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NURSING HOMES: ELIMINATE MICHIGAN-BASED CLINICAL PRACTICE GUIDELINES

Senate Bill 64 (reported from committee as H-1)
Sponsor: Sen. Goeff Hansen
House Committee: Health Policy
Senate Committee: Families, Seniors, and Human Services

Complete to 6-15-15

BRIEF SUMMARY: The bill would update the way in which the Department of Licensing and Regulation establishes compliance with, and standards for, nursing homes, eliminating some of the department's responsibility and shifting that responsibility to the nursing homes, themselves.

FISCAL IMPACT: Senate Bill 64, as passed by the Senate, would have a fiscal impact on the Department of Licensing and Regulatory Affairs (LARA) to the extent that LARA would no longer be required to develop, adopt, implement, biennially review, and update, clinical process guidelines and compliance protocols with outcome measures nor provide training to surveyors and providers concerning clinical process guidelines. According to LARA, the annual expenditures associated with performing these functions is approximately $270,000 for personnel, training, and travel costs.

LARA would also be required to post peer-reviewed, evidence-based, nationally recognized clinical process guidelines and peer-review, evidence-based, best-practice resources used in training sessions on its website; however, LARA currently posts content pertaining to the clinical process guidelines adopted by LARA and thus there would not likely be a change in costs associated with relevant web postings.

THE APPARENT PROBLEM:

The Bureau of Health Care Services and its Long-Term Care Division within the Michigan Department of Licensing and Regulatory Affairs, licenses and regulates Michigan's 451 long-term care facilities—including 435 nursing homes that meet the federal Centers of Medicare and Medicaid certification requirements, and another 16 nursing homes that are state licensed, but not federally certified.

In 2012, the Michigan legislation enacted Public Act 322 (formerly Senate Bill 884) to require the Long-Term Care Division to file a report with the legislature each year before March 1, to report, among other things, the patterns of citations issued against nursing homes. These deficiencies are categorized by both scope and severity (A through L with the higher being the more threatening), and the data are arrayed on a matrix. See ***Background Information***, below. In 2014, Michigan nursing homes had a total of 3,368 deficiencies—an average of about 7 citations per home.

Citations are issued when nursing homes fail to meet acceptable standards of care or best practices—called "clinical process guidelines" in the nursing home industry. Under Michigan law, clinical process guidelines must be written and updated by the Long-term Care Division of the Bureau of Health Affairs in the department.

When Public Act 322 went into effect about three years ago, one of its provisions required that the bureau biennially review and update all clinical process guidelines (originally developed between 2004 and 2008), adding necessary topics, and taking into account recommendations from an advisory workgroup. As those revised guidelines were developed, they were to be included in nursing home surveyor training sessions.

However, when the workgroup met on January 15, 2014, the update effort was abandoned. According to the workgroup's minutes, *"It was agreed by all members…that due to lack of funding and other reasons, they did not feel that they would be able to update the Clinical Process Guidelines that are currently in place, nor would it be in the best interest of the facilities (and could negatively impact those facilities that have already done an outstanding job) by requiring them to use the Clinical Process Guidelines."* Instead, the workgroup members advised that Public Act 322 be amended to remove the requirement that the department develop Michigan-specific clinical process guidelines.

In addition, now under the law, after a nursing home is cited for a violation, it may avoid a follow-up inspection, if it submits an affidavit having evidence of 'substantial compliance' with the law. To be eligible to request 'substantial compliance' and avoid an on-site revisit, the Michigan statute specifies that there may be no deficiencies with a scope and severity originating higher than level D—a category denoting an *isolated* incidence of "*no actual harm with potential for more than minimal harm that is not immediate jeopardy*."

In contrast, federal rules say a higher, more harmful category—level H—is the category that denotes a deficiency which clearly constitutes substandard quality of care. Level H is a violation that is not isolated, but rather denotes *a pattern* "of actual harm that is not immediate jeopardy."

Legislation has been introduced to eliminate the requirement that Michigan-based clinical process guidelines be developed for Michigan nursing homes, and also to increase the scope and severity level—from D to G—at which a 'substantial compliance' affidavit can be filed, in lieu of a site re-visit that ensures a return to acceptable practices.

