NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**

(for NQF staff use**) Has all requested information been provided? Yes**
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM
Organization: Pennsylvania Patient Safety Authority
Street Address: 5200 Butler Pike
City/State/Zip: Plymouth Meeting, PA 19462
Telephone Number: 610-825-6000 x5040
Fax Number: 610-834-1275
Email Address: clacker@ecri.org

Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event:
Patient death or serious disability associated with a medication error (eg, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☒ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home

☒ Outpatient or Office-based Surgery Center ☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:	

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Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
Street Address: 2550 University avenue W Suite 350S
City/State/Zip: Saint Paul, MN 55114
Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient death or serious disability associated with a medication error

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☐ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☒ Ambulatory Practice / Physician Offices

☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large),	**Y**☐ **N**☐

provide name of initiative(s), locations, Web page URL(s):

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**

(for NQF staff use**) Has all requested information been provided?** Yes
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: William R. Scharf, M.D.
Organization: OSF Healthcare System
Street Address: 800 N.E. Glen Oak Avenue
City/State/Zip: Peoria, IL
Telephone Number: 309-655-4806
Fax Number:
Email Address: **William.scharf@osfhealthcare.org**

Date of Submission (*MM/DD/YY*)**:** **06/10/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☐ **X Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient death or serious disability associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐X **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Patient death or serious disability associated with a medication error (e.g. errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration as well as administration of a drug in a patient with a known allergy to that drug).

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** The current specification is fairly concise but omits an important and overlooked form of harm which is administering a drug to a patient with an allergy to that drug.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ XYes ☐ No **If yes, please explain:** the modifications could pick up a category of medication error that are not currently reported

Y☐
N☐

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)*

Applicable Care Settings (Mark all to which event is relevant)
- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please specify*):

Reviewer Comments/Rationale:

2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures ——NQF 0020: Documentation of allergies and adverse reactions in the outpatient record

Reviewer Comments:

RECOMMENDATION

Steering Committee:
Do you recommend the proposed change? ☐ **Y** ☐ **N** ☐ **A**
Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable , and clearly defined occurrence **Y** ☐ **N** ☐
Name of Proposed New Event:

3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS

Brief Description of Event:

The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Y** ☐ **N** ☐

Briefly summarize the Evidence Base that the event is preventable and provide citations:

The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* **Y** ☐ **N** ☐
Please check the appropriate consequence and describe it
- ☐ Death or ☐ risk of death
- ☐ Loss of a body part or ☐ risk of loss **Describe:**
- ☐ Disability or ☐ risk of disability **Describe:**
- ☐ Loss of bodily function or ☐ risk of loss **Describe:**

The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Y** ☐ **N** ☐
Definitions:
Codes and descriptors (if used):
Instructions for counting events, calculating rates, and providing context for low frequency:

Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)* **Y** ☐ **N** ☐

Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y☐ N☐**
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:	**Y☐ N☐**
Reviewer Comments/Rationale:	

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	**Y☐ N☐ A☐**
Steering Committee Reviewer Name:	

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety
☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness **Consumer Care Need** ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**
Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
Street Address: 2550 University Avenue W. Suite 350S
City/State/Zip: Saint Paul, MN 55114
Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient death or seriously disability associated with blood or blood products

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y☐ N☐**

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☒ Ambulatory Practice / Physician Offices

☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures NQF0350: Transfusion Reaction (PDI 13); NQF 0349: Transfusion Reaction (PSI 16)	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION
Submitter: Julie Apold **Organization:** Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations. **Street Address:** 2550 University Avenue W. Suite 350S **City/State/Zip:** Saint Paul, MN 55114 **Telephone Number:** 651-641-1121 **Fax Number:** 651-659-1477 **Email Address:** **japold@mnhospitals.org**
Date of Submission (*MM/DD/YY*)**: 6/16/10** **Is this submission about a currently endorsed SRE or a proposed new SRE?** ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event: Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility.	
Suggested Change: ☒ **Specify the Applicable Care Setting(s) marked below** ☐ **Remove Endorsement** ☐ **Modify SRE Specifications** **Describe Suggested Modification(s) in specific detail:** **Rationale for removing endorsement or modifying the SRE** *(include pertinent evidence, data)***:** **If modifications are made,** *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:** (for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)*	**Y**☐ **N**☐
Applicable Care Settings (Mark all to which event is relevant) ☒ Hospital ☐ Skilled Nursing Facility (SNF) / Nursing home ☒ Outpatient or Office-based Surgery Center	

☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
Street Address: 2550 University Avenue W. Suite 350S
City/State/Zip: Saint Paul, MN 55114
Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient death or serious disability associated with hypoglycemia.

