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.

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?) ☐ Yes ☒ No

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☒ Skilled Nursing Facility (SNF) / Nursing home
<table>
<thead>
<tr>
<th>NQF # event_no</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Reviewer Comments/Rationale:</strong></td>
<td></td>
</tr>
<tr>
<td>2b. ADDITIONAL INFORMATION for CURRENTLY ENDORSED SERIOUS REPORTABLE EVENT</td>
<td>Provide any additional information that should be considered:</td>
<td></td>
</tr>
<tr>
<td>Susceptibility to Inaccuracies, Errors, or Unintended Consequences</td>
<td>Identify susceptibility to inaccuracies, errors, or unintended consequences of the event and describe how these potential problems could be audited.</td>
<td></td>
</tr>
<tr>
<td>(for NQF staff use)</td>
<td>Identify related endorsed measures N/A</td>
<td></td>
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<tr>
<td>Reviewer Comments:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>RECOMMENDATION</td>
<td></td>
</tr>
<tr>
<td>Steering Committee:</td>
<td>Do you recommend the proposed change?</td>
<td>Y</td>
</tr>
<tr>
<td>Do you recommend the proposed change with modification?</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Specify the modification</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Comments/Rationale:</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>3a. NEW SERIOUS REPORTABLE EVENT</td>
<td>The Event is a discrete, auditable, and clearly defined occurrence</td>
<td>Y</td>
</tr>
<tr>
<td>Name of Proposed New Event:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>3b. PREVENTABLE, SERIOUS, UNAMBIGUOUS</td>
<td>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)</td>
<td>Y</td>
</tr>
<tr>
<td>Briefly summarize the Evidence Base that the event is preventable and provide citations:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>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)</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Please check the appropriate consequence and describe it</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>□ Death or □ risk of death</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>□ Loss of a body part or □ risk of loss Describe:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>□ Disability or □ risk of disability Describe:</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>□ Loss of bodily function or □ risk of loss Describe:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>The event is Unambiguous (Refers to an event that is clearly defined and easily identified)</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Definitions:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Codes and descriptors (if used):</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Instructions for counting events, calculating rates, and providing context for low frequency:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Reviewer Comments/Rationale:</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY</td>
<td>Describe the outcome that demonstrates that the event is adverse (Describes a negative consequence of care that results in unintended injury or illness)</td>
<td>Y</td>
</tr>
<tr>
<td>Describe how the event is indicative of a problem in a healthcare facility’s safety systems:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Describe why the event is important for public credibility or accountability:</td>
<td>Y</td>
<td></td>
</tr>
</tbody>
</table>
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:

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
- [ ] care coordination
- [ ] palliative and end of life care
- [ ] patient and family engagement
- [ ] population health
- [ ] 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:
<table>
<thead>
<tr>
<th>Steering Committee Reviewer Name</th>
<th></th>
</tr>
</thead>
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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.

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?)*

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
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/Rationale:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence
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)*

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)*

**Please check the appropriate consequence and describe it**

- Death or \[\square\] risk of death
- Loss of a body part or \[\square\] risk of loss **Describe:**
- Disability or \[\square\] risk of disability **Describe:**
- Loss of bodily function or \[\square\] risk of loss **Describe:**

*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:

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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:

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):

Reviewer Comments/Rationale:

<table>
<thead>
<tr>
<th>3d. SETTINGS, DATA SOURCES</th>
</tr>
</thead>
</table>

**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:

<table>
<thead>
<tr>
<th>3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT</th>
</tr>
</thead>
</table>

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:

Steering Committee Reviewer Name:

<table>
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<tr>
<th>4. PRIORITY AREAS</th>
</tr>
</thead>
</table>

(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:
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.

