliance due date of October 16, 2017 (inspection # 2017_582548_0012) [s. 15. (1) (a)]

Additional Required Actions:

CO # - 001 will be served on the licensee. Refer to the "Order(s) of the Inspector".

Issued on this 4th day of April, 2018

Signature of Inspector(s)/Signature de l'inspecteur ou des inspecteurs

Original report signed by the inspector.

Ontario

Ministry of Health and Long-Term Care

Order(s) of the Inspector
Pursuant to section 153 and/or section 154 of the *Long-Term Care Homes Act, 2007,* S.O. 2007, c.8

Ministére de la Santé et des Soins de longue durée

Ordre(s) de l'inspecteur
Aux termes de l'article 153 et/ou de l'article 154 *de la Loi de 2007 sur les foyers de soins de* longue durée, L.O. 2007, chap. 8

Long-Term Care Homes Division
Long-Term Care Inspections Branch

Division des foyers de soins de longue durée
Inspection de soins de longue durée

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Name of Inspector (ID #) / Nom de l'inspecteur (No) :	JESSICA LAPENSEE (133)
Inspection No. / No de l'inspection :	2018_625133_0004
Log No. / No de registre :	015805-17
Type of Inspection / Genre d'inspection:	Follow up
Report Date(s) / Date(s) du Rapport :	Apr 4, 2018
Licensee / Titulaire de permis :	Hilltop Manor Nursing Home Limited 1005 St. Lawrence Street, P.O. Box 430, MERRICKVILLE, ON, K0G-1N0
LTC Home / Foyer de SLD :	Hilltop Manor Nursing Home (Merrickville) 1005 St Lawrence Street, P.O. Box 430, MERRICKVILLE, ON, K0G-1N0
Name of Administrator / Nom de l'administratrice ou de l'administrateur :	Jim Parsons

To Hilltop Manor Nursing Home Limited, you are hereby required to comply with the following order(s) by the date(s) set out below:

Order # / Ordre no : 001

Order Type / Genre d'ordre : Compliance Orders, s. 153. (1) (a)

Linked to Existing Order / Lien vers ordre existant: 2017_582548_0012, CO #001;

Pursuant to / Aux termes de :

O.Reg 79/10, s. 15. (1) Every licensee of a long-term care home shall ensure that where bed rails are used,
(a) the resident is assessed and his or her bed system is evaluated in accordance with evidence-based practices and, if there are none, in accordance with prevailing practices, to minimize risk to the resident;
(b) steps are taken to prevent resident entrapment, taking into consideration all potential zones of entrapment; and
(c) other safety issues related to the use of bed rails are addressed, including height and latch reliability. O. Reg. 79/10, s. 15 (1).

Order / Ordre :

The licensee must be compliant with O. Reg. 79/10, s. 15 (1)

Specifically the licensee must:

a) Ensure that residents #001, #002 and #003, and any other resident, are assessed in accordance with the prevailing practices document "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings (FDA, 2003)". Specifically, a risk benefit assessment as prescribed is to be documented, following a resident assessment process as prescribed, and the identified interdisciplinary team members are to approve of the use of bed rails, before the decision to use bed rails is made.

Grounds / Motifs :

1. 1. The licensee has failed to comply with compliance order (CO) #001 from inspection #2017_582548_0012 served on July 18, 2017 with a compliance date of October 16, 2017.

The licensee was ordered to:

1. Develop and implement a documented interdisciplinary team assessment process for all residents with one or more bed rails in use, and for all residents for which the use of one or more bed rails are being considered. The process shall include an individual resident assessment and shall specifically include all factors, elements and conditions as outlined in the prevailing practices document "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings" (FDA, 2003). As well, the process shall consider the general guidance outlined within the Treatment Programs/Care Plans section of the FDA 2003 clinical guidance document.