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☐ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☒ Ambulatory Practice / Physician Offices

☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures SP 32: Glycemic Control	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large),	**Y**☐ **N**☐

provide name of initiative(s), locations, Web page URL(s):

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**

(for NQF staff use) **Has all requested information been provided?** Yes
Staff Notes to Submitter (*if submission returned*)**:**

Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**

Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Margaret Driscoll
Organization: Children's Hospital Boston
Street Address: 300 Longwood Avenue
City/State/Zip: Boston, MA 02115
Telephone Number: 617-355-7359
Fax Number: 617-730-0637
Email Address: Margaret.driscoll@childrens.harvard.edu

Date of Submission (*MM/DD/YY*)**:** 06/16/10
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient Death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☒ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Include exclusions or exclusionary language addressing issues specific to hypoglycemia in infants and children.

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** The brain of infants and young children is large relative to body mass and its energy requirement is primarily derived from the oxidation of circulating glucose. To meet the high demand for glucose, the rate of glucose production in infants and young children is approximately 3 times that of older children and mature adults. Maintenance of glucose homeostasis in the newborn period and in early childhood is more precarious than later in childhood and in adults. During a period when normal feeding is interrupted, as typically occurs during serious illness or owing to surgery or other procedures, infants and children cannot sustain the high rate of glucose

Y☐
N☐

production. For these reasons, when normal feeding patterns are disturbed by intercurrent illness infants and young children are more prone than adolescents and adults to develop hypoglycemia.

In addition, there are numerous uncommon or rare specific causes of hypoglycemia in infants and children. Hyperinsulinism is the most common cause of persistent hypoglycemia in infants and young children. Several distinct genetic forms of congenital hyperinsulinism cause recurrent and severe hypoglycemia and are often difficult to treat. Despite adequate medical care, permanent neurologic sequelae may occur in children with these disorders. In older infants and toddlers, a variety of uncommon heritable metabolic abnormalities account for most cases of hypoglycemia, which most often presents during intercurrent illness or when feeding is interrupted. In light of these considerations, we believe that hypoglycemia in infants and children should be an exception.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes*

Applicable Care Settings (Mark all to which event is relevant)

☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center
☐ Ambulatory Practice / Physician Offices
☐ Other (*Please specify*):

Reviewer Comments/Rationale:

2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered: In conclusion, we do not regard hypoglycemia to always be preventable or an unexpected complication in children.

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures —SP 32: Glycemic Control

Reviewer Comments:

RECOMMENDATION

Steering Committee:
Do you recommend the proposed change? ☐ **Y**☐ **N**☐ **A**☐
Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable , and clearly defined occurrence **Y**☐ **N**☐
Name of Proposed New Event:

3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS

Brief Description of Event:

The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that* **Y**☐

occurs because of an error or other system failure) **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)***:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3d. SETTINGS, DATA SOURCES	
Applicable Care Settings (Mark all to which event is relevant) ☐ Hospital ☐ Skilled Nursing Facility (SNF) / Nursing home ☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please describe*):	
Data Source *Check the source(s) for the information on the SRE.* ☐ Electronic administrative data/ claims ☐ Electronic Clinical Data *(e.g., MDS)* ☐ Incident Reports ☐ Medical Record including Electronic ☐ Pharmacy data ☐ Public health data/vital statistics ☐ Quality / Risk Management Databases ☐ Registry data (or database) ☐ Reports to External Bodies (states, federal) ☐ Regulatory or Accreditation data (FDA, OSHA, etc.) ☐ Special or unique data, specify: **Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:** **Data dictionary/code table attached** ☐ **OR at web page URL:**	
Process(es) to Collect Data Provide additional information about how the data regarding the event are collected. Address verifiability, reliability, and validity, if possible**.**	
Reviewer Comments/Rationale:	
3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT	

Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	**Y** ☐ **N** ☐ **A** ☐
Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).** **National Priority Partners Priority Area** ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse **IOM Quality Domain** ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness **Consumer Care Need** ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.
Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Erin Graydon Baker
Organization: Partners Healthcare
Street Address: 115 4th Ave
City/State/Zip: Needham/MA/02494
Telephone Number: 781-433-3776
Fax Number: 781-433-3667
Email Address: egraydonbaker@partners.org

Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? x☐ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient Death or Serious Disability Associated with Hypoglycemia

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
x☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Re-define serious disability as" injury requiring extended hospitalization, prolonged loss of function (affecting the ability to perform activities of daily living) for at least 30 days". Change "associated "to "caused by".

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:** The term "associated "in this case may be loosely interpreted.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes x☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes*

Y☐
N☐

Applicable Care Settings (Mark all to which event is relevant)
x☐ Hospital

x☐ Skilled Nursing Facility (SNF) / Nursing home x☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.* More accurate representation of SRE	
(for NQF staff use) Identify related endorsed measures SP32: Glycemic Control	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:	N☐
Reviewer Comments/Rationale:	

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	**Y☐** **N☐** **A☐**
Steering Committee Reviewer Name:	

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
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Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Death or serious disability associated with failure to identify and treat hyperbilirubinimia in neonates.

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☐ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center

☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.
Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Erin Graydon Baker
Organization: Partners Healthcare
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Email Address: egraydonbaker@partners.org

Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? x☐ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient Death or Serious Disability Associated with Failure to Identify and Treat Hyperbilirubinemia

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
x☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Define serious disability since the effect might not be apparent for years. Change the definition to reflect " hospitalized neonates within the first 28days"

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data):* Most neonates are discharged within 28 days. We would not have control over their care after discharge.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes x☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes* **Y☐ N☐**

Applicable Care Settings (Mark all to which event is relevant)
x☐ Hospital

☐ Skilled Nursing Facility (SNF) / Nursing home ☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.* More accurate representation of SRE	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*: N☐

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y☐ N☐ A☐
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM
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Fax Number: 610-834-1275
Email Address: clacker@ecri.org

Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event:
Stage 3 or 4 pressure ulcers acquired after admission to a health care facility

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☒ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center

☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures SP 27: Pressure Ulcer Prevention; NQF 0199: Average-risk residents with pressure ulcers; NQF 0198: High-risk residents with pressure ulcers; NQF 0181: Increase in number of pressure ulcers; NQF 0201: Pressure Ulcer Prevalence; NQF 0538: Pressure Ulcer Prevention Included in Plan of Care; NQF 0539: Pressure Ulcer Prevention Plans Implemented; NQF 0540: Pressure Ulcer Risk Assessment Conducted; NQF 0187: Recently hospitalized residents with pressure ulcers (risk adjusted)	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐

	N☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:	Y☐ N☐
Reviewer Comments/Rationale:	

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	Y☐ N☐ A☐
Steering Committee Reviewer Name:	

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
Street Address: 2550 University Avenue W. Suite 350S
City/State/Zip: Saint Paul, MN 55114
Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Stage III or IV pressure ulcers acquired after admission to a healthcare facility.

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☒ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:
1) Recommend modifying to "Stage III, IV or unstageable pressure ulcers, avoidable and unavoidable, acquired after admission to healthcare facility.
2) In specifications, exclude deep tissue injury."

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**
1) Recent changes in staging by the National Pressure Ulcer Advisory Panel and feedback from MN pressure ulcer experts indicate that unstageable pressure ulcers are most likely at a Stage III or IV. Minnesota has been reporting unstageables since 2007. This change has led to significant additional learnings. Over the past two years, 68% of reported pressure ulcers in Minnesota were unstageable.
2) Specifying that Deep tissue injuries are not included will provide additional consistency in reporting.

