

Adverse Health Events Update

Summary

This proposal updates Minnesota's adverse health events reporting law to reflect definitions adopted by the National Quality Forum. The changes include the addition of several new reportable events and the deletion or revision of several others.

Background

Passed in 2003, Minnesota's adverse health events reporting law requires all hospitals and ambulatory surgical centers licensed in Minnesota to submit reports to the Minnesota Department of Health (MDH) whenever one of 28 events happens. Facilities subject to the reporting law are also required to conduct an internal investigation (known as a Root Cause Analysis) for each event. They are further required to submit a summary of the investigation results, along with a corrective action plan, to MDH. MDH works closely with the Minnesota Hospital Association (MHA), Stratis Health, individual hospitals and surgical centers, and other stakeholders to learn from each event, and to develop best practices and standards to prevent recurrences.

The events included in Minnesota's adverse health events reporting law are based on a list of 28 Serious Reportable Events developed by the National Quality Forum (NQF). In June 2011, NQF approved the Serious Reportable Events in Healthcare – 2011 Update. The modified NQF list adds four new events, eliminates two other events,

and makes technical or definitional changes to several more.

While Minnesota's adverse health event reporting law is based on the NQF Serious Reportable Events list, changes to the national NQF list do not automatically trigger changes in Minnesota's law without legislative action. Therefore, Minnesota's reporting requirements are being updated at this time to reflect the new NQF standards.

Key Features

MDH proposes making the following changes to Minnesota's adverse health events reporting law:

1. Add four new types of events to the reporting law:
 - a. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting;
 - b. The irretrievable loss of an irreplaceable biological specimen (with or without injury);
 - c. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results; and
 - d. Patient death or serious injury associated with the introduction of a metallic object into the MRI area.
2. Remove three events from the list:

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- a. Death or serious disability associated with spinal manipulative therapy;
 - b. Death or serious disability associated with hypoglycemia (now included as a medication error); and
 - c. Death or serious disability associated with hyperbilirubinemia (now included as an example of ‘failure to follow up on test results’).
3. Replace the terms “serious disability” and “significant injury” with the term “serious injury” throughout the reporting law.
 4. Expand the term “surgery” to read “surgery or other invasive procedure” throughout the reporting law.
 5. Expand the types of patients covered in the “discharge to the wrong person” category to include patients of any age who lack decision-making capacity (rather than just infants).
 6. Expand the suicide category to include self-harm that results in serious injury or death.
 7. Expand the category of reportable pressure ulcers to include ‘unstageable’ ulcers.
 8. Make minor changes to several other event definitions.

Timing

Under this proposal, the new definitions go into effect at the beginning of the adverse health events reporting year. The changes would therefore apply to events discovered on or after October 7, 2013.

Impact of Changes

Several of the proposed technical or definitional changes formalize what is already current practice in Minnesota. Since 2008, based on national guidance from the National Pressure Ulcer Advisory Panel, MDH has required that unstageable

pressure ulcers be reported as adverse health events. The formalization of that language in statute will not increase reporting burden for hospitals. Similarly, MDH has always interpreted “surgery” to include other invasive procedures performed inside or outside of the operating room. Therefore, the formalization of that definition in statute will not change how the reporting system works in practice.

Of the three events MDH proposes to remove, two will be captured under other events and the third (death or serious disability related to spinal manipulative therapy) has never been reported in Minnesota during the nine years the system has been in place.

In 2011, MDH worked with the Minnesota Hospital Association to pilot test the four new events, and determine whether the NQF definitions were understandable and workable for hospitals. The pilot test found that while some additional definitional guidance may be needed once the changes go into effect, hospitals considered the events serious and worthy of reporting. Pilot test participants understood the event definitions, were able to identify potential events in their own data, and could enter them into the system without undue burden.

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