2. Ensure the interdisciplinary team assessment process identifies potential nursing/medical and environmental interventions or changes, which may serve as an alternative to bed rail use and the alternatives are trialed if appropriate and dependent on the resident's assessment, during a specified observation period prior to the application of any bed rails or prior to the removal from the use of any bed rails.

3. Ensure the interdisciplinary team clearly documents the final results of the assessment/reassessment, including the risk-benefit analysis and ensuing recommendation.

4. Update the written plan of care based on each resident's assessment/reassessment by the interdisciplinary team. Include all required information as specified in the FDA 2003 clinical guidance document.

5. Assess risk for entrapment of all resident beds-in-use by clearly documenting an inventory of each bed make and model and corresponding mattress, evaluating each bed system entrapment dimensional criteria for the four entrapment zones and all corrective actions.

6. Develop and deliver education to all staff who have involvement with the use of bed rails in the home with regards to the Ontario Regulation 79/10,s. 15 (1) (a), related to the assessment of the resident in accordance with the FDA 2003 clinical guidance document to minimize risk to the resident.

The licensee completed steps 2, 4, 5 and 6 in CO #001

The licensee failed to complete step 1 in CO #001 for resident #002 regarding the development and implementation of a documented interdisciplinary team assessment process, including all factors, elements and conditions outlined in the prevailing practices document.

The licensee failed to complete step 3 in CO #001 for residents #001, #002 and #003 regarding documentation of the risk-benefit assessment. It is noted that the documentation of the risk benefit assessment is a condition outlined in the prevailing practices document. As such, step 1 and step 3 are interrelated.

Background:

In August, 2012, the acting Director of the Performance Improvement and Compliance Branch, with the Ministry of Health and Long Term Care, issued a memo to all Long Term Care Home Administrators about the risk of bed-related entrapment. The memo directed that the Health Canada guidance document titled "Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards" (HC guidance document) was to be used by all homes as a best practice document. The HC guidance document characterizes, where bed rails are used, the body parts at risk for life threatening entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, recommends dimensional limits for the gaps in some of the potential entrapment areas, and prescribes test tools and methods to measure and assess gaps in some of the potential entrapment zones. The HC guidance document includes the titles of two additional companion documents by the Food and Drug Administration (FDA) in the United States. The companion documents referred to in the HC Guidance Document are identified as useful resources and outline prevailing practices related to the use of bed rails. Prevailing practices are predominant, generally accepted and widespread practices that are used as a basis for clinical decision-making. One of the companion documents is titled "Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings (U.S., FDA, 2003). The 2003 FDA clinical guidance document provides necessary guidance in establishing a clinical assessment where bed rails are used. In the 2003 FDA clinical guidance document, it is specified that any decision to use or to discontinue use of bed rails should be made within the context of an individualized resident assessment using an interdisciplinary team. Numerous factors are to be considered and are specified. The process is to result in a documented risk benefit assessment in the resident's health care

record. The decision to use or to discontinue use of bed rails is to be made by the interdisciplinary team; and the effectiveness of the bed rails is to be reviewed regularly.

The 2003 FDA clinical guidance document includes several specific references related to a risk benefit assessment. It is indicated that evaluation is needed to assess the relative risk of using the bed rail compared with not using it for an individual resident (page 3). It is indicated that the resident's chart should include a risk benefit assessment that identifies why other care interventions are not appropriate or not effective if previously attempted and determined not to be the treatment of choice for the resident (page 4). It is indicated that the decision to use bed rails should be based on a comprehensive assessment and identification of the resident's needs, which include comparing the potential for injury or death associated with the use or non-use of bed rails and the benefits for an individual resident (page 5). Finally, it is indicated that if clinical and environmental interventions have proven to be unsuccessful in meeting the resident's assessed needs or a determination has been made that the risk of bed rail use is lower than that of other interventions or of not using them, bed rails may be indicated for use, and documentation of the risk benefit assessment should be in the resident's health care record (page 7).

