CONFERENCE CALL OF THE SERIOUS REPORTABLE EVENTS IN HEALTHCARE STEERING COMMITTEE

September 14, 2010

Steering Committee Members Present: Gregg Meyer, MD, MSc (Co-Chair); Sally Tyler, MPA (Co-Chair); Tejal Gandhi, MD, MPH; Christine Goeschel, RN, MPA; Cynthia Hoen, Esq,, MPH, FACHE; Helen Lau, RN, MHROD, BSN, BMus; Kathryn McDonagh, PhD; John Morley, MD, FACP; Deborah Nadzam, PhD, RN, FAAN; Martha Radford, MD, FACC, FAHA; Stancel Riley, Jr., MD, MPA, MPH; Diane Rydrych, MA; Doron Schneider, MD, FACP; Eric Tangalos, MD, FACP, AGSF, CMD; Michael Victoroff, MD

Steering Committee Members Absent: Leah Binder; Patrick Brennan, MD; Philip Schneider, FASHP, MS

NQF Staff: Peter Angood, MD; Helen Burstin, MD, MPH; Melinda Murphy, RN, MS; Lindsey Tighe, MS

WELCOME AND INTRODUCTIONS

Dr. Angood welcomed the Committee members and thanked them for their participation on the call. Dr. Meyer and Ms. Tyler informed the Committee members that the purpose of this call would be to review the submitted modifications and Technical Advisory Panel (TAP) recommendations for the existing Serious Reportable Events (SREs) in the prioritized healthcare environments for expansion of the SREs. Those environments are Skilled Nursing Facilities (SNFs), Ambulatory Outpatient Practices, and Ambulatory and Office-based Surgery Centers.

REVIEW OF THE EXISTING SREs

The TAP chairs reviewed the TAP recommendations for the existing SREs event by event. Recommendations from the TAPs are found in a separate spreadsheet capturing a summary of the TAP discussions.

Committee members reviewed the existing events, the submitted modifications to the events, and the TAP recommendations. Committee recommendations with respect to the material reviewed as well as the rationale for any modifications are found in the table below.

With respect to the current "Criminal Events," the Committee recommended that the category heading be modified to "Potential Criminal Events" because these events are not always criminal in nature (for example, accidental injury of a staff member by a patient).

Existing Serious Reportable Event	SC Recommendation for Event Modification	SC Rationale for Modification	Applicable Settings	Additional Comments
Death or serious disability (kernicterus) associated with an failure to identify and treat hyperbilirubinemia in neonates	**Remove endorsement of the event**	• The event is an instance of failure to follow up with a patient (a new event submission recommended for endorsement). As such, SC stated that death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates should be used as an example in the implementation guidance for the new event and should not be a standalone event.		
Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	**Stage 3 or 4, or unstageable pressure ulcers acquired after admission to a healthcare setting**	• SC stated that the presence of an unstageable pressure ulcer acquired after admission should be reported. The injury is serious and adverse; this also clarifies the event and eliminates loopholes whereby institutions could avoid reporting the event. • SC recommended the use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital.	• Hospital, • Outpatient/Office-based Surgery Centers • Long-Term Care/Skilled Nursing Facilities	• SC acknowledged that not all pressure ulcers are preventable, but all should be reported. When the event is reviewed, preventability can be assessed. • Deep tissue injury should not be included in this event, because deep tissue injury is a suspected injury, not a confirmed one.
Patient death or serious disability due to spinal manipulative therapy	**Remove endorsement of the event**	• This event captures provider error rather than system or process error, which is unlike all of the other SREs.		
Artificial insemination with the wrong donor sperm or wrong egg	*No changes*		• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices	• SC acknowledged that this event could be viewed as an instance of wrong procedure; however, the occurrence of this event is so serious that all instances need to

