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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Public Copy/Copie du public

Report Date(s) / Date(s) du apport	Inspection No / No de l'inspection	Log # / Registre no	Type of Inspection / Genre d'inspection
Mar 28, 2017	2017_625133_0006	001762-17	Follow up

Licensee/Titulaire de permis

UNITED COUNTIES OF LEEDS AND GRENVILLE
746 County Road 42 P.O Box 100 ATHENS ON K0E 1B0

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

MAPLE VIEW LODGE
746 COUNTY ROAD, 42 EAST P.O. BOX 100 ATHENS ON K0E 1B0

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 6th, 7th, 8th, 2017

The follow up inspection was related to a compliance order regarding the use of bed rails. As a result of the inspection, the compliance order was closed with a link to a subsequent compliance order.

During the course of the inspection, the inspector(s) spoke with the Administrator, the Director of Care, registered and non registered nursing staff, and residents.

During the course of the inspection, the Inspector observed specified resident's bed systems with a focus on bed rails. The Inspector reviewed resident assessment documents related to bed rail use and components of some resident's health care records, including written care plans. The Inspector reviewed manufacturer specifications for two specified types of bed rails in use at the home at the time of the inspection. The inspector viewed three Surge Learning courses that the Director of Care (DOC) indicated were now mandatory for specified staff in response to the compliance order and a pamphlet developed by the DOC in response to the compliance order, related to bed safety. The Inspector reviewed the bed system evaluation document for all residents' bed systems in the home, completed by the DOC in January 2017.

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 ensure that where bed rails were used, residents were assessed in accordance with prevailing practices, to minimize risk to the resident.

On January 18, 2017, the licensee was served with a compliance order pursuant O. Reg. 79/10, s. 15 (1). The order type was as per LTCHA, 2007, s. 153 (1) (a), in that the licensee was ordered to take specified action to achieve compliance. The compliance order was to have been complied with by February 28, 2017. On February 28th, 2017, the home's Director of Care submitted an action plan with supporting documentation in response to the compliance order.

The licensee was ordered to complete the following:

1. Amend the home's existing Bed Rail Assessment to include all relevant questions and guidance related to bed safety hazards found in the Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Home and Home Care Settings (U.S. F.D.A, April 2003) recommended as the prevailing practice for individualized resident assessment of bed rails in the Health Canada guidance document Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards, 2008.

The amended questionnaire shall, at a minimum, include questions that can be answered by the assessors related to:

a. the resident while sleeping for a specified period of time to establish their habits,

patterns of sleep, behaviors and other relevant factors prior to the application of any bed rails; and

b. the alternatives that were trialled prior to using one or more bed rails and document whether the alternatives were effective or not during an observation period.

2. An interdisciplinary team shall assess all residents who use one or more bed rails using the amended bed safety assessment and document the assessed results and recommendations for each resident.

3. Update the written plan of care for those residents where changes were identified after re-assessing each resident using the amended bed safety assessment form. Include in the written plan of care any necessary accessories that may be required to mitigate any identified bed safety hazards.

4. An on-going monitoring process shall be established to ensure that all staff apply the bed rails as specified in the plan of care (i.e. when and how many).

5. Develop an education and information package for staff, families and residents identifying the regulations and prevailing practices governing adult hospital beds in Ontario, the risks of bed rail use, whether beds pass or fail entrapment zone testing, the role of the SDM and licensee with respect to resident assessments and any other relevant facts or myths associated with bed systems and the use of bed rails.

On March 6th, 2017, the Director of Care (DOC) explained to the Inspector that she had not understood that the compliance order was to have been complied with by February 28, 2017. The DOC explained that she thought that an action plan was required by the compliance date. The DOC explained that the action plan that she had submitted outlined the program that she would be putting into place and that it was an ongoing project. As such, the DOC acknowledged that the compliance order had not been fully complied with.

On August 21, 2012, a notice was issued to Long Term Care Home Administrators from the Ministry of Health and Long Term Care, Performance Improvement and Compliance Branch identifying a document produced by Health Canada (HC) titled "Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability and Other Hazards, 2008" (HC Guidance Document). In the notice, it is written that this HC Guidance Document is expected to be used "as a best practice document". 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). This document provides necessary guidance in establishing a clinical assessment where bed rails are used. It is identified that the population at risk for entrapment are residents who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction and acute urinary retention that cause them to move about the bed or try to exit from the bed. Other contributing risk factors are identified, including the absence of timely nursing care and technical issues related to the bed system. Evaluation is needed to assess the relative risk of using bed rails compared with not using bed rails for each individual resident. Decision regarding the use of bed rails is be made within the context of an individualized resident assessment using an interdisciplinary team with input from the resident and family or legal guardian. This process is to include a comparison between the potential for injury or death associated with the use or non-use of bed rails and the benefits for an individual resident. The assessment is to consider numerous factors including (but not limited to) the resident's medical needs, sleep habits and patterns, cognition, mobility (in and out of bed), risk of falling, and the sleeping environment. Diagnoses, symptoms, conditions and/or behavioral symptoms for which the use of a bed rail is being considered are to be addressed. Nursing/medical and environmental interventions are to be identified. If clinical and environmental interventions have proved to be unsuccessful in meeting the resident's assessed need 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 used. Documentation of the risk-benefit assessment is required. The decision to use bed rails is to be approved by the interdisciplinary team that assessed the resident; and the effectiveness of the bed rail is to be reviewed regularly.