Related to the home's new resident assessment process regarding bed rail use:

On March 6, 2018, the Director of Care (DOC) #101 informed the Inspector that there had been two different methods, for two different groups of residents. For the 60 residents in the home at the time that the home initially responded to the compliance order, a document titled "Bed Safety Assessment" (BSA) was manually completed by the DOC and signed by the team members present for discussion of the completed document, including the home's Physiotherapist (PT, #106). DOC #101 indicated that the completion of the BSA document included the review of the resident's most recent "Sleep Evaluation/Summary", and the "Activity Admission Assessment", both within the resident's electronic health care record. For residents admitted after the home's initial response to the compliance order, the DOC informed the Inspector that the documented assessment process consisted of the "Initial Physiotherapy Assessment", the "Sleep Evaluation/Summary", the "Activity Admission Assessment", and the "Bed Safety Assessment 2", all within the resident's electronic health care record. DOC #101 indicated that the "Bed Safety Assessment 2" document was completed on the seventh day following a resident's admission, by DOC #101,

and this included a review of the two previously noted assessments and the sleep evaluation, with documentation of the final decision. DOC #101 indicated that the final decision is considered a team decision, including PT #106 and the Director of Activation (DA) #107, given the review of their assessments. The DOC indicated that in response to the compliance order, all three quarter rails and half rails were taken out of use. The DOC indicated that the home currently had two identified types of quarter rails in use.

Related to resident #001:

On one day during the inspection, resident #001 was observed on their bed, with an identified type of bed rail on one side of the bed in a specified position and the same type of bed rail on the other side of the bed in a specified position. At the time of observation, resident #001 was lying on their bed in a specified position. Personal Support Worker (PSW) #102 confirmed to the Inspector that bed rails were always in use for resident #001, in the observed positions. Later that day, resident #001 was again observed on their bed, in a similar position. When asked why bed rails were in use for resident #001, PSW #104 indicated that they had seen the resident use the bed rail on one side of the bed in a specified way. PSW #104 indicated that they had never seen the resident use the bed rail on the other side of the bed. PSW #104 indicated that resident #001 goes in and out of their bed independently. During the discussion with PSW #104, the Inspector observed resident #001 quickly get up and out of their bed, on a specified side of the bed, without use of the bed rail on that side of the bed. Resident #001 then mobilized down the hallway with use of their mobility device. PSW #104 indicated that resident #001 is physically active. Resident #001 was observed on their bed the next day, with the two bed rails in the same positions as observed the previous day. Resident #001 was lying on their bed in a specified position, different than had been observed the previous day. Two days later, resident #001 was observed on their bed, with the two bed rails in the same positions as previously observed. Resident #001 was lying on their bed in a specified position, different than had been previously observed.

Resident #001 was assessed as part of the home's initial response to the compliance order. On March 7, 2018, the Inspector reviewed resident #001's "Bed Safety Assessment" (BSA) document, dated with an identified date in 2017. At the end of the "PT/OT" section, in part 3, it was indicated "Bed rails are CONTRAINDICATED. Further Assessment required". Within the Nursing Assessment section, question #12 was "Were bed rails contraindicated at any

time during this nursing assessment?" The answer selected was "Yes". In the "Bed rail Decision" section, answer "b" was selected, which was "Alternative device has been implemented". In the "Documentation" section, a) ii) was selected, which was "Bed rail/s Contraindicated, alternative/assistive device implemented, task and care plan updated". There was further notation related to the type of bedrails and type of bed that were to be in use for resident #001. The Inspector also reviewed the other previously referenced documents associated to the BSA document.

The documents reviewed for resident #001 did not include a documented risk-benefit assessment, as per the FDA 2003 clinical guidance document (see "Background" for further explanatory detail).

On March 7, 2018, the Inspector interviewed DOC #101 about resident #001's assessment. DOC #101 explained what the contraindications were related to. DOC #101 indicated that at the time of the assessment, it was less of a risk to have bed rails in use for resident #001 as opposed to not, despite the noted contraindications, as resident #001 could not turn when in bed without the bed rails. DOC #101 indicated that bed rails were required for resident #001 for bed mobility.