			• Long-Term Care/Skilled Nursing Facilities	be reported. As such, it should remain a standalone event.
Death or serious disability of a patient associated with an electric shock while being cared for in a healthcare facility	**Death or serious injury of a patient or staff member associated with an electric shock in the course of a patient care process while being cared for in a healthcare setting**	• SC recommended that staff members should be included in this event. • In order to ensure that this event did not capture electric shock to electricians/other staff working with electrical equipment unrelated to patient care, SC recommended use of the phrase "in the course of a patient care process." • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability. • SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	• SC requested input from technical experts as to whether the exclusion of patients undergoing planned treatments such as electric countershock/elective cardioversion is warranted.
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 toxic substances	**Any incident in which a system designated for delivery of oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances**	• SC recommended inclusion of instances where gas is not delivered to a patient, such as when a gas line has been shut off or a gas tank is empty. The patient is not receiving a prescribed intervention due to a system or process error.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	
Patient death or serious disability associated with a burn incurred from any source while being cared for in a	**Death or serious injury of a patient or staff member associated with a burn incurred from any source while**	• SC recommended that staff members should be included in this event. • SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician	

healthcare facility	**being cared for in a healthcare setting**	disability. • SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital.	Offices • Long-Term Care/Skilled Nursing Facilities	
Patient death or serious disability associated with a fall while being cared for in a healthcare facility	**Patient death or serious injury associated with a fall either during or after being cared for in a healthcare setting**	• SC recommended use of the term "serious injury" rather than "serious disability" because the adverse outcome to the patient may not result in disability or additional disability. • SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	• SC stated that there needs to be further clarity of what it means when a patient is under care and at what point an individual is considered a patient and thus the responsibility of the healthcare provider. A subcommittee will review and provide further recommendations.
Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	**Patient death or serious injury associated with the use of physical restraints while being cared for in a healthcare setting**	• SC recommended use of the term "physical" as a descriptor of restraints in order to clarify that this does not include drugs used to restrain a patient.	• Hospital, • Outpatient/Office-based Surgery Centers • Long-Term Care/Skilled Nursing Facilities	
Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	*No changes*		• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	• SC stated that occurrence of this event is infrequent, and consequently the burden of reporting is minimal. • This event is to be reported as an SRE in order to find ways to prevent the occurrence of the event. The intention of reporting criminal events to the judicial

				system is punishment of the offenders. As such, SC recommended that this event be maintained on the SRE listing.
Abduction of a patient of any age	*No changes*		• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	• SC stated that occurrence of this event is infrequent, and consequently the burden of reporting is minimal. This event is to be reported as an SRE in order to find ways to prevent the occurrence of the event. The intention of reporting criminal events to the judicial system is punishment of the offenders. As such, SC recommended that this event be maintained on the SRE listing.
Sexual assault on a patient within or on the grounds of a healthcare facility	**Sexual assault on a patient or staff member within a healthcare setting**	• SC recommended inclusion of staff members in the reporting of this event, because sexual assault to either staff or patient is indicative of a serious safety issue. • SC recommended use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	• SC stated that occurrence of this event is infrequent, and consequently the burden of reporting is minimal. • This event is to be reported as an SRE in order to find ways to prevent the occurrence of the event. The intention of reporting criminal

				events to the judicial system is punishment of the offenders. As such, SC recommended that this event be maintained on the SRE listing.
Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare facility	**Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a healthcare setting**	• SC recommended use of the term "serious injury" rather than "significant injury" to be consistent with the other SREs. • SC recommended the use of the term "healthcare setting" rather than "healthcare facility" to be more encompassing of healthcare environments other than the inpatient hospital.	• Hospital, • Outpatient/Office-based Surgery Centers • Ambulatory Practice Settings/Physician Offices • Long-Term Care/Skilled Nursing Facilities	• SC stated that occurrence of this event is infrequent, and consequently the burden of reporting is minimal. • This event is to be reported as an SRE in order to find ways to prevent the occurrence of the event. The intention of reporting criminal events to the judicial system is punishment of the offenders. As such, SC recommended that this event be maintained on the SRE listing.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

A summary of this call will be emailed to Committee members within the next few weeks.

The Steering Committee will next meet by conference call on Wednesday, September 29, 2010, at 4 pm ET to continue evaluation of the Serious Reportable Events.

The meeting was adjourned.