With regards to part 1 of the order:

It was determined that the two assessments, in preliminary use, to be completed by

registered nursing staff to determine if bed rails were to remain in use or be put into use, did not include all relevant questions or any guidance related to bed safety found in the F.D.A 2003 clinical guidance document that are to ultimately to lead to the decision that bed rails may be used or may remain in use.

The DOC explained to the Inspector that the home did not previously have a Bed Rail Assessment in place. The DOC specified that for residents' with two full bed rails in place as a restraint, there was a "Restraint Initial Assessment" in place as well as a "Restraint Monthly Review". The DOC explained that in response to part 1 of the order, she was bringing three new assessments into use: "Restraint/PASD Assessment", "Restraint Alternatives" and "Bed Rail Assessment v2". The DOC clarified that she believed that a "Bed Rail Assessment v1" document existed within the Point Click Care library, but that it was never in use at the home. The DOC indicated that the three assessments were to be collectively seen as the Bed Rail Assessment required in part 1 of the order.

The DOC explained that the "Restraint/PASD Assessment" and the "Restraint Alternatives" would be completed for all residents with bed rails in use and for all new residents, regardless of if the bed rails were considered a restraint or a PASD. The DOC confirmed that that these two assessments would be completed to determine if bed rails were required. The "Bed Rail Assessment V2" would be completed if it had been determined that bed rails were going to be put into use, to better understand the risk related to bed rail use for the resident. The assessments would be completed by a registered nurse.

As per the FDA 2003 clinical guidance document, a multidisciplinary team assessment is to occur, to ultimately conduct a risk benefit assessment which includes comparing the potential for injury or death associated with use or non-use of bed rails to the benefit for an individual resident, prior to the conclusion that bed rails may be used or removed from use.

The "Restraint/PASD Assessment" and "Restraints Alternatives" assessment were reviewed. They did not lead to a risk-benefit assessment as required. They did not include the following, as specified in the FDA 2003 clinical guidance document: medical diagnosis, condition, symptoms; sleep habits; medication; acute medical or surgical interventions; underlying medical conditions; existence of delirium; ability to toilet self safely; communication; or mobility in bed.

The two noted assessments do not include any of the elements or conditions, as specified in the FDA 2003 clinical guidance document, related to the sleeping environment.

With regards to part 1a of the order:

It was determined that the three noted assessments did not consider the resident while sleeping for a specified period.

The DOC explained that the "specified period of time" was to be the time during which the assessments would be completed. The DOC explained that the assessments may be completed on the day, evening or night shift. The DOC confirmed that the resident while sleeping was not a factor.

With regards to current residents, the DOC explained that the assessment questions were to be answered based on a review of nursing notes.

With regards to new residents, the DOC explained that the assessment questions were to be answered based on a review of the information provided upon admission.

Following discussion throughout the inspection, the DOC acknowledged that such a process may not allow the home to establish the resident's sleep habits, patterns of sleep and other relevant factors prior to the application of bed rails or prior to the removal of bed rails.

The "Restraint/PASD Assessment" and "Restraint Alternatives" and Bed Rail Assessment V2 did not include questions that can be answered to establish a resident's sleep habits or patterns of sleep prior to the application of any bed rails or prior to the decision to remove bed rails from use.

With regards to part 1b of the order:

The "Restraint/PASD Assessment" included an "Interventions attempted" section which included 22 options that could be selected related to an unspecified restraint.

The "Restraints Alternatives" assessment included nine categories of alternative interventions tried, for all restraints in use, and made no specific reference to alternatives that were/would be trialled prior to using one or more bed rails or prior to discontinuing

the use of bed rails.

Looking at resident #006 completed assessment and referral package, the DOC clarified that where it was indicated that alternative interventions had been tried, in fact this reflected interventions that could be considered should the recommendation to change the type of bed rails in place be approved by the Bed Safe team.

As per the 2003 FDA clinical guidance document, clinical and environmental interventions are to be identified and trialed if indicated. If the interventions prove unsuccessful in meeting the resident's assessed needs, or a determination is made that the risk of bed rail use is lower than that of other interventions or of not using them, bed rails may be used or may remain in use.