1. CONTACT INFORMATION

| Street Address: 800 N.E. Glen Oak Avenue | City/State/Zip: Peoria, IL |
| Telephone Number: 309-655-4806 | Email Address: William.scharf@osfhealthcare.org |
| Date of Submission (MM/DD/Y): 06/10/10 |

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 (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 to a patient with an 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? [ ] Yes [ ] No If yes, please explain: the modifications could pick up a category of medication error that are not currently reported.
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? □

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

**Name of Proposed New Event:**

**Y □ □ N □ □ A □**

### 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:

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:

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:

**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 □ □ A □**
Describe how the event is indicative of a problem in a healthcare facility’s safety systems:  

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):  

Reviewer Comments/Rationale:

<table>
<thead>
<tr>
<th>Applicable Care Settings (Mark all to which event is relevant)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Hospital</td>
<td></td>
</tr>
<tr>
<td>Skilled Nursing Facility (SNF) / Nursing home</td>
<td></td>
</tr>
<tr>
<td>Outpatient or Office-based Surgery Center</td>
<td></td>
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<tr>
<td>Ambulatory Practice / Physician Offices</td>
<td></td>
</tr>
<tr>
<td>Other (Please describe)</td>
<td></td>
</tr>
</tbody>
</table>

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  
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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:

<table>
<thead>
<tr>
<th>3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT</th>
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</thead>
<tbody>
<tr>
<td>Provide any additional information that should be considered:</td>
<td></td>
</tr>
</tbody>
</table>

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:  

Steering Committee Reviewer Name:

<table>
<thead>
<tr>
<th>4. PRIORITY AREAS</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).</td>
<td></td>
</tr>
</tbody>
</table>

National Priority Partners Priority Area  
- patient and family engagement  
- population health  
- safety  
- care coordination  
- palliative and end of life care  
- overuse
<table>
<thead>
<tr>
<th>IOM Quality Domain</th>
<th>□ effectiveness</th>
<th>□ efficiency</th>
<th>□ equity</th>
<th>□ patient-centered</th>
<th>□ safety</th>
<th>□ timeliness</th>
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<tbody>
<tr>
<td>Consumer Care Need</td>
<td>□ Getting Better</td>
<td>□ Living With Illness</td>
<td>□ Staying Healthy</td>
<td></td>
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<td></td>
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(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices:

Steering Committee Reviewer Name:
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.

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?) ☒ ☐

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
### 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:**

### 3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

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)*

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)*

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)*

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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:

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):

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:

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
- care coordination
- palliative and end of life care
- population health
- safety
- 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:
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.

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 3505
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?) ☒ Yes ☐ No

Applicable Care Settings (Mark all to which event is relevant)
☒ Hospital
☐ Skilled Nursing Facility (SNF) / Nursing home
☒ Outpatient or Office-based Surgery Center
### 2b. ADDITIONAL INFORMATION for CURRENTLY ENDORED 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**

<table>
<thead>
<tr>
<th>Steering Committee:</th>
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<tr>
<td>Do you recommend the proposed change?</td>
<td>☐</td>
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<tr>
<td>Do you recommend the proposed change with modification?</td>
<td>☐</td>
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<tr>
<td>Specify the modification</td>
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</table>

**Comments/Rationale:**

### 3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

**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)*

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)*

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)*

**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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:

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):

Reviewer Comments/Rationale:

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<th>3d. SETTINGS, DATA SOURCES</th>
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<tr>
<td><strong>Applicable Care Settings (Mark all to which event is relevant)</strong></td>
</tr>
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<td>☐ Other (Please describe):</td>
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</table>

| **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:

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<tbody>
<tr>
<td><strong>Provide any additional information that should be considered:</strong></td>
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<tr>
<td>Susceptibility to Inaccuracies, Errors, or Unintended Consequences</td>
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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:

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Steering Committee Reviewer Name:

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<td>National Priority Partners Priority Area ☐ patient and family engagement</td>
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<tr>
<td>Consumer Care Need ☐ Getting Better</td>
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<tr>
<td>☐ Living With Illness</td>
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(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices:

Steering Committee Reviewer Name:
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.