THE CONTENT OF THE BILL:

Senate Bill 64 (H-1) would amend the Public Health Code (MCL 333.20155 et al) to update the way in which the Department of Licensing and Regulation establishes compliance with, and standards for, nursing homes. The bill would take effect 90 days after it was enacted into law.

Overall, Senate Bill 64 (H-1) would do all of the following:

- Refer to a nursing home "resident" rather than to a nursing home "patient."
- Delete a requirement that the Department of Licensing and Regulatory Affairs (LARA) develop and adopt clinical process guidelines and compliance protocols with outcome measures for nursing homes in specific areas of care.
- Require, instead, that a nursing home use peer-reviewed, evidence-based, nationally recognized clinical process guidelines, as well as peer-reviewed, evidence-based best practice resources to develop and implement resident care policies and compliance protocols with measurable outcomes in specific practice areas.
- Eliminate the requirement that the department instruct and train surveyors in the clinical process compliance guidelines used to cite deficiencies.
- Require LARA to post on its website all peer-reviewed, evidence-based, nationally recognized clinical process guidelines and peer-reviewed, evidence-based best-practice resources used in a training session.
- Require LARA's process for reviewing and authorizing the issuance of certain citations to be a consistent and accurate application of federal and state survey protocols, and defined regulatory standards (rather than assuring the effective use of clinical process guidelines).
- If funds are available, require LARA to give grants and other awards to nursing homes to encourage the rapid implementation of policies and protocols from peer-reviewed, evidence-based, nationally recognized guidelines to promote performance excellence, rather than to encourage the rapid implementation or maintenance of guidelines developed by LARA.
- Require LARA to maintain clear and uniform peer-reviewed, evidence-based best-practice resources (rather than to develop clinical process guidelines), for the use and maintenance of bed rails and properly fitted mattresses.
- Increase the scope and severity level—from D to G—at which a 'substantial compliance' affidavit can be filed, in lieu of a site re-visit that ensures a return to acceptable practices.
- Eliminate the 15-day deadline by which an investigation must begin following receipt of a written complaint.

A more detailed description of the bill follows.

Development & Use of Guidelines & Best Practice Resources

Article 17 of the Public Health Code, entitled "Facilities and Agencies," requires LARA to develop and adopt *clinical process guidelines*. Now under the law, the department must establish and adopt clinical process guidelines and compliance protocols with outcome measures for the following areas and for other topics where it determines that clarification will benefit providers and consumers of long-term care:

- Bed rails
- Adverse drug effects
- Falls
- Pressure sores
- Nutrition and hydration, including heat-related stress
- Pain management

- Depression and depression pharmacotherapy
- Heart failure
- Urinary incontinence
- Dementia
- Osteoporosis
- Altered mental states.
- Physical and chemical restraints
- Culture change principles, person-centered caring, and self-directed care.

The bill, instead, would require a nursing home to use *peer-reviewed evidence-based, nationally recognized clinical process guidelines and best-practice resources* to develop and implement resident care policies and compliance protocols with measurable outcomes, specifically in the following, nearly identical, clinical practice areas:

- Use of bed rails
- Adverse drug effects
- Prevention of falls
- Prevention of pressure ulcers
- Nutrition and hydration
- Pain management
- Depression and depression pharmacotherapy
- Heart failure
- Urinary incontinence
- Dementia care
- Osteoporosis
- Altered mental states
- Physical and chemical restraints
- Person-centered care principles

In an area of clinical practice that is not listed above, Senate Bill 64 (H-1) would permit a nursing home to use peer-reviewed, evidence-based, nationally recognized clinical process guidelines or best-practice resources to develop and implement resident care policies and compliance protocols with measurable outcomes, to promote performance excellence.

Currently, LARA must biennially review and update all clinical process guidelines as needed and must continue to develop and implement clinical process guidelines for topics that have not been developed from the current list and other topics identified as a result of quarterly meetings with stakeholders that are required under the Code. Senate Bill 64 (H-1) would delete that provision.

Surveyor Training

Now, the Public Health Code requires LARA to include training on new and revised clinical process guidelines in the joint provider and surveyor training sessions as those guidelines are developed and revised. Instead, Senate Bill 64 (H-1) would allow (rather than require) LARA to include training on new and revised peer-reviewed, evidence-based, nationally recognized clinical process guidelines or peer-reviewed, evidence-based, best-practice resources that contain measurable outcomes, in its joint provider and surveyor

training sessions. Under the bill, the purposes for doing so would be to assist provider efforts toward improved regulatory compliance and performance excellence, and to foster a common understanding of accepted best-practice standards between providers and the survey agency.