If modifications are made, *are the changes likely to result in a substantial change in the current count* **Y☐ N☐**

of SREs? X Yes ☐ No **If yes, please explain:** Over the past two years, 68% of reported pressure ulcer in Minnesota last year were unstageable. (for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes*	
Applicable Care Settings (Mark all to which event is relevant) ☒ Hospital ☒ Skilled Nursing Facility (SNF) / Nursing home ☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures SP 27: Pressure Ulcer Prevention; NQF 0199: Average-risk residents with pressure ulcers; NQF 0198: High-risk residents with pressure ulcers; NQF 0181: Increase in number of pressure ulcers; NQF 0201: Pressure Ulcer Prevalence; NQF 0538: Pressure Ulcer Prevention Included in Plan of Care; NQF 0539: Pressure Ulcer Prevention Plans Implemented; NQF 0540: Pressure Ulcer Risk Assessment Conducted; NQF 0187: Recently hospitalized residents with pressure ulcers (risk adjusted)	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):**	**Y**☐ **N**☐

Instructions for counting events, calculating rates, and providing context for low frequency:

Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)* **Y☐ N☐**

Describe how the event is indicative of a problem in a healthcare facility's safety systems: **Y☐ N☐**

Describe why the event is important for public credibility or accountability: **Y☐ N☐**

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)***:**

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible**.**

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:	
4. PRIORITY AREAS	
(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).** **National Priority Partners Priority Area** ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse **IOM Quality Domain** ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness **Consumer Care Need** ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy	
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION
Submitter: Margaret Driscoll **Organization:** Children's Hospital Boston **Street Address:** 300 Longwood Avenue **City/State/Zip:** Boston, MA 02115 **Telephone Number:** 617-355-7359 **Fax Number:** 617-730-0637 **Email Address:** Margaret.driscoll@childrens.harvard.edu
Date of Submission (*MM/DD/YY*)**: 06/16/10** **Is this submission about a currently endorsed SRE or a proposed new SRE?** ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Name of Event: Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	
Suggested Change: ☐ **Specify the Applicable Care Setting(s) marked below** ☐ **Remove Endorsement** ☒ **Modify SRE Specifications** **Describe Suggested Modification(s) in specific detail:** Include exclusionary language for unavoidable pressure ulcers as defined by the National Pressure Ulcer Advisory Panel. The National Pressure Ulcer Advisory Panel defines unavoidable as "means that the individual developed a pressure ulcer even though the provider had evaluated the individual's clinical condition and pressure risk factors; defined and implemented interventions that are consistent with individual needs goals and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate." **Rationale for removing endorsement or modifying the SRE:** The National Pressure Ulcer Advisory Panel's recent consensus statement (March 3, 2010) agreed that patients who choose not to participate in their own pressure ulcer prevention could develop unavoidable pressure ulcers. They also agreed that there are clinical situations in which the development of pressure ulcers can be unavoidable including patients in	**Y**☐ **N**☐

critical care where hemodynamic instability may preclude turning or repositioning and lead to unavoidable pressure ulcers. We believe a thoughtful and interdisciplinary analysis of all aspects of a Stage 3 or 4 pressure ulcer found in a hospitalized patient will help determine if a pressure ulcer is avoidable, versus a pressure ulcer caused by a breach of care, and as such, some pressure ulcers may be deemed unavoidable, and not fall into the SRE category.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)*

Applicable Care Settings (Mark all to which event is relevant)

☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center
☐ Ambulatory Practice / Physician Offices
☐ Other (*Please specify*):

Reviewer Comments/Rationale:

2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures SP 27: Pressure Ulcer Prevention; NQF 0199: Average-risk residents with pressure ulcers; NQF 0198: High-risk residents with pressure ulcers; NQF 0181: Increase in number of pressure ulcers; NQF 0201: Pressure Ulcer Prevalence; NQF 0538: Pressure Ulcer Prevention Included in Plan of Care; NQF 0539: Pressure Ulcer Prevention Plans Implemented; NQF 0540: Pressure Ulcer Risk Assessment Conducted; NQF 0187: Recently hospitalized residents with pressure ulcers (risk adjusted)——

Reviewer Comments:

RECOMMENDATION

Steering Committee:
Do you recommend the proposed change? ☐
Do you recommend the proposed change with modification? ☐ Specify the modification

Comments/Rationale:

Y☐ **N**☐ **A**☐

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable , and clearly defined occurrence **Y**☐ **N**☐
Name of Proposed New Event:

3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS

Brief Description of Event:

The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Y**☐ **N**☐

Briefly summarize the Evidence Base that the event is preventable and provide citations:

The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* **Y**☐ **N**☐
Please check the appropriate consequence and describe it
☐ Death or ☐ risk of death
☐ Loss of a body part or ☐ risk of loss **Describe:**

☐ Disability or ☐ risk of disability **Describe:**
☐ Loss of bodily function or ☐ risk of loss **Describe:**

The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Y☐ N☐**
Definitions:
Codes and descriptors (if used):
Instructions for counting events, calculating rates, and providing context for low frequency:

Reviewer Comments/Rationale:

3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)* **Y☐ N☐**

Describe how the event is indicative of a problem in a healthcare facility's safety systems: **Y☐ N☐**

Describe why the event is important for public credibility or accountability: **Y☐ N☐**

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)***:**

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center
☐ Ambulatory Practice / Physician Offices
☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

☐ Electronic administrative data/ claims
☐ Electronic Clinical Data *(e.g., MDS)*
☐ Incident Reports
☐ Medical Record including Electronic
☐ Pharmacy data
☐ Public health data/vital statistics
☐ Quality / Risk Management Databases
☐ Registry data (or database)
☐ Reports to External Bodies (states, federal)
☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible**.**

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION	
Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	**Y** ☐ **N** ☐ **A** ☐
Steering Committee Reviewer Name:	

4. PRIORITY AREAS
(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**
National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse
IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness
Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**
Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.
Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Erin Graydon Baker
Organization: Partners Healthcare
Street Address: 115 4th Ave
City/State/Zip: Needham/MA/02494
Telephone Number: 781-433-3776
Fax Number: 781-433-3667
Email Address: egraydonbaker@partners.org

Date of Submission (*MM/DD/YY*)**: 06/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? x☐ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Stage 3 or 4 Pressure Ulcers

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
x☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail: Exclude Stage 3 to Stage 4 if Stage 3 is present on admission. Exclude Stage 3 and 4 if unstageable or deep tissue injury was recognized on admission. Delineate Pressure Ulcers to preventable versus non preventable. Consider a separate category of Pressure Ulcers that are device related, e.g., due to casts, splints, etc.

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data):* Ulcers present on admission in already debilitated patients are not likely to be prevented from advancing to the next stage.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes x☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y☐ N☐**

Applicable Care Settings (Mark all to which event is relevant)

x☐ Hospital x☐ Skilled Nursing Facility (SNF) / Nursing home ☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.* One unintended consequence may be lack of follow up from NH or SFN when patients are admitted to the hospital with a pressure ulcer.	
(for NQF staff use) Identify related endorsed measures SP 27: Pressure Ulcer Prevention; NQF 0199: Average-risk residents with pressure ulcers; NQF 0198: High-risk residents with pressure ulcers; NQF 0181: Increase in number of pressure ulcers; NQF 0201: Pressure Ulcer Prevalence; NQF 0538: Pressure Ulcer Prevention Included in Plan of Care; NQF 0539: Pressure Ulcer Prevention Plans Implemented; NQF 0540: Pressure Ulcer Risk Assessment Conducted; NQF 0187: Recently hospitalized residents with pressure ulcers (risk adjusted)	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of*	**Y**☐

care that results in unintended injury or illness)	N☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	Y☐ N☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:	Y☐ N☐
Reviewer Comments/Rationale:	

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Comments/Rationale:**	Y☐ N☐ A☐
Steering Committee Reviewer Name:	

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety

☐ care coordination ☐ palliative and end of life care ☐ overuse
IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness
Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy
(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**
Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #: NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM
Organization: Pennsylvania Patient Safety Authority
Street Address: 5200 Butler Pike
City/State/Zip: Plymouth Meeting, PA 19462
Telephone Number: 610-825-6000 x5040
Fax Number: 610-834-1275
Email Address: clacker@ecri.org

Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event:
Patient death or serious disability due to spinal manipulative therapy

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☒ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☐ Outpatient or Office-based Surgery Center

☒ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability:	**Y**☐ **N**☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

The SRE Steering Committee with NQF member and public input has defined Serious Reportable Events (SREs) as preventable, serious, and unambiguous adverse events. The Committee further notes that some types of SREs are universally preventable and should never occur while other types of SREs are largely preventable and over time it may be possible to reduce these to zero as knowledge and safe practices evolve. Both types of SREs should be publicly reported.

Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
Street Address: 2550 University Avenue W. Suite 350S
City/State/Zip: Saint Paul, MN 55114
Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Patient death or serious disability due to spinal manipulative therapy.

Suggested Change:
☐ **Specify the Applicable Care Setting(s) marked below**
☒ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**
1) In seven years of reporting, Minnesota has never had a reportable event under this category.
2) Events reported under this category would be more likely related to provider technique than system issues.

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☒ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* *Yes* **Y**☐ **N**☐

Applicable Care Settings (Mark all to which event is relevant)

☐ Hospital ☐ Skilled Nursing Facility (SNF) / Nursing home ☐ Outpatient or Office-based Surgery Center ☐ Ambulatory Practice / Physician Offices ☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐

Describe why the event is important for public credibility or accountability: Y☐ N☐

If the event is used in a public reporting initiative (disclosure of performance results to the public at large), *provide name of initiative(s), locations, Web page URL(s)*:

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? Y☐ N☐ A☐
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**	
Steering Committee Reviewer Name:	

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Submitters: Complete all the non-shaded areas of this form**. Please fill out a separate form for each event you are submitting to NQF for consideration.** This form may be used to submit comments/changes to existing SREs or submit new SREs.

Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Cynthia Lacker, RN, MS, LNCC, CPHRM
Organization: Pennsylvania Patient Safety Authority
Street Address: 5200 Butler Pike
City/State/Zip: Plymouth Meeting, PA 19462
Telephone Number: 610-825-6000 x5040
Fax Number: 610-834-1275
Email Address: clacker@ecri.org

Date of Submission (*MM/DD/YY*)**: 06/16/2010**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Artificial insemination with the wrong sperm or donor egg

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☒ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☐ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☐ Ambulatory Practice / Physician Offices

☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
The event is Preventable *(Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure)* **Briefly summarize the Evidence Base that the event is preventable and provide citations:**	**Y**☐ **N**☐
The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large),	**Y**☐ **N**☐

provide name of initiative(s), locations, Web page URL(s):

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

- ☐ Electronic administrative data/ claims
- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
- ☐ Quality / Risk Management Databases
- ☐ Registry data (or database)
- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name:

NATIONAL QUALITY FORUM

Serious Reportable Event Submission & Evaluation

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Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

(for NQF staff use) **NQF Review #:** **NQF Project:**
(for NQF staff use**) Has all requested information been provided? Yes** **Staff Notes to Submitter** (*if submission returned*)**:**
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**
Staff Reviewer Name(s):

1. CONTACT INFORMATION

Submitter: Julie Apold
Organization: Minnesota Alliance for Patient Safety (includes Minnesota Hospital Association, Minnesota Department of Health, Minnesota Medical Association and over 50 other public-private healthcare organizations.
Street Address: 2550 University Avenue W. Suite 350S
City/State/Zip: Saint Paul, MN 55114
Telephone Number: 651-641-1121
Fax Number: 651-659-1477
Email Address: **japold@mnhospitals.org**

Date of Submission (*MM/DD/YY*)**: 6/16/10**
Is this submission about a currently endorsed SRE or a proposed new SRE? ☒ **Currently Endorsed** ☐ **New Submission** *(If new submission, skip to section 3a)*

2a. CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT

Name of Event: Artificial insemination with the wrong donor sperm or wrong egg.