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### 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:**
- [X] 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:

**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
- [X] Ambulatory Practice / Physician Offices

(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?)  
- [ ] Yes  
- [ ] No
**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

### 3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

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)*

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)*

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)*

Definitions:

Codes and descriptors (if used):

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

### 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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:

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),
### 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:

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

### 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

### RECOMMENDATION

Steering Committee: Do you recommend for endorsement? 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:
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.

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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.
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? ☐
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 ☒
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)

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)*

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)*

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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:

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):

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)*
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- Pharmacy data
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- 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:**

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<thead>
<tr>
<th>RECOMMENDATION</th>
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<tr>
<td>Y □</td>
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<tr>
<td>N □</td>
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<td>A □</td>
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**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.

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<th>(for NQF staff use) NQF Review #:</th>
<th>NQF Project:</th>
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<td><strong>Staff Notes to Submitter (if submission returned):</strong></td>
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<tr>
<td><strong>Staff Notes to Reviewers (issues or questions regarding any criteria):</strong></td>
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<tr>
<td><strong>Staff Reviewer Name(s):</strong></td>
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### 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?)**

- [x] Yes
- [ ] No

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

- [x] Hospital
### 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 SP32: Glycemic Control*

### RECOMMENDATION

**Steering Committee:**

- Do you recommend the proposed change? [ ]
- Do you recommend the proposed change with modification? [ ] Specify the modification

### 3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

- 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)*

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)*

*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)*

Definitions:

- Codes and descriptors (if used):
- Instructions for counting events, calculating rates, and providing context for low frequency:

### 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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:

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):

Reviewer Comments/Rationale:

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<td>□ Other (Please describe):</td>
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**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:

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**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:

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| Y □ | N □ | A □ |

| Steering Committee Reviewer Name: |

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

| 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:

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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.

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: Death or serious disability associated with failure to identify and treat hyperbilirubinemia 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?) ☒ ☐

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

### 3d. SETTINGS, DATA SOURCES

**Applicable Care Settings (Mark all to which event is relevant)**
- [ ] Hospital
- [ ] Skilled Nursing Facility (SNF) / Nursing home
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**Data Source Check the source(s) for the information on the SRE.**
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**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:

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:
NQF # event_no -
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Reviewer Comments/Rationale:

3d. SETTINGS, DATA SOURCES

Applicable Care Settings (Mark all to which event is relevant)
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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
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Reviewers: Complete all the yellow and pink highlighted areas of the form. Provide the rationale for your ratings.

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:
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 ☐
### 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

### 3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

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)*

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)*

*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)*

Definitions:

- Codes and descriptors (if used):
- Instructions for counting events, calculating rates, and providing context for low frequency:

### Reviewer Comments:

**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)*

Describe how the event is indicative of a problem in a healthcare facility’s safety systems:
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):

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
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- [ ] 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:

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
<table>
<thead>
<tr>
<th>Consumer Care Need</th>
<th>Getting Better</th>
<th>Living With Illness</th>
<th>Staying Healthy</th>
</tr>
</thead>
</table>

(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
If yes, please explain: Over the past two years, 68% of reported pressure ulcer in Minnesota last year were unstageable.

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.

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:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence
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)

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)

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)
Definitions:
Codes and descriptors (if used):
**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

**Reviewer Comments/Rationale:**
4. PRIORITY AREAS

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

<table>
<thead>
<tr>
<th>National Priority Partners Priority Area</th>
<th>patient and family engagement</th>
<th>population health</th>
<th>safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>care coordination</td>
<td></td>
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<td>equity</td>
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(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices:

Steering Committee Reviewer Name:
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.

