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NURSING HOME REGULATION GUIDELINES

House Bill 5146 (Substitute H-2) First Analysis (10-10-01)

Sponsor: Rep. Joanne Voorhees
Committee: Senior Health, Security and Retirement

THE APPARENT PROBLEM:

Public Act 171 of 2000 (enrolled House Bill 5460) required the Department of Consumer and Industry Services to clarify certain terms as they are used in the regulation of nursing homes. The 2000 legislation required the department to consult with nursing home provider groups, the American Medical Directors Association, the Department of Community Health, the state long term care ombudsman, and the federal Health Care Finance Administration (now the Centers for Medicare and Medicaid Services, or CMMS) in clarifying the terms. The terms include: "immediate jeopardy", "harm", "potential harm", "avoidable", and "unavoidable". These terms are used to assess negative patient outcomes (i.e., deaths and injuries). A finding that a negative outcome that is an "unavoidable" consequence of a patient's condition is not intended to result in a citation. However, if a negative outcome is determined to be "avoidable", further assessment is necessary to determine whether the patient has suffered [actual] "harm" as opposed to "potential harm", and whether or not the resident has been placed in "immediate jeopardy".

Obviously, how these terms are understood by the various parties (nursing home providers vs. regulators) is significant. How the terms are applied will determine whether there has been a violation, and also the severity of the violation. Public Act 171 of 2000 was enacted largely because nursing home providers reported that they saw many inconsistencies in the way survey teams operated, and that this resulted in an highly subjective and unfair regulatory climate. During debate on the bill that became P.A. 171, the Department of Consumer and Industry Services defended its regulatory record, and cited pressure by federal regulators to increase its efforts to protect nursing home residents. Consumer groups generally took issue with the legislation, calling it an attempt to "regulate the regulators".

In any case, P.A. 171 eventually was enacted and contained not only the requirement for defining the terms listed above, but requirements that survey team members have certain kinds of education and

experience, that the department provide joint training for surveyors and providers, and that the department report to the legislature on its performance in conducting surveys and complaint investigations.

As required by P.A. 171, the Department of Consumer and Industry Services convened a workgroup to clarify the terms used in nursing home surveys. Its report was released on June 1, 2001. In addition to developing definitions of the terms themselves, the workgroup concluded that both state surveyors and nursing home providers could benefit from more specific guidance to identify appropriate practices related to various aspects of care. The report notes that clinical practice guidelines adopted by various nongovernmental groups, such as professional organizations, may be helpful when they are mutually accepted and based on medical evidence. To this end, legislation has been introduced to place into statute many of the conclusions of the clarification workgroup, including its definitions of the applicable terms, additional factors to consider when applying the terms, and a requirement that the department continue to work with stakeholder groups to develop clinical practice guidelines (also called clinical process guidelines) for various aspects of nursing home care.

THE CONTENT OF THE BILL:

House Bill 5146 would amend the Public Health Code (MCL 333.20155) to place in the statute definitions of the terms specified in Public Act 171 ("immediate jeopardy", "harm", "potential harm", "avoidable", and "unavoidable"), and to require the department to develop clinical process guidelines for applying the terms. The language in the bill is nearly the same as that in the workgroup's report, entitled "Clarification of Terms Used in Long Term Care Enforcement", dated June 1, 2001, published by the Department of Consumer and Industry Services.

"Immediate jeopardy". The term would be defined to mean "a situation in which immediate corrective

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action is necessary because the nursing home's noncompliance with one or more requirements of participation has caused or is likely to cause serious injury, harm, impairment, or death to a resident receiving care in a nursing home".

Further, the bill would specify that the likelihood of immediate jeopardy is reasonably higher if there is evidence of a flagrant failure by the nursing home to comply with a clinical process guideline established under the bill than if the nursing home has substantially and continuously complied with those guidelines. If federal regulations and guidelines are not clear, and if the clinical process guidelines have been recognized, a process failure giving rise to an immediate jeopardy could involve an egregious widespread or repeated process failure and the absence of reasonable efforts to detect and prevent the process failure.

In determining whether or not there is immediate jeopardy, the survey agency would have to consider at least all of the following:

- Whether the nursing home could reasonably have been expected to know about the deficient practice and to stop it, but did not stop it;
- Whether the nursing home could reasonably have been expected to identify the deficient practice and to correct it, but did not correct it;
- Whether the nursing home could reasonably have been expected to anticipate that serious injury, serious harm, impairment, or death might result from continuing the deficient practice, but did not so anticipate;
- Whether the nursing home could reasonably have been expected to know that a widely accepted high-risk practice is or could be problematic, but did not know; and,
- Whether the nursing home could reasonably have been expected to detect the process problem in a more timely fashion, but did not.