The preliminary assessment process in place for residents with bed rails in use did not provide for the trialling of alternative interventions, if indicated, during an observation period.

With regards to part 2 of the order:

It was determined that an interdisciplinary team had not assessed any of the residents who use one or more bed rails.

The DOC informed that there were 28 residents with bed rails in use in the home.

The DOC informed that to date, the three noted assessments with subsequent referral to the "Bed Safe" team had been completed for six residents. All six residents had two full bed rails in use, as restraints. Discontinuation of the bed rails was recommended for two of the residents (resident #001 and #007), and a change in the type of bed rails used was recommended for one (resident #006) of the residents.

The assessments and referrals were all completed by the home's RAI coordinator on March 2, 2017.

The DOC explained that the "Bed Safe" team had been created but had not yet met to go through the final steps of the action plan. This team was to be comprised of herself, maintenance staff, and at least one Personal Support Worker and a Registered Nurse working on the day the team met. The idea behind the team was that they would meet on a routine basis and review the bed rail related assessments done by the registered

nursing staff. The DOC would discuss the assessments with the team, review if the current restraints were effective, if there was a need to reduce or eliminate the use of the restraints, or if there was something better suited for the resident. The DOC highlighted that for residents for which a change or discontinuation of bed rails had been recommended by the RAI Coordinator, there would be discussion with the physician prior to bringing the issue to the "Bed Safe" team for final decision making. All existing residents would go through the referral process. All new residents' assessments, or subsequent requests for changes to the use of bed rails, would be reviewed by the Bed Safe team on a monthly or quarterly basis.

Following discussions throughout the inspection, the DOC acknowledged that her action plan did not provide for an interdisciplinary team assessment of all existing residents who use one or more bed rails or for new residents for whom bed rails are being considered.

With regards to part 3 of the order:

As none of the residents with bed rails in use had been through the complete reassessment process, the DOC confirmed that there had been no updates to the written plans of care in this regard.

With regards to part 4 of the order:

The DOC confirmed that an ongoing monitoring process to ensure that all staff apply the bed rails as specified in the plan of care had yet not been implemented.

With regards to part 5 of the order:

The DOC explained that she had brought three Surge learning education courses into use, for staff. The courses were as follows: "Bedrail entrapment testing and safety", "Minimization of restraints" and "Minimizing restraining, staff training presentation – least restraint, last resort". The courses were viewed by the Inspector.

As per the DOC, six percent (%), 11.8 %, and 10.6% of the assigned staff had completed the three courses, respectively.

The DOC explained that she had developed a pamphlet for families and residents, titled "A Guide to Bedrail Use and Alternatives at Maple View Lodge – Information for Residents and their Families". The pamphlet was reviewed by the Inspector.

While information was presented about the overall topic of restraints, which bed rails may or may not be considered, information was not provided related to the regulations and prevailing practices governing adult hospital beds in Ontario, specific to bed rails. Information was not provided related to the role of the SDM and licensee with respect to resident assessments associated with bed systems and the use of bed rails.

With regards to resident #001, referenced as resident #018 in the previous order report:

As per discussion with the DOC, resident #018 had a referral in place for the Bed Safe team, with a recommendation by the RAI coordinator to further assess for the possibility of discontinuing use of two full bed rails for the resident.

With regards to resident #002, referenced as resident #009 in the previous order report:

On March 6th, 2017, the DOC informed that the resident still had a "buddy" rail in place and that it was same design as what was on resident #003 and resident #004's beds. The rail resembled an upside down U, with an inside opening of approximately 18 inches by 11 inches, with extensions under the mattress secured to the bed frame with zip ties. The upper portion of the rails were covered with a protective black foam.

The DOC confirmed that she had conducted an evaluation of the resident's bed system the week of January 5th, 2017 and that the buddy rail failed the Zone 1 test. Entrapment Zone 1 is the space within the rail and as per the HC guidance document the space is to be less than 4 ¾ inches.

The Inspector asked the DOC if such a bed rail device was indicated for use on adult hospital beds as per the manufacturer specifications. The DOC did not have this information and could not verify if the rails were indicated for use or not.

The DOC indicated that she had been looking for a different type of "buddy" rail for resident #002, as the resident was adamant that he/she required the rail for bed mobility. The DOC had a replacement in a box in her office and indicated she intended that this new type of rail would be put onto resident #002's's bed that day. The rail was referred to as an "M-Rail" and described as an "adjustable bedside handrail", manufactured by Hartmobility. The DOC conducted an online search and located the installation instructions for the device, and it was determined that the device was not indicated for use on any part of a hospital bed that can move or be adjusted. As the hospital beds in

use for the residents can be articulated in a variety of ways, it was concluded that this device should not be in use in the home and would not be an acceptable alternative for resident #002.