---

### 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  

### 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  
- [x] 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
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:

3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence
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)

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)
Please check the appropriate consequence and describe it
☐ Death or ☐ risk of death
☐ Loss of a body part or ☐ risk of loss Describe:
### 3c. ADVERSE, SAFETY SYSTEM PROBLEM, IMPORTANT FOR ACCOUNTABILITY

<table>
<thead>
<tr>
<th>Description</th>
<th>Y</th>
<th>N</th>
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</thead>
<tbody>
<tr>
<td>Describe the outcome that demonstrates that the event is adverse (Describes a negative consequence of care that results in unintended injury or illness)</td>
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<td>N</td>
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**Reviewer Comments/Rationale:**

### 3d. SETTINGS, DATA SOURCES

<table>
<thead>
<tr>
<th>Applicable Care Settings (Mark all to which event is relevant)</th>
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<tbody>
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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: |

### 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:**
<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Steering Committee: Do you recommend for endorsement?</strong></td>
</tr>
<tr>
<td><strong>Comments/Rationale:</strong></td>
</tr>
<tr>
<td><strong>Steering Committee Reviewer Name:</strong></td>
</tr>
</tbody>
</table>

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<th>4. PRIORITY AREAS</th>
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<tr>
<td>(for NQF staff use) Select the most relevant priority area(s), quality domain(s), and consumer need(s).</td>
</tr>
<tr>
<td><strong>National Priority Partners Priority Area</strong></td>
</tr>
<tr>
<td>□ patient and family engagement</td>
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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.

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?)

Applicable Care Settings (Mark all to which event is relevant)
### 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 SNF 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/Rationale:

**RECOMMENDATION**

**Steering Committee:**

- Do you recommend the proposed change? [ ]
- Do you recommend the proposed change with modification? [ ] Specify the modification

### 3a. NEW SERIOUS REPORTABLE EVENT

The event is a discrete, auditable, and clearly defined occurrence

**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)*

- 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)*

- 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)*

**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*}
Describe how the event is indicative of a problem in a healthcare facility’s safety systems: **Y**

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):

Reviewer Comments/Rationale:

<table>
<thead>
<tr>
<th>3d. SETTINGS, DATA SOURCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable Care Settings (Mark all to which event is relevant)</td>
</tr>
<tr>
<td>□ Hospital</td>
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<td>□ Other (Please describe):</td>
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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
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- □ 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:

<table>
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<tr>
<th>3e. ADDITIONAL INFORMATION for NEW SERIOUS REPORTABLE EVENT</th>
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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:

<table>
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Steering Committee Reviewer Name:

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<th>4. PRIORITY AREAS</th>
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(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
<table>
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<tr>
<th>care coordination</th>
<th>palliative and end of life care</th>
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<td>IOM Quality Domain</td>
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(for NQF staff use) Notes on similar/related endorsed SREs and/or Safe Practices:

Steering Committee Reviewer Name:
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:

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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
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<td>Do you recommend the proposed change?</td>
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<td>Do you recommend the proposed change with modification?</td>
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<td>Specify the modification</td>
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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)
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- 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:

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
- care coordination
- palliative and end of life care
- overuse
- population health
- safety
- 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.

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<td>Has all requested information been provided?</td>
<td>Yes</td>
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</table>

**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:**

**Yes**

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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):

Reviewer Comments/Rationale:

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

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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:

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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:

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Steering Committee: Do you recommend for endorsement?
Comments/Rationale:

Steering Committee Reviewer Name:

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(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
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(for NQF staff use)
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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.

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

(for NQF staff use) The proposed change is justified (Does the rationale justify the proposed change?) ☒ Yes ☐ No
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:

### 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:

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:

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:

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)*

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

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):

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
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- [ ] 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:

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:
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.

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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Date of Submission (MM/DD/YY): 6/16/10
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: 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
### 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

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<th>Reviewer Comments/Rationale:</th>
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### RECOMMENDATION

**Steering Committee:**

Do you recommend the proposed change? ☐

Do you recommend the proposed change with modification? ☐ Specify the modification

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<th>Comments/Rationale:</th>
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### 3a. NEW SERIOUS REPORTABLE EVENT

The Event is a discrete, auditable, and clearly defined occurrence

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)*

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)*

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)*

Definitions:

Codes and descriptors (if used):

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

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### 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)*

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

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),
### 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:

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<th>Y</th>
<th>N</th>
<th>A</th>
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**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:**