Under the bill, and for surveyor, provider and public reference, the department would have to post on its website all peer-reviewed, evidence-based, nationally recognized clinical process guidelines, and also all peer-reviewed, evidence-based best-practice resources used in a training session.

Now, the Public Health Code also requires LARA to instruct and train surveyors in the clinical process guidelines adopted by the department in citing deficiencies. Senate Bill 64 (H-1) would delete that requirement.

Further, the bill would require surveyors, when making compliance decisions, to consider peer-reviewed, evidence-based, nationally recognized clinical process guidelines and similarly vetted best-practice resources having measurable outcomes, as those used by a nursing home to develop and implement resident care policies and compliance protocols.

Review

The Public Health Code requires LARA to maintain the process by which it reviews and authorizes the issuance of a citation for 'immediate jeopardy' or 'substandard quality of care', before a statement of deficiencies is made final. The review must assure that the applicable concepts, clinical process guidelines, and other tools are being used consistently, accurately, and effectively. Senate Bill 64 (H-1), instead, would require the review to assure the consistent and accurate application of federal and state survey protocols and defined regulatory standards.

Grants & Awards

The Public Health Code requires LARA, if funds are available, to give grants, awards, or other recognition to nursing homes to encourage the rapid implementation or maintenance of the clinical process guidelines adopted by the Department. Senate Bill 64 (H-1), instead, would require LARA, upon the availability of funds, to give grants, awards, or other recognition to nursing homes to encourage the rapid development and implementation of resident care policies and compliance protocols that were created from peer-reviewed, evidence-based, nationally recognized clinical process guidelines or peer-reviewed, evidence-based best-practice resources with measurable outcomes, to promote performance excellence.

Bed Rails

Now, the Code requires a nursing home to give each resident who uses a hospital-type bed (or to the resident's patient advocate) the option of having bed rails. Under the law, the department must develop clear and uniform guidelines to be used in determining what constitutes acceptable bed rails, proper maintenance of bed rails, properly fitted mattresses, and other hazards created by improperly positioned bed rails, mattresses, or beds. Senate Bill 64 (H-1) would retain these provisions, but require the department to maintain clear

and uniform peer-reviewed, evidence-based best-practice resources (rather than to develop guidelines), for this purpose.

Now under the law, the department must develop the bed-rail guidelines in consultation with the long-term care workgroup established under the Code. Senate Bill 64 (H-1), instead, would require LARA to maintain the peer-reviewed, evidence-based best-practice resources for bed rails, in consultation with the long-term care stake-holders workgroup.

Further and under the law, the Code requires that an individual representing manufacturers of bed rails, two residents or family members, and an individual with expertise in bed rail installation and use be added to the long-term care stake-holders workgroup. As part of a report it makes to the legislature, the department must consider the recommendations of the hospital bed safety work group established by the U.S. Food and Drug Administration, if those recommendations are available at the time the report is submitted. Senate Bill 64 (H-1) would delete these requirements.

Nursing Home Resident

Throughout this section of the Code, Senate Bill 62 (H-1) would change the term nursing home "patient" to nursing home "resident." Now the Code defines "patient" as a person who receives care or services at a nursing home. Under the bill, "patient" would mean a resident, and "resident" would mean an individual who receives care or services at a nursing home.

Scope and Severity of Violations Regarding 'Substantial Compliance'

Now under the law, a nursing home cited for violations may file an affidavit of 'substantial compliance', rather than undergoing a re-inspection. However, the law specifies that there may be no deficiencies with a scope and severity *originating higher than level D*. Senate Bill 64 (H-1) would change this provision to specify there could be no deficiencies with a scope and severity *originating higher than level F*. Further, Senate Bill 64 (H-1) specifies that citations with a scope and severity of level F or below may go through a desk review by the department, upon thorough review of the 'plan of correction.' Under the bill, citations with a scope and severity of level G or higher are not to be considered for a desk review.