The "buddy" rail was removed from the resident #002's bed on March 8th, 2017.

With regards to resident #003, referenced as resident #016 in the previous order report, and resident #004:

On March 6th, 2017, the DOC informed that resident #003 still had what the home referred to as a "buddy" rail in place on his/her bed, as previously described for resident #002. The DOC confirmed that she had conducted an evaluation of the resident's bed system the week of January 5th, 2017 and that the buddy rail failed the Zone 1 test.

The DOC informed that resident #004, not referenced in the previous order report, had the same type of "buddy" rail in place.

The DOC explained that she had asked nursing and maintenance staff to remove the "buddy" rails in January 2017 as they were no longer needed for the residents and had failed the entrapment testing.

The buddy rails were removed from resident #003 and resident #004's beds the evening of March 6th, 2017.

Following the onsite inspection, the Inspector determined that the "buddy" rails in use for resident #002, #003 and #004 were manufactured by Drive Medical, referenced as "Home Bed Assist Handle", and were only indicated for use on box spring type beds, not for articulating hospital beds as were in use for all residents in the home.

As observed by the Inspector on March 7th, 2017, resident #004 had two full bed rails on his/her bed in addition to the "buddy" rail that had been in place. As per discussion with Personal Support Worker #S102, the full rail closest to the wall was always up when resident #004 was in bed. The logo information board within the resident's bedroom, and the resident's written care plan as provided by the DOC on March 7th, 2017, did not make reference to the use of any type of bed rail for resident #004.

With regards to resident #005, referenced as resident #042 in the previous order report:

The DOC informed the inspector that the resident still had a "buddy" rail on his/her bed and that it was of a different design than the "buddy" rail on resident #002, #003, #004's beds. The DOC indicated that she had evaluated the resident's bed system in January 2017 and that all of the entrapment zones had passed the prescribed testing process.

On March 7th, 2017, the Inspector observed that the resident had an "M-Rail" on the left side of his/her bed. The head of the bed was articulated at the time of observation, at an approximate 30 degree angle. As previously referenced, the Inspector and the DOC had become aware, on March 6th, 2017, that such a bed rail device was not indicated for use on parts of a hospital bed that can move or be adjusted. The resident informed the Inspector that when he/she is in bed, the head of the bed was always in this raised position.

The "M-Rail" was removed from resident #005's bed on March 8th, 2017.

In summary, the home failed to comply with compliance order #001, issued as a result of Resident Quality Inspection #2016_444602_0040, on January 18th, 2017. There is a history of non-compliance. The scope of the non-compliance described above is widespread given the number of residents utilizing one or more bed rails. The non-compliance presents a potential for harm given the failure to assess residents related to the risk of bed rail use as per prevailing practices described in the FDA 2003 clinical guidance document. As a result of these three factors, a subsequent compliance order will be issued. [s. 15. (1) (a)]

Additional Required Actions:

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

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

Issued on this 28th day of March, 2017

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

Public Copy/Copie du public

Name of Inspector (ID #) / Nom de l'inspecteur (No) :	JESSICA LAPENSEE (133)
Inspection No. / No de l'inspection :	2017_625133_0006
Log No. / Registre no:	001762-17
Type of Inspection / Genre d'inspection:	Follow up
Report Date(s) / Date(s) du Rapport :	Mar 28, 2017
Licensee / Titulaire de permis :	UNITED COUNTIES OF LEEDS AND GRENVILLE 746 County Road 42, P.O Box 100, ATHENS, ON, K0E-1B0
LTC Home / Foyer de SLD :	MAPLE VIEW LODGE 746 COUNTY ROAD, 42 EAST, P.O. BOX100, ATHENS, ON, K0E-1B0
Name of Administrator / Nom de l'administratrice ou de l'administrateur :	Linda Chaplin

To UNITED COUNTIES OF LEEDS AND GRENVILLE, you are hereby required to comply with the following order(s) by the date(s) set out below:

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

Order # / Ordre no : 001

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

Linked to Existing Order / Lien vers ordre existant: 2016_444602_0040, 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 is ordered to:

1. Develop and implement a documented multidisciplinary 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 a sleeping environment assessment and the observation of the resident in bed, while sleeping and not sleeping, for a specified period of time. The individual resident assessment and sleeping environment assessment 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 that the multidisciplinary team assessment process identifies potential nursing/medical and environmental interventions or changes, which may serve as alternative to bed rail use, and that the interventions or changes 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 use of any bed rails.

3. Ensure that the multidisciplinary team reassesses resident's with one or more bed rails in use, at a minimum, whenever there is a change in the resident's health status.