Related to resident #002:

On one of the inspection days, resident #002 was observed lying on their bed, in a specified way, with an identified type of bedrail on one side of their bed in a specified position. It was observed that there was no bed rail affixed to the other side of resident #002's bed. Two days later, resident #002 confirmed to the Inspector that the bed rail was always in the observed position when they were in their bed. Resident #002 indicated that they could use the rail in a specified way. The next day, resident #002 was observed lying on their bed, in the same position as previously observed, with the bed rail in the same position as previously observed.

Resident #002 was admitted to the home on an identified date in 2017. It was confirmed by DOC #101 that one bed rail was put into use for resident #002 on the resident's admission day. DOC #101 indicated that this was done following an initial nursing assessment at the time of admission and a conclusion that the resident needed a bed rail for bed mobility. DOC #101 indicated that the team assessment process had occurred after the application of a bed rail for resident

#002. DOC #101 indicated that upon completion of the "Bed Safety Assessment 2" document, on resident #002's seventh day in the home, the final decision was that one bed rail should continue to be in use for the resident. As per the FDA 2003 clinical guidance document, any decision regarding bed rail use is to be made within the framework of a prescribed resident assessment, by an interdisciplinary team, resulting in a documented risk benefit assessment.

Resident #002 was assessed, in relation to bed rail use, using the second method implemented by the home. All of the previously described components of the second bed rail related assessment process for resident #002 were reviewed. The documents reviewed for resident #002 did not include a documented risk-benefit assessment, as per the FDA 2003 clinical guidance document (see "Background" for further explanatory detail).

As previously referenced, it was identified by DOC #101 that PT #106 was a part of the interdisciplinary team that assesses residents and approves the use of bed rails. As resident #002 was assessed, in relation to bed rail use, with the second method implemented by the home, the physiotherapy component of the assessment process was the "Initial Physiotherapy Assessment" (IPA). Resident #002's IPA was reviewed. The IPA did not make any reference to bed rails. This was in noted contrast to the "PT/OT" portion of the previously referenced "Bed Safety Assessment" (BAS) document, used for the first group of resident's that were assessed, where a recommendation was made in relation to bed rail use and consideration was given to the use of an alternative devices. On March 7, 2018, PT #106 indicated to the Inspector that they had participated in team decision making about the use of bed rails for the 60 residents that were in the home at the time of the initial response to the compliance order, using the BAS document. The PT indicated that with regards to residents admitted to the home after that time, such as resident #002, they had not been involved in making decisions about bed rail use. PT #106 indicated that they were aware that DOC #101 reviewed the IPA that they completed for new residents, such as resident #002, when DOC #101 completed the "Bed Safety Assessment 2" document and made a final decision concerning bed rail use. PT #106 confirmed that they were not a part of a team process for approving the use of bed rails for resident #002. As per the FDA 2003 clinical guidance document, the use of bed rails should be approved by the interdisciplinary team.

Related to resident #003:

On one of the inspection days, resident #003 was observed lying on their bed, in a specified position, with an identified type of bed rail on one side of the bed in a specified position. It was observed that there was no bed rail affixed to the other side of resident #003's bed. At the time of observation, PSW #103 confirmed that the bed rail was always in the observed position. PSW #103 indicated that resident #003 used the bed rail in specified ways, and, that the bed rail served a specified purpose related to a specified aspect of the resident's health condition. Three days later, resident #003 was again observed lying on their bed, in the previously observed position, with the bed rail in the previously observed position.

Resident #003 was assessed as part of the home's initial response to the compliance order. On March 7, 2018, the Inspector reviewed resident #003's "Bed Safety Assessment" (BAS) document, dated with an identified date in 2017. Within the Nursing Assessment section, question #12 was "Were bed rails contraindicated at any time during this nursing assessment?" The answer selected was "Yes". In the Documentation section, it was indicated that one identified type of bed rail on a specified side of the bed would be in use for resident #003. The Inspector also reviewed the other previously referenced documents associated to the BAS.