Investigation Deadline

Now under the law, upon receipt of a complaint, the department must determine, based on the allegations presented, whether state or federal certification regulations are in danger of being violated. The department must investigate the complaint according to the urgency determined, and that investigation must begin within 15 days after receipt of the written complaint by the department. Senate Bill 64 (H-1) would eliminate that 15-day investigation deadline, and instead specify that the investigation must begin within the time frame consistent with federal guidelines for investigations or complaints against nursing homes.

HOUSE COMMITTEE ACTION:

The members of the House Health Policy committee reported out Senate Bill 64 (H-1) with four changes from the Senate-passed version of the bill.

First, amendments were added to Section 1104 of the Public Health Code—in particular, to the definitions subsection—to update the definitions of "department" and "director" to mean the department and the director of the Department of Health and Human Services (rather than to the State Department of Community Health.)

Second, amendments were added to Section 20104 of the Public Health Code—also a definitions subsection—to add definitions of "department" and of "director" to mean the department and director of the Department of Licensing and Regulatory Affairs.

Third, amendments were added to Section 201551 of the Public Health Code to change the department's regulatory response after a nursing home violates the rules. Now a nursing home can submit an affidavit of 'substantial compliance' rather than undergo a re-inspection to assure a return to acceptable practices. Further, the law specifies that there may be no deficiencies with a scope and severity *originating higher than level D*. Senate Bill 64 (H-1) would change this provision to specify there could be no deficiencies with a scope and severity *originating higher than level F*. Further, Senate Bill 64 (H-1) specifies that citations with a scope and severity of level F or below may go through a desk review by the department, upon thorough review of the 'plan of correction.' Citations with a scope and severity of level G or higher are not to be considered for a desk review. See ***Background Information*** to view the "Scope and Severity Matrix."

Fourth, amendments were added to section 21799a of the Public Health Code to change the time frame during which the department must begin an investigation. Now under the law, upon receipt of a complaint, the department must determine, based on the allegations presented, whether state or federal certification regulations are in danger of being violated. The department must investigate the complaint according to the urgency determined, and that investigation must begin within 15 days after receipt of the written complaint by the department. Senate Bill 64 (H-1) would *eliminate that 15-day deadline*, and instead specify that the investigation must begin within the time frame consistent with federal guidelines for investigations or complaints against nursing homes**.**

BACKGROUND INFORMATION:

LARA's Long-Term Care Division. The mission of the Long Term Care Division of the Bureau of Health Services in the Department of Licensing and Regulatory Affairs follows.

> "The Long Term Care Division is responsible for assuring that residents in Michigan's [. . .] nursing homes receive the highest quality of care and quality of life in accordance with all state and federal requirements. Survey and certification activities assure that vulnerable nursing home residents are protected from abuse, neglect, misappropriation of personal property, and inadequate or inappropriate care and services. The Long Term Care Division includes the Complaint and Allegations Section, responsible for receiving and responding to consumer

complaints and facility reported incidents. Administrative functions related to data management, staff and provider training, and enforcement are located within the Long Term Care Division. Additionally, the Nurse Aide Registry Program and the Long Term Care Workforce Background Check Program are overseen within the Long Term Care Division as well."

Long-Term Care Report to Legislature. To review the Long-Term Care Division's report to the legislature, entitled "Long-Term Care Report on Protocol for Review of Citation Patterns: Survey Information & Data," published on March 1, 2015, visit the following website:
http://www.michigan.gov/documents/lara/BHCS_LTC_PA_322_2012_Report_03-01-2015_483923_7.pdf

Scope and Severity of Nursing Home Violations. 'Scope and Severity' is a system of rating the seriousness of deficiencies. A "deficiency" is a regulatory requirement that a survey finds is not being met. 'Scope and Severity' is a national system used by all state survey agencies, and the federal Health Care Financing Administration when conducting nursing home Medicare and Medicaid certification surveys. For each deficiency, the surveyor determines the level of harm to the resident or resident(s) involved, and the scope of the problem within the nursing home. The surveyor then assigns an alphabetical scope and severity value, A through L, to the deficiency. "A" is the least serious and "L" is the most serious rating. The scope and severity matrix is an integral part of how nursing home scores are calculated in the scoring system.