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

5. Update the written plan of care based on the residents' assessment/ reassessment by the interdisciplinary team. Include all required information as specified in the FDA 2003 clinical guidance document, such as related to the use of bed rails for a medical symptom or condition vs. bed rails used for a resident's mobility and/or transferring.

6. Develop and deliver education to all staff who have involvement with the use of bed rails in the home with regards to 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.

Grounds / Motifs :

1. The Licensee has failed to ensure that where bed rails were used, residents were assessed in accordance with prevailing practices, to minimize risk to the resident.

On January 18, 2017, the licensee was served with a compliance order pursuant O. Reg. 79/10, s. 15 (1). The order type was as per LTCHA, 2007, s. 153 (1) (a), in that the licensee was ordered to take specified action to achieve compliance. The compliance order was to have been complied with by February 28, 2017. On February 28th, 2017, the home's Director of Care submitted an action plan with supporting documentation in response to the compliance order.

The licensee was ordered to complete the following:

1. Amend the home's existing Bed Rail Assessment to include all relevant questions and guidance related to bed safety hazards found in the Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals,

Long Term Care Home and Home Care Settings (U.S. F.D.A, April2003) recommended as the prevailing practice for individualized resident assessment of bed rails in the Health Canada guidance document Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards, 2008.

The amended questionnaire shall, at a minimum, include questions that can be answered by the assessors related to:

a. the resident while sleeping for a specified period of time to establish their habits, patterns of sleep, behaviors and other relevant factors prior to the application of any bed rails; and

b. the alternatives that were trialled prior to using one or more bed rails and document whether the alternatives were effective or not during an observation period.

2. An interdisciplinary team shall assess all residents who use one or more bed rails using the amended bed safety assessment and document the assessed results and recommendations for each resident.

3. Update the written plan of care for those residents where changes were identified after re-assessing each resident using the amended bed safety assessment form. Include in the written plan of care any necessary accessories that may be required to mitigate any identified bed safety hazards.

4. An on-going monitoring process shall be established to ensure that all staff apply the bed rails as specified in the plan of care (i.e. when and how many).

5. Develop an education and information package for staff, families and residents identifying the regulations and prevailing practices governing adult hospital beds in Ontario, the risks of bed rail use, whether beds pass or fail entrapment zone testing, the role of the SDM and licensee with respect to resident assessments and any other relevant facts or myths associated with bed systems and the use of bed rails.

On March 6th, 2017, the Director of Care (DOC) explained to the Inspector that she had not understood that the compliance order was to have been complied with by February 28, 2017. The DOC explained that she thought that an action

plan was required by the compliance date. The DOC explained that the action plan that she had submitted outlined the program that she would be putting into place and that it was an ongoing project. As such, the DOC acknowledged that the compliance order had not been fully complied with.

On August 21, 2012, a notice was issued to Long Term Care Home Administrators from the Ministry of Health and Long Term Care, Performance Improvement and Compliance Branch identifying a document produced by Health Canada (HC) titled "Adult Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability and Other Hazards, 2008" (HC Guidance Document). In the notice, it is written that this HC Guidance Document is expected to be used "as a best practice document". 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). This document provides necessary guidance in establishing a clinical assessment where bed rails are used. It is identified that the population at risk for entrapment are residents who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction and acute urinary retention that cause them to move about the bed or try to exit from the bed. Other contributing risk factors are identified, including the absence of timely nursing care and technical issues related to the bed system. Evaluation is needed to assess the relative risk of using bed rails compared with not using bed rails for each individual resident. Decision regarding the use of bed rails is be made within the context of an individualized resident assessment using an interdisciplinary team with input from the resident and family or legal guardian. This process is to include a comparison between the potential for injury or death associated with the use or non-use of bed rails and the benefits for an individual resident. The assessment is to consider numerous factors including (but not limited to) the resident's medical needs, sleep habits and patterns, cognition, mobility (in and out of bed), risk of falling, and the sleeping environment.

Diagnoses, symptoms, conditions and/or behavioral symptoms for which the use of a bed rail is being considered are to be addressed. Nursing/medical and environmental interventions are to be identified. If clinical and environmental interventions have proved to be unsuccessful in meeting the resident's assessed need 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 used. Documentation of the risk-benefit assessment is required. The decision to use bed rails is to be approved by the interdisciplinary team that assessed the resident; and the effectiveness of the bed rail is to be reviewed regularly.

With regards to part 1 of the order:

It was determined that the two assessments, in preliminary use, to be completed by registered nursing staff to determine if bed rails were to remain in use or be put into use, did not include all relevant questions or any guidance related to bed safety found in the F.D.A 2003 clinical guidance document that are to ultimately to lead to the decision that bed rails may be used or may remain in use.