The documents reviewed for resident #003 did not include a documented risk-benefit assessment, as per the FDA 2003 clinical guidance document (see "Background" for further explanatory detail).

On March 8, 2018, the Inspector interviewed the DOC about resident #003's BAS document. DOC #101 explained what the contraindication was in relation to. DOC #101 indicated that at the time of the assessment, the benefit of bed mobility outweighed the risks related to bed rail use for resident #003.

The licensee has failed to comply with O. Reg. 79/10, s. 15 (1) in that the licensee has failed to ensure that where bed rails are used, the resident is assessed in accordance with prevailing practices, to minimize risk to the resident.

In summary, the severity of the issues identified was determined to be a level 2 as there was potential for actual harm to the residents. The scope of the issues identified was level 3 as they related to three of the three residents reviewed. The home had a compliance history of 4 as there was ongoing non-compliance

with O. Reg. 79/10, s. 15 that included:
- voluntary plan of correction (VPC) issued August 20, 2015 (inspection #2015_285126_0030)
- compliance order (CO) #001 issued July 18, 2017 with a compliance due date of October 16, 2017 (inspection # 2017_582548_0012) [s. 15. (1) (a)] (133)

This order must be complied with by /
Vous devez vous conformer à cet ordre d'ici le : Jul 09, 2018

REVIEW/APPEAL INFORMATION

TAKE NOTICE:

The Licensee has the right to request a review by the Director of this (these) Order(s) and to request that the Director stay this (these) Order(s) in accordance with section 163 of the Long-Term Care Homes Act, 2007.

The request for review by the Director must be made in writing and be served on the Director within 28 days from the day the order was served on the Licensee.

The written request for review must include,

(a) the portions of the order in respect of which the review is requested;
(b) any submissions that the Licensee wishes the Director to consider; and
(c) an address for services for the Licensee.

The written request for review must be served personally, by registered mail, commercial courier or by fax upon:

Director
c/o Appeals Coordinator
Long-Term Care Inspections Branch
Ministry of Health and Long-Term Care
1075 Bay Street, 11th Floor
TORONTO, ON
M5S-2B1
Fax: 416-327-7603

When service is made by registered mail, it is deemed to be made on the fifth day after the day of mailing, when service is made by a commercial courier it is deemed to be made on the second business day after the day the courier receives the document, and when service is made by fax, it is deemed to be made on the first business day after the day the fax is sent. If the Licensee is not served with written notice of the Director's decision within 28 days of receipt of the Licensee's request for review, this (these) Order(s) is(are) deemed to be confirmed by the Director and the Licensee is deemed to have been served with a copy of that decision on the expiry of the 28 day period.

The Licensee has the right to appeal the Director's decision on a request for review of an Inspector's Order(s) to the Health Services Appeal and Review Board (HSARB) in accordance with section 164 of the Long-Term Care Homes Act, 2007. The HSARB is an independent tribunal not connected with the Ministry. They are established by legislation to review matters concerning health care services. If the Licensee decides to request a hearing, the Licensee must, within 28 days of being served with the notice of the Director's decision, give a written notice of appeal to both:

Health Services Appeal and Review Board and the Director

Attention Registrar
151 Bloor Street West
9th Floor
Toronto, ON M5S 2T5

Director
c/o Appeals Coordinator
Long-Term Care Inspections Branch
Ministry of Health and Long-Term Care
1075 Bay Street, 11th Floor
TORONTO, ON
M5S-2B1
Fax: 416-327-7603

Upon receipt, the HSARB will acknowledge your notice of appeal and will provide instructions regarding the appeal process. The Licensee may learn more about the HSARB on the website www.hsarb.on.ca.