	Scope of the Deficiency		
Severity of the Deficiency	***Isolated***	***Pattern***	***Widespread***
Immediate jeopardy to resident health or safety	J	K	L
Actual harm that is not immediate jeopardy	G	H	I
No actual harm with potential for more than minimal harm that is not immediate jeopardy	D	E	F
No actual harm with potential for minimal harm	A	B	C

Shaded boxes within the grid denote deficiency ratings which constitute Substandard Quality of Care ***if*** *the requirement which is not met is one that falls under the following federal regulations:*

- *42 CFR 483.13 Resident behavior and facility practices*
- *42 CFR 483.15 Quality of life*
- *42 CFR 483.25 Quality of care*

According to the Long-Term Care Division report, Michigan's 451 dually certified nursing homes had a total of 3,368 deficiencies during 2014.

All 2014 deficiencies, by category, are as follows:

A = N/A	D = 2,085	G = 198	J = 35
B = 77	E = 570	H = 6	K = 0
C = 75	F = 321	I = 0	L = 1

Of the 3, 368 deficiencies, 42 deficiencies (about 1 percent) fell within the categories H though L, which is the new proposed threshold at which 'substantial compliance' affidavits would not be permitted, and an on-site revisit or inspection would be required. In contrast, now, under the current lower threshold in the law which begins at Level E and continues through Level L, there were 1,131 deficiencies (or about 33 percent) that nursing home operators could not correct without an on-site verification visit by state regulators.

ARGUMENTS:

For:

Proponents of the bill note that, increasingly, nursing homes are owned by regional and sometimes national health care corporations that operate nursing homes in many states throughout the nation. Consequently, nursing home operators say one set of rules, nationwide, can best assure uniform compliance with high standards of care. For that reason and others, they argue that Michigan's regulatory framework for nursing homes should track federal rules and regulations, and not exceed them. To that end, those who support the bill argue that Michigan should not develop its own "clinical process guidelines," but rather rely on the resources and best practices the nursing home industry follows, nationwide.

Proponents such as the Health Care Association of Michigan note that "…in the intervening years since Michigan specific CPGs were established, many other nationally-recognized evidence-based clinical process guidelines and best practice resources have become available, and are being widely used by providers for the purpose of improving and maintaining the quality of care for residents." These CPGs cover more topics than Michigan's out-of-date CPGs, and the list of topics continues to expand. "Based upon the availability of superior nationally recognized, evidence-based guidance," a committee appointed to update Michigan's CPGs recommends, instead, that they be abandoned completely. This bill accomplishes that end.

Proponents of the bill note that nursing homes are held accountable for providing appropriate health and medical care by insurance companies—most especially the federal Medicare program—and that it is these third-party payers that incentivize nursing homes to meet high standards.

Against:

Opponents of the bill argue it weakens the regulation of nursing homes in Michigan, by, among other things, decreasing the number of, and response time for, the follow-up inspections that occur after deficiencies are cited and complaints are filed. As amended, this legislation raises the severity of the deficiencies that will be eligible for 'substantial compliance' affidavits, rather than follow-up site visits to ensure a return to good practice.

For example, there were 3,368 deficiencies cited in Michigan's 451 nursing homes during 2014. Had SB 64 (H-1) been in effect that year, more than 98 percent of cited nursing homes would have been able to submit affidavits of 'substantial compliance' rather than be re-visited. In contrast, under the current threshold in our law, 66 percent—far fewer—were able to do so.

Opponents of the bill, including the Elder Law Section of the State Bar, observe that the language of the bill is very vague, because there is no specific reference to a particular set of clinical process guidelines. One wonders, then, against what standard of care will a nursing home's staff be measured? If LARA is not determining regulatory guidelines, how does a resident or resident's family know what guidelines are in place? How will consistency be insured across the board? The bill is, at best, confusing—both for nursing home residents and nursing home owners alike. At worst, the bill could make nursing homes less safe, turn a blind eye toward mediocre practices, and hold nursing homes less accountable to their residents, most of whom are frail and elderly.

POSITIONS:

The Michigan County Medical Care Facilities Council supports the bill. (5-19-15)

The Health Care Association of Michigan supports the bill. (5-19-15)

The Department of Licensing and Regulation supports the bill. (5-19-15)

The Elder Law and Disability Rights Section opposes the bill. (5-19-15)

The Michigan Elder Justice Initiative opposes the bill. (6-9-15)

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