The DOC explained to the Inspector that the home did not previously have a Bed Rail Assessment in place. The DOC specified that for residents' with two full bed rails in place as a restraint, there was a "Restraint Initial Assessment" in place as well as a "Restraint Monthly Review". The DOC explained that in response to part 1 of the order, she was bringing three new assessments into use: "Restraint/PASD Assessment", "Restraint Alternatives" and "Bed Rail Assessment v2". The DOC clarified that she believed that a "Bed Rail Assessment v1" document existed within the Point Click Care library, but that it was never in use at the home. The DOC indicated that the three assessments were to be collectively seen as the Bed Rail Assessment required in part 1 of the order.

The DOC explained that the "Restraint/PASD Assessment" and the "Restraint Alternatives" would be completed for all residents with bed rails in use and for all new residents, regardless of if the bed rails were considered a restraint or a PASD. The DOC confirmed that that these two assessments would be completed to determine if bed rails were required. The "Bed Rail Assessment V2" would be completed if it had been determined that bed rails were going to be put into use, to better understand the risk related to bed rail use for the resident. The assessments would be completed by a registered nurse.

As per the FDA 2003 clinical guidance document, a multidisciplinary team assessment is to occur, to ultimately conduct a risk benefit assessment which includes comparing the potential for injury or death associated with use or non-use of bed rails to the benefit for an individual resident, prior to the conclusion that bed rails may be used or removed from use.

The "Restraint/PASD Assessment" and "Restraints Alternatives" assessment were reviewed. They did not lead to a risk-benefit assessment as required. They did not include the following, as specified in the FDA 2003 clinical guidance document: medical diagnosis, condition, symptoms; sleep habits; medication; acute medical or surgical interventions; underlying medical conditions; existence of delirium; ability to toilet self safely; communication; or mobility in bed.

The two noted assessments do not include any of the elements or conditions, as specified in the FDA 2003 clinical guidance document, related to the sleeping environment.

With regards to part 1a of the order:

It was determined that the three noted assessments did not consider the resident while sleeping for a specified period.

The DOC explained that the "specified period of time" was to be the time during which the assessments would be completed. The DOC explained that the assessments may be completed on the day, evening or night shift. The DOC confirmed that the resident while sleeping was not a factor.

With regards to current residents, the DOC explained that the assessment questions were to be answered based on a review of nursing notes.

With regards to new residents, the DOC explained that the assessment questions were to be answered based on a review of the information provided upon admission.

Following discussion throughout the inspection, the DOC acknowledged that such a process may not allow the home to establish the resident's sleep habits, patterns of sleep and other relevant factors prior to the application of bed rails or prior to the removal of bed rails.

The "Restraint/PASD Assessment" and "Restraint Alternatives" and Bed Rail Assessment V2 did not include questions that can be answered to establish a resident's sleep habits or patterns of sleep prior to the application of any bed rails or prior to the decision to remove bed rails from use.

With regards to part 1b of the order:

The "Restraint/PASD Assessment" included an "Interventions attempted" section which included 22 options that could be selected related to an unspecified restraint.

The "Restraints Alternatives" assessment included nine categories of alternative interventions tried, for all restraints in use, and made no specific reference to alternatives that were/would be trialled prior to using one or more bed rails or prior to discontinuing the use of bed rails.

Looking at resident #006 completed assessment and referral package, the DOC clarified that where it was indicated that alternative interventions had been tried, in fact this reflected interventions that could be considered should the recommendation to change the type of bed rails in place be approved by the Bed Safe team.

As per the 2003 FDA clinical guidance document, clinical and environmental interventions are to be identified and trialed if indicated. If the interventions prove unsuccessful in meeting the resident's assessed needs, or a determination is made that the risk of bed rail use is lower than that of other interventions or of not using them, bed rails may be used or may remain in use.

The preliminary assessment process in place for residents with bed rails in use did not provide for the trialling of alternative interventions, if indicated, during an observation period.

With regards to part 2 of the order:

It was determined that an interdisciplinary team had not assessed any of the residents who use one or more bed rails.

The DOC informed that there were 28 residents with bed rails in use in the

home.

The DOC informed that to date, the three noted assessments with subsequent referral to the "Bed Safe" team had been completed for six residents. All six residents had two full bed rails in use, as restraints. Discontinuation of the bed rails was recommended for two of the residents (resident #001 and #007), and a change in the type of bed rails used was recommended for one (resident #006) of the residents.

The assessments and referrals were all completed by the home's RAI coordinator on March 2, 2017.

The DOC explained that the "Bed Safe" team had been created but had not yet met to go through the final steps of the action plan. This team was to be comprised of herself, maintenance staff, and at least one Personal Support Worker and a Registered Nurse working on the day the team met. The idea behind the team was that they would meet on a routine basis and review the bed rail related assessments done by the registered nursing staff. The DOC would discuss the assessments with the team, review if the current restraints were effective, if there was a need to reduce or eliminate the use of the restraints, or if there was something better suited for the resident. The DOC highlighted that for residents for which a change or discontinuation of bed rails had been recommended by the RAI Coordinator, there would be discussion with the physician prior to bringing the issue to the "Bed Safe" team for final decision making. All existing residents would go through the referral process. All new residents' assessments, or subsequent requests for changes to the use of bed rails, would be reviewed by the Bed Safe team on a monthly or quarterly basis.

Following discussions throughout the inspection, the DOC acknowledged that her action plan did not provide for an interdisciplinary team assessment of all existing residents who use one or more bed rails or for new residents for whom bed rails are being considered.

With regards to part 3 of the order:

As none of the residents with bed rails in use had been through the complete reassessment process, the DOC confirmed that there had been no updates to the written plans of care in this regard.

With regards to part 4 of the order:

The DOC confirmed that an ongoing monitoring process to ensure that all staff apply the bed rails as specified in the plan of care had yet not been implemented.

With regards to part 5 of the order:

The DOC explained that she had brought three Surge learning education courses into use, for staff. The courses were as follows: "Bedrail entrapment testing and safety", "Minimization of restraints" and "Minimizing restraining, staff training presentation – least restraint, last resort". The courses were viewed by the Inspector.

As per the DOC, six percent (%), 11.8 %, and 10.6% of the assigned staff had completed the three courses, respectively.

The DOC explained that she had developed a pamphlet for families and residents, titled "A Guide to Bedrail Use and Alternatives at Maple View Lodge – Information for Residents and their Families". The pamphlet was reviewed by the Inspector.

While information was presented about the overall topic of restraints, which bed rails may or may not be considered, information was not provided related to the regulations and prevailing practices governing adult hospital beds in Ontario, specific to bed rails. Information was not provided related to the role of the SDM and licensee with respect to resident assessments associated with bed systems and the use of bed rails.

With regards to resident #001, referenced as resident #018 in the previous order report:

As per discussion with the DOC, resident #018 had a referral in place for the Bed Safe team, with a recommendation by the RAI coordinator to further assess for the possibility of discontinuing use of two full bed rails for the resident.

With regards to resident #002, referenced as resident #009 in the previous order report:

On March 6th, 2017, the DOC informed that the resident still had a "buddy" rail in place and that it was same design as what was on resident #003 and resident #004's beds. The rail resembled an upside down U, with an inside opening of approximately 18 inches by 11 inches, with extensions under the mattress secured to the bed frame with zip ties. The upper portion of the rails were covered with a protective black foam.

The DOC confirmed that she had conducted an evaluation of the resident's bed system the week of January 5th, 2017 and that the buddy rail failed the Zone 1 test. Entrapment Zone 1 is the space within the rail and as per the HC guidance document the space is to be less than 4 ¾ inches.

The Inspector asked the DOC if such a bed rail device was indicated for use on adult hospital beds as per the manufacturer specifications. The DOC did not have this information and could not verify if the rails were indicated for use or not.

The DOC indicated that she had been looking for a different type of "buddy" rail for resident #002, as the resident was adamant that he/she required the rail for bed mobility. The DOC had a replacement in a box in her office and indicated she intended that this new type of rail would be put onto resident #002's's bed that day. The rail was referred to as an "M-Rail" and described as an "adjustable bedside handrail", manufactured by Hartmobility. The DOC conducted an online search and located the installation instructions for the device, and it was determined that the device was not indicated for use on any part of a hospital bed that can move or be adjusted. As the hospital beds in use for the residents can be articulated in a variety of ways, it was concluded that this device should not be in use in the home and would not be an acceptable alternative for resident #002.

The "buddy" rail was removed from the resident #002's bed on March 8th, 2017.

With regards to resident #003, referenced as resident #016 in the previous order report, and resident #004:

On March 6th, 2017, the DOC informed that resident #003 still had what the home referred to as a "buddy" rail in place on his/her bed, as previously described for resident #002. The DOC confirmed that she had conducted an evaluation of the resident's bed system the week of January 5th, 2017 and that

the buddy rail failed the Zone 1 test.

The DOC informed that resident #004, not referenced in the previous order report, had the same type of "buddy" rail in place.

The DOC explained that she had asked nursing and maintenance staff to remove the "buddy" rails in January 2017 as they were no longer needed for the residents and had failed the entrapment testing.

The buddy rails were removed from resident #003 and resident #004's beds the evening of March 6th, 2017.

Following the onsite inspection, the Inspector determined that the "buddy" rails in use for resident #002, #003 and #004 were manufactured by Drive Medical, referenced as "Home Bed Assist Handle", and were only indicated for use on box spring type beds, not for articulating hospital beds as were in use for all residents in the home.

As observed by the Inspector on March 7th, 2017, resident #004 had two full bed rails on his/her bed in addition to the "buddy" rail that had been in place. As per discussion with Personal Support Worker #S102, the full rail closest to the wall was always up when resident #004 was in bed. The logo information board within the resident's bedroom, and the resident's written care plan as provided by the DOC on March 7th, 2017, did not make reference to the use of any type of bed rail for resident #004.

With regards to resident #005, referenced as resident #042 in the previous order report:

The DOC informed the inspector that the resident still had a "buddy" rail on his/her bed and that it was of a different design than the "buddy" rail on resident #002, #003, #004's beds. The DOC indicated that she had evaluated the resident's bed system in January 2017 and that all of the entrapment zones had passed the prescribed testing process.

On March 7th, 2017, the Inspector observed that the resident had an "M-Rail" on the left side of his/her bed. The head of the bed was articulated at the time of observation, at an approximate 30 degree angle. As previously referenced, the Inspector and the DOC had become aware, on March 6th, 2017, that such a bed

rail device was not indicated for use on parts of a hospital bed that can move or be adjusted. The resident informed the Inspector that when he/she is in bed, the head of the bed was always in this raised position.

The "M-Rail" was removed from resident #005's bed on March 8th, 2017.

In summary, the home failed to comply with compliance order #001, issued as a result of Resident Quality Inspection #2016_444602_0040, on January 18th, 2017. There is a history of non-compliance. The scope of the non-compliance described above is widespread given the number of residents utilizing one or more bed rails. The non-compliance presents a potential for harm given the failure to assess residents related to the risk of bed rail use as per prevailing practices described in the FDA 2003 clinical guidance document. As a result of these three factors, a subsequent compliance order will be issued.

(133)

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

This order must be complied with by /
Vous devez vous conformer à cet ordre d'ici le : Jun 26, 2017

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 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 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 SUR LE RÉEXAMEN/L'APPEL

PRENDRE AVIS

En vertu de l'article 163 de la Loi de 2007 sur les foyers de soins de longue durée, le titulaire de permis peut demander au directeur de réexaminer l'ordre ou les ordres qu'il a donné et d'en suspendre l'exécution.

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

La demande de réexamen doit contenir ce qui suit :

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

La demande écrite est signifiée en personne ou envoyée par courrier recommandé ou par télécopieur au:

Directeur
a/s Coordinateur des appels
Inspection de soins de longue durée
Ministère de la Santé et des Soins de longue durée
1075, rue Bay, 11e étage
Ontario, ON
M5S-2B1
Fax: 416-327-7603

Les demandes envoyées par courrier recommandé sont réputées avoir été signifiées le cinquième jour suivant l'envoi et, en cas de transmission par télécopieur, la signification est réputée faite le jour ouvrable suivant l'envoi. Si le titulaire de permis ne reçoit pas d'avis écrit de la décision du directeur dans les 28 jours suivant la signification de la demande de réexamen, l'ordre ou les ordres sont réputés confirmés par le directeur. Dans ce cas, le titulaire de permis est réputé avoir reçu une copie de la décision avant l'expiration du délai de 28 jours.

En vertu de l'article 164 de la Loi de 2007 sur les foyers de soins de longue durée, le titulaire de permis a le droit d'interjeter appel, auprès de la Commission d'appel et de révision des services de santé, de la décision rendue par le directeur au sujet d'une demande de réexamen d'un ordre ou d'ordres donnés par un inspecteur. La Commission est un tribunal indépendant du ministère. Il a été établi en vertu de la loi et il a pour mandat de trancher des litiges concernant les services de santé. Le titulaire de permis qui décide de demander une audience doit, dans les 28 jours qui suivent celui où lui a été signifié l'avis de décision du directeur, faire parvenir un avis d'appel écrit aux deux endroits suivants :

À l'attention du registraire
Commission d'appel et de révision
des services de santé
151, rue Bloor Ouest, 9e étage
Toronto (Ontario) M5S 2T5

Directeur
a/s Coordinateur des appels
Inspection de soins de longue durée
Ministère de la Santé et des Soins de longue durée
1075, rue Bay, 11e étage
Ontario, ON
M5S-2B1
Fax: 416-327-7603

La Commission accusera réception des avis d'appel et transmettra des instructions sur la façon de procéder pour interjeter appel. Les titulaires de permis peuvent se renseigner sur la Commission d'appel et de révision des services de santé en consultant son site Web, au www.hsarb.on.ca.

Issued on this 28th day of March, 2017

Signature of Inspector /
Signature de l'inspecteur :

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

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