RENSEIGNEMENTS RELATIFS AUX RÉEXAMENS DE DÉCISION ET AUX APPELS

PRENEZ AVIS :

Le/la titulaire de permis a le droit de faire une demande de réexamen par le directeur de cet ordre ou de ces ordres, et de demander que le directeur suspende cet ordre ou ces ordres conformément à l'article 163 de la Loi de 2007 sur les foyers de soins de longue durée.

La demande au directeur doit être présentée par écrit et signifiée au directeur dans les 28 jours qui suivent la signification de l'ordre au/à la titulaire de permis.

La demande écrite doit comporter ce qui suit :

a) les parties de l'ordre qui font l'objet de la demande de réexamen;
b) les observations que le/la titulaire de permis souhaite que le directeur examine;
c) l'adresse du/de la titulaire de permis aux fins de signification.

La demande de réexamen présentée par écrit doit être signifiée en personne, par courrier recommandé, par messagerie commerciale ou par télécopieur, au :

Directeur
a/s du coordonnateur/de la coordonnatrice en matière d'appels
Direction de l'inspection des foyers de soins de longue durée
Ministère de la Santé et des Soins de longue durée
1075, rue Bay, 11e étage
Toronto ON M5S 2B1
Télécopieur : 416 327-7603

Quand la signification est faite par courrier recommandé, elle est réputée être faite le cinquième jour qui suit le jour de l'envoi, quand la signification est faite par messagerie commerciale, elle est réputée être faite le deuxième jour ouvrable après le jour où la messagerie reçoit le document, et lorsque la signification est faite par télécopieur, elle est réputée être faite le premier jour ouvrable qui suit le jour de l'envoi de la télécopie. Si un avis écrit de la décision du directeur n'est pas signifié au/à la titulaire de permis dans les 28 jours de la réception de la demande de réexamen présentée par le/la titulaire de permis, cet ordre ou ces ordres sont réputés être confirmés par le directeur, et le/la titulaire de permis est réputé(e) avoir reçu une copie de la décision en question à l'expiration de ce délai.

Le/la titulaire de permis a le droit d'interjeter appel devant la Commission d'appel et de révision des services de santé (CARSS) de la décision du directeur relative à une demande de réexamen d'un ordre ou des ordres d'un inspecteur ou d'une inspectrice conformément à l'article 164 de la Loi de 2007 sur les foyers de soins de longue durée. La CARSS est un tribunal autonome qui n'a pas de lien avec le ministère. Elle est créée par la loi pour examiner les questions relatives aux services de santé. Si le/la titulaire décide de faire une demande d'audience, il ou elle doit, dans les 28 jours de la signification de l'avis de la décision du directeur, donner par écrit un avis d'appel à la fois à :

la Commission d'appel et de révision des services de santé et au directeur

À l'attention du/de la registrateur(e)
151, rue Bloor Ouest, 9e étage
Toronto ON M5S 2T5

Directeur
a/s du coordonnateur/de la coordonnatrice en matière d'appels
Direction de l'inspection des foyers de soins de longue durée
Ministère de la Santé et des Soins de longue durée
1075, rue Bay, 11e étage
Toronto ON M5S 2B1
Télécopieur : 416 327-7603

À la réception de votre avis d'appel, la CARSS en accusera réception et fournira des instructions relatives au processus d'appel. Le/la titulaire de permis peut en savoir davantage sur la CARSS sur le site Web www.hsarb.on.ca.

Issued on this 4th day of April, 2018

Signature of Inspector /
Signature de l'inspecteur :

Ontario

Ministry of Health and Long-Term Care

Order(s) of the Inspector
Pursuant to section 153 and/or section 154 of the *Long-Term Care Homes Act, 2007,* S.O. 2007, c.8

Ministére de la Santé et des Soins de longue durée

Ordre(s) de l'inspecteur
Aux termes de l'article 153 et/ou de l'article 154 *de la Loi de 2007 sur les foyers de soins de* longue durée, L.O. 2007, chap. 8

Name of Inspector / Nom de l'inspecteur : JESSICA LAPENSEE

Service Area Office / Bureau régional de services : Ottawa Service Area Office