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Adverse Health Events Update

Summary

This legislative change has updated 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

Minnesota's adverse health events reporting law was passed in 2003, and 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, and submit a summary of the results of that investigation, and the accompanying 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 their recurrence.

The events included in Minnesota's adverse health events reporting law are based on a list of 28 Serious Reportable Events that was developed by the National Quality Forum (NQF). In June 2011, NQF approved the Serious Reportable Events in Healthcare – 2011 Update. The newly modified NQF list adds four new events, eliminates two other events, and makes technical or definitional events 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 have been updated to reflect the new NQF standards.

Key Features

Changes to Minnesota's adverse health events reporting law are as follows:

1. Four new types of events have been added 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 healthcare 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
   d. Death or serious injury of a patient associated with the introduction of a metallic object into the MRI area
2. Three events have been removed from the list:
   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. The term "serious disability" and "significant injury" have been replaced by "serious injury" throughout the reporting law;
4. The term "surgery" has been expanded to read "surgery or other invasive procedure" throughout the reporting law (this is consistent with definitional guidelines that are already in place in Minnesota);
5. The types of patients covered in the "discharge to the wrong person" category have been expanded to include patients of any age who lack decision-making capacity (rather than just infants);
6. The suicide category has been expanded to include self-harm that results in serious injury or death;
7. Reportable pressure ulcers have been expanded to include 'unstageable' ulcers (this is consistent with definitional guidelines that are already in place in Minnesota); and
8. Several other event definitions have undergone minor changes.

Timing

The new definitions would go into effect at the beginning of the next adverse health events reporting year, affecting events discovered on or after October 7th, 2013.

Impact of Changes

Several of the technical or definitional changes that have been made merely 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; the formalization of that definition in statute will not change how the reporting system works in practice.

Of the three events being removed, two will now be captured under other events; 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, the events were felt by hospitals to be serious and worthy of reporting. Pilot test participants were able to understand the event definitions, identify potential events in their own data, and enter them into the system without undue burden.

MDH will be working with its partners throughout 2013 to formulate definitions and guidance around the new reportable events. This will also be an ongoing task, as questions arise once reporting begins.

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