The bill specifies that the existence of one or more of the above-listed factors, and especially the existence of three or more of those factors simultaneously, could lead to a conclusion that the situation is one in which the nursing home's practice makes adverse events likely to occur if immediate intervention is not undertaken, and therefore constitutes "immediate jeopardy". Further, the bill says that if none of the

factors are present, the situation could involve harm or potential harm that is not "immediate jeopardy".

"Actual harm". The bill would define "actual harm" to mean "a negative outcome to a resident that has compromised the resident's ability to maintain or reach, or both, his or her highest practicable physical, mental, and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services". "Harm" would not include a deficient practice that only may cause or has caused limited consequences to the resident.

In determining whether a negative outcome is of limited consequence, if the "State Operations Manual" or "The Guidance to Surveyors" published by the federal Centers for Medicare and Medicaid Services does not provide specific guidance, the department could consider whether most people in similar circumstances would feel that the damage was of such short duration or impact as to be inconsequential or trivial. In such a case, the consequence of a negative outcome could be considered more limited if it occurs in the context of overall procedural consistency with an accepted clinical process guideline adopted under the bill, as compared to a substantial inconsistency with or variance from the guideline.

Further, if the publications do not provide specific guidance, the department could consider the degree of a nursing home's adherence to a clinical process guideline adopted under the bill in considering whether the degree of compromise and future risk to the resident constitutes actual harm. The bill specifies that the risk of significant compromise to the resident could be considered greater in the context of substantial deviation from the guidelines than in the case of overall adherence.

"Avoidable" and "unavoidable". The bill states that "to improve consistency and to avoid disputes over 'avoidable' and 'unavoidable' outcomes, nursing homes and survey agencies must have a common understanding of accepted process guidelines and of the circumstances under which it can reasonably be said that certain actions or inactions will lead to avoidable negative outcomes". If the state and federal publications cited above were not specific, a nursing home's overall documentation of compliance with a clinical process guideline with a process indicator adopted according to the bill would be relevant information in considering whether a negative outcome was "avoidable" or "unavoidable", and could be considered in the application of that term.

Clinical process guidelines. The Department of Consumer and Industry Services would be required to develop and adopt clinical process guidelines to be used in applying the terms “immediate jeopardy”, “harm”, “potential harm”, “avoidable”, and “unavoidable”. In developing the guidelines, the department would have to consult with clarification workgroup (those parties who participated in clarifying the terms as required in the 2000 legislation). Clinical process guidelines and compliance protocols with outcome measures would have to be developed for all of the following areas, and for others if determined beneficial by the department: bed rails, adverse drug effects, falls, pressure sores, nutrition and hydration, pain management, depression and depression pharmacology, heart failure, urinary incontinence, dementia, osteoporosis, and altered mental states.

Further, the department would be required to create a clinical advisory committee to review and make recommendations regarding the clinical process guidelines with outcome measures. The committee would have to include physicians, registered professional nurses, and licensed practical nurses, and at least some of them would have to be nursing home employees. The clarification workgroup would review the clinical process guidelines and outcome measures after the clinical advisory committee, and make the final recommendations to the department before the guidelines were adopted.

The department would be required to train nursing home surveyors in the use of the clinical process guidelines adopted under the bill.

Other DCIS responsibilities. The department would have to create a process by which the director of the Division of Nursing Home Monitoring or his or her designee, or the director of the Division of Operations or a designee, reviews and authorizes the issuance of citations for “immediate jeopardy” or “substandard quality of care” before the statement of deficiencies is made final. The review would be to assure that the applicable concepts, clinical process guidelines, and other tools developed under the bill were being used consistently, accurately, and effectively. As used in this provision, the terms “immediate jeopardy” and “substandard quality of care” would mean those terms as defined by the federal Center for Medicare and Medicaid Services.

The department could give grants, awards, or other recognition to nursing homes to encourage the rapid implementation of the clinical process guidelines adopted under the bill.

Finally, the department would be required to assess the effectiveness of the bill and file an annual report on the implementation of the clinical process guidelines with the legislative committees with jurisdiction over matters pertaining to nursing homes. The first report would have to be filed on July 1 of the year following the year the bill took effect.

BACKGROUND INFORMATION:

Nursing home regulation. In its role as the state’s regulator of nursing homes, the Department of Consumer and Industry Services is required to make annual visits to each nursing home for the purpose of survey, evaluation, and consultation. In addition to these visits, survey teams return to nursing homes to follow up on citations issued and to ensure that corrective measures have been taken. Further, the department makes unannounced visits to investigate complaints.

Citations that are disputed by nursing home administrators can be reviewed by the Michigan Peer Review Organization in an informal deficiency dispute resolution process. The MPRO is a five-member group consisting of active and former nursing home professionals. If the home still disputes a citation after review by the MPRO, a formal appeal process is available, consisting of a hearing before an administrative law judge (at either the state or federal level, depending on the citation). A ruling by an administrative law judge may be appealed through the judicial system.

Depending on how serious and widespread the deficiencies found, regulators may impose sanctions ranging from repeat visits by surveyors, greater oversight, civil fines, and, most seriously, the loss of Medicaid certification, loss of authority to provide on-the-job training for nurses’ aides (requiring training to be done at greater cost in other training programs), and ultimately, loss of licensure for the facility.

According to a September, 2001 report from the Department of Consumer and Industry Services, during the period of September 1, 2000 to August 31, 2001, the department issued 5,923 citations to nursing homes. Of the citations issued, 486 (8.2 percent) were appealed, 122 (2 percent) were amended or deleted (overturned), and 7 (0.1 percent) were still pending as of the date of the report.

Public Act 171 of 2000. As noted above, P.A. 171 of 2000 required the Department of Consumer and Industry Services to, among other things, clarify

certain terms as these terms are used in the regulation of nursing homes. For more information about P.A. 171, see the House Legislative Analysis Section's analysis of enrolled House Bill 5460, dated 6-22-00.

FISCAL IMPLICATIONS:

With regard to the bill as originally introduced, the House Fiscal Agency reported that the bill would increase costs to the Department of Consumer and Industry Services by an indeterminate amount. (10-8-01)

ARGUMENTS:

For:

The bill would continue the process started under Public Act 171 of 2000, whose stated goal was to make nursing home regulation more consistent and fair. It would place in the statute the recommendations of the "clarification workgroup", a group consisting of representatives of nursing home providers, state and federal regulators, and consumer advocacy organizations, who adopted proposed definitions of critical terms used in nursing home surveys and citations. In addition to the actual definitions, the workgroup developed language to provide additional guidance in applying the definitions, generally emphasizing a nursing home's overall pattern of compliance with "processes" (or routines of care) that represent reasonable approaches to good quality nursing care, and not on the occasional "aberration" or mistake. In other words, if a nursing home continually shows a high level of compliance with regulations, it should not necessarily be penalized for a bad outcome for a particular resident if that outcome was caused by an unusual or unforeseen event. The group further recommended the adoption of "clinical process guidelines", with specific outcome measures, to further define and clarify "best practices" in nursing home care.

More specificity in definitions and practices will help both providers and regulators to focus the survey process on the needs of residents, rather than on the adversarial nature that has become the norm. Ultimately, residents and their families should benefit from a more conciliatory approach to regulation.

Against:

Nursing home regulations and care standards, and guidance on how to implement them, are already plentiful and very detailed. And, federal law and regulations control how regulators must approach many issues. It may not be permissible for the state

to "clarify" federal definitions and terminology. More importantly, the bill would inappropriately shift the focus of surveys from the outcome experienced by the resident (e.g., an injury due to a fall), to the process used by the facility. This is contrary to the emphasis of federal law, and would work against the best interests of patients. This approach seems to be a way to create loopholes to shield providers from enforcement actions. Further, it is unnecessary to implement yet another level of scrutiny of serious citations issued by surveyors; these decisions are already reviewed by supervisors, and providers have opportunity to appeal. This provision can be viewed as a way to intimidate surveyors into reducing citations.

This bill seems to be another in a series of attempts to "regulate the regulators", based on an assumption that enforcement efforts are overzealous and biased against the nursing home industry. However, it should be noted that fully 98 percent of citations issued during the past year have been either *not* appealed, or upheld upon appeal. Instead of watering down nursing home regulation, consumer advocacy groups argue that stronger enforcement efforts are needed in order to protect vulnerable frail adults in long term care facilities.

POSITIONS:

The Department of Consumer and Industry Services supports the bill. (10-9-01)

The Health Care Association of Michigan supports the bill. (10-9-01)

The Michigan Association of Homes and Services for the Aging supports the bill. (10-9-01)

The Michigan County Medical Care Facilities Council supports the bill. (10-9-01)

The Michigan Health and Hospital Association supports the bill. (10-9-01)

The Michigan Campaign for Quality Care opposes the bill. (10-9-01)

Analyst: D. Martens

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.