Suggested Change:
☒ **Specify the Applicable Care Setting(s) marked below**
☐ **Remove Endorsement**
☐ **Modify SRE Specifications**

Describe Suggested Modification(s) in specific detail:

Rationale for removing endorsement or modifying the SRE *(include pertinent evidence, data)***:**

If modifications are made, *are the changes likely to result in a substantial change in the current count of SREs?* ☐ Yes ☐ No **If yes, please explain:**

(for NQF staff use) **The proposed change is justified** *(Does the rationale justify the proposed change?)* **Y**☐ **N**☐

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
☒ Ambulatory Practice / Physician Offices

☐ Other (*Please specify*):	
Reviewer Comments/Rationale:	
2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT	
Provide any additional information that should be considered:	
Susceptibility to Inaccuracies, Errors, or Unintended Consequences *Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.*	
(for NQF staff use) Identify related endorsed measures N/A	
Reviewer Comments:	
RECOMMENDATION	
Steering Committee: **Do you recommend the proposed change?** ☐ Do you recommend the proposed change with modification? ☐ Specify the modification **Comments/Rationale:**	**Y**☐ **N**☐ **A**☐
3a. NEW SERIOUS REPORTABLE EVENT	
The Event is a discrete, auditable , and clearly defined occurrence **Name of Proposed New Event:**	**Y**☐ **N**☐
3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS	
Brief Description of Event:	
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The event is Serious *(Describes an event that can result in death or loss of a body part, disability or loss of bodily function or risk thereof for harm)* *Please check the appropriate consequence and describe it* ☐ Death or ☐ risk of death ☐ Loss of a body part or ☐ risk of loss **Describe:** ☐ Disability or ☐ risk of disability **Describe:** ☐ Loss of bodily function or ☐ risk of loss **Describe:**	**Y**☐ **N**☐
The event is Unambiguous *(Refers to an event that is clearly defined and easily identified)* **Definitions:** **Codes and descriptors (if used):** **Instructions for counting events, calculating rates, and providing context for low frequency:**	**Y**☐ **N**☐
Reviewer Comments/Rationale:	
3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY	
Describe the outcome that demonstrates that the event is adverse *(Describes a negative consequence of care that results in unintended injury or illness)*	**Y**☐ **N**☐
Describe how the event is indicative of a problem in a healthcare facility's safety systems:	**Y**☐ **N**☐
Describe why the event is important for public credibility or accountability: If the event is used in a public reporting initiative (disclosure of performance results to the public at large),	**Y**☐ **N**☐

provide name of initiative(s), locations, Web page URL(s):

Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)

- ☐ Hospital
- ☐ Skilled Nursing Facility (SNF) / Nursing home
- ☐ Outpatient or Office-based Surgery Center
- ☐ Ambulatory Practice / Physician Offices
- ☐ Other (*Please describe*):

Data Source *Check the source(s) for the information on the SRE.*

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- ☐ Electronic Clinical Data *(e.g., MDS)*
- ☐ Incident Reports
- ☐ Medical Record including Electronic
- ☐ Pharmacy data
- ☐ Public health data/vital statistics
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- ☐ Reports to External Bodies (states, federal)
- ☐ Regulatory or Accreditation data (FDA, OSHA, etc.)
- ☐ Special or unique data, specify:

Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.); include Web page URL where available:

Data dictionary/code table attached ☐ OR at web page URL:

Process(es) to Collect Data
Provide additional information about how the data regarding the event are collected.
Address verifiability, reliability, and validity, if possible.

Reviewer Comments/Rationale:

3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT

Provide any additional information that should be considered:

Susceptibility to Inaccuracies, Errors, or Unintended Consequences
Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.

(for NQF staff use) Identify related endorsed measures

Reviewer Comments:

RECOMMENDATION

Steering Committee: Do you recommend for endorsement? **Y☐ N☐ A☐**
Comments/Rationale:

Steering Committee Reviewer Name:

4. PRIORITY AREAS

(for NQF staff use) **Select the most relevant priority area(s), quality domain(s), and consumer need(s).**

National Priority Partners Priority Area ☐ patient and family engagement ☐ population health ☐ safety ☐ care coordination ☐ palliative and end of life care ☐ overuse

IOM Quality Domain ☐ effectiveness ☐ efficiency ☐ equity ☐ patient-centered ☐ safety ☐ timeliness

Consumer Care Need ☐ Getting Better ☐ Living With Illness ☐ Staying Healthy

(for NQF staff use) **Notes on similar/related endorsed SREs and/or Safe Practices:**

Steering Committee Reviewer Name: