

## **ADVERSE (“NEVER”) EVENTS**

### **Background**

Adverse health care events, also called “never events,” are events that should not occur in the health care setting and that cause patient death or serious disability. In 2002, the National Quality Forum (NQF) endorsed a list of 27 adverse events that are serious, largely preventable, and of concern to both the public and health care providers for the purpose of public accountability. The list has been used by several states, including California, as the basis for public reporting of adverse events. Current efforts within the health care delivery system to improve quality and implement value based purchasing have led some states and the federal government to consider and/or adopt non-payment policies for adverse events.

While over half of the states require hospitals to report adverse events, there are no examples of states that withhold payment for adverse events. Information compiled by the National Academy for State Health Policy (NASHP) cataloguing state adverse event reporting requirements does not identify any states that link reporting to payment. One state, Minnesota, has a voluntary non-billing policy that was negotiated by hospitals and insurance companies. In April 2008, Maine passed a law prohibiting hospitals from charging a patient or insurer for services as a result of a preventable adverse event.

Beginning in October 2008, the Centers for Medicare and Medicaid Services (CMS) will no longer reimburse hospitals for the treatment of 8 hospital-acquired complications in the Medicare program.

### **Reporting Adverse Events in California**

In 2006, Senate Bill (SB) 1301 (Chapter 647, Statutes of 2006) required that hospitals report to the California Department of Public Health (CDPH) whenever an adverse event occurs. The statute defines adverse events as all of the 27 NQF-endorsed adverse events and a 28<sup>th</sup> general event defined as “an adverse event or series of events that cause the death or serious disability of a patient, personnel, or visitor.” These events fit into six categories ranging from surgical events to criminal events and include wrong site surgery, administration of incompatible blood and patient death associated with falls. (See Attachment I for a complete list.)

When CDPH receives a report of an adverse event, CDPH conducts an investigation into the event and takes appropriate action as needed. Some of these events receive monetary penalties of \$25,000 for immediate jeopardy violations and others result in facility deficiencies requiring plans of correction.

California hospitals began reporting these adverse events on July 1, 2007. CDPH currently reports the events in aggregate by category. Under the terms of SB 1301, the California Department of Public Health (CDPH) will make this information readily

accessible to the public on January 1, 2009. As of January 1, 2015, CDPH will post this information on its internet website.

### **Agreement on Policy, Confusion on Implementation**

There is a strong consensus in the health policy community that non-billing and non-payment for never events is appropriate. However, how to implement such a policy is still in the developmental phase. Medicare's implementation is the farthest along and is based on the use of Diagnosis Related Groups (DRGs). This approach is not replicable for other payers who do not use the DRGs.

Many issues still need to be worked out. These include:

- When an adverse event occurs, what exactly should not be billed for/paid? Hospital? Anesthesiologist? Nursing? Doctor?
- Which providers should be subject to the requirements? Hospitals? Surgical Centers?
- When does the actual adverse event start and end? Is the hospital required to document the condition upon admission in order to establish the timeline?
- If a non-billing policy is chosen, then how can purchasers audit to ensure providers are not billing for these events?

### **Proposed Legislation**

AB 2146 (Feuer). AB 2146, currently in the Senate Appropriations Committee, requires MRMIB and the Department of Health Care Services (DHCS) to develop uniform policies and practices governing the non-payment of hospital acquired conditions that are consistent with CMS policies and practices and to evaluate annually additional health care providers and/or hospital acquired conditions that should be subject to the non-payment policies.

Governor's Proposal. Seeking a phased approach to comprehensive health care reform, the Governor is proposing a non-billing and non-payment policy for adverse events. A non-billing policy prohibits health care providers from billing for adverse events. A non-payment policy requires payers to deny reimbursement for adverse events. MRMIB staff worked with DHCS, CDPH, the California Health and Human Services Agency (CHHS), and Governor's Office staff to develop an approach for non-billing and non-payment policies that the state could implement.

The proposal establishes state policy that health care providers shall not bill, and patients and payers shall not be required to pay for, substantiated adverse events. The providers subject to the adverse events policy are hospitals and surgical centers. The proposal contains protections to ensure the policy is not implemented in a way that would limit patient access to health care, or payment to health care providers for necessary follow up care. It requires the CDPH to collect patient name and payer

source and provide reports of substantiated adverse events to MRMIB and DHCS and other state payors.

Development of the specific policies and practices for the non-billing and non-payment for adverse events relies on a Health Care Cost and Quality Transparency Committee (HCCQTC) which is separately being created as part of this phased approach to comprehensive health care reform. MRMIB's executive director serves as an ex officio, non-voting member of the Committee.

Duties of the HCCQTC related to never events include:

- Develop policies and practices for determining the services that will not be billed/paid;
- Develop method to monitor and enforce these policies;
- Develop guidelines to be used by providers and payers that distinguish services and charges directly related to the adverse event from those needed to correct or treat the consequences of the event;
- Make recommendations on additional adverse events that should be added to the list
- Make recommendations on additional providers who should be subject to the never events policy

The Committee must make initial recommendations on these issues to the Secretary of CHHS no later than September 1, 2010. The Secretary will then approve the recommendations or refer the plan back to the Committee. Upon approval, affected departments would develop regulations implementing the policies.

This proposal also establishes the Office of Quality Improvement and Reporting within CDPH to reduce adverse events and improve patient safety and quality of care. The Office will perform various duties including: establishing a reporting system within the Office for receiving adverse event reports; analyzing adverse event reports, corrective action plans and root cause analyses and other patient safety work product submitted to the Office by providers; identifying patterns of systemic failure in the health system and identifying corrective measures; providing recommendations from their analysis to the facilities involved in adverse events; and developing educational programs and best practices for providers and the public.

The proposal requires that contracts between health plans and providers and health insurers and providers are consistent with the non-payment and non-billing policies of the Centers for Medicare and Medicaid Services (CMS) and the recommendations of the HCCQTC. The proposal prohibits balance billing of patients for charges not paid by a health plan or health insurer for adverse events. The proposal also allows the Director of the Department of Managed Health Care and the Insurance Commissioner to require additional documentation to ensure provider contracts provide medically necessary care and reimbursement.

As currently drafted, the proposal requires MRMIB to implement the non-billing and non-payment policies and practices developed by the HCCQTC for “the program.” MRMIB assumes that the intent is to have the non-billing and non-payment policies apply to all its programs including the Healthy Families Program (HFP), Access for Infants and Mothers (AIM) and the Major Risk Medical Insurance Program (MRMIP). However, the current language in the proposal does not address all three programs. The proposal prohibits providers from balance billing patients for charges not paid by state programs for adverse events.

If the Secretary approves the recommendations of the Committee, MRMIB would have to amend its regulations and contracts with participating plans in HFP, AIM and MRMIP to ensure that plans neither reimburse health care providers for the costs associated with adverse events nor include any unpaid costs for adverse events in proposed contract rates.

The proposal requires DHCS to implement the non-billing and non-payment policies and practices developed by the HCCQTC in its fee-for-service Medi-Cal program, and, to the extent feasible, in its other programs. DHCS will require Medi-Cal managed care plans implement similar non-billing and non-payment policies in their provider contracts. The proposal prohibits providers from balance billing patients for charges not paid by state programs for adverse events. The proposal requires providers to exclude costs related to adverse events subject to non-billing or non-payment procedures from their Office of Statewide Health Planning and Development (OSHPD) Annual Disclosure Report and their Medi-Cal 2552-96 Cost Report. The proposal ensures that implementation will occur only to the extent that federal financial participation is available and existing funds are not jeopardized.

**ATTACHMENT 1**  
**SB 1301 Reportable Adverse Events****Surgical events:**

1. Surgery on the wrong body part
2. Surgery on the wrong person
3. Wrong surgical procedure
- 4. *Retention of foreign object in a patient after surgery or other procedure\****
5. Death during or up to 24 hours after induction of anesthesia after surgery on an otherwise healthy patient

**Product or device events:**

6. Patient death or serious disability associated with use of a contaminated device, drug or biologic provided by the facility
7. Patient death or serious disability associated with use or function of a device in patient care in which the device is used or functions other than as intended
- 8. *Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility\****

**Patient protection events:**

9. Infant discharged to the wrong person
10. Patient death or serious disability associated with patient disappearance for 4 hours or longer
11. Patient suicide or attempted suicide resulting in serious disability

**Care management events:**

12. Patient death or serious disability associated with a medication error
- 13. *Patient death or disability associated with incompatible blood\****
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy
15. Patient death or serious disability directly related to hypoglycemia
16. Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life
- 17. *A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progress from Stage 2 to Stage 3 if Stage 2 was recognized upon admission\****
18. Patient death or serious disability due to spinal manipulative therapy

**Environmental events:**

19. Patient death or serious disability associated with electric shock
20. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance
21. Patient death or serious disability associated with a burn
- 22. *Patient death or serious disability associated with a fall\****
23. Patient death or serious disability associated with the use of restraints or bedrails

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**\* Event included on CMS' list of non-reimbursable events.**

**Criminal events:**

- 24. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
- 25. Abduction of a patient of any age
- 26. Sexual assault on a patient within or on the grounds of a health facility
- 27. Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility

**Other (not NQF-endorsed):**

- 28. An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor