Highmark Reimbursement Policy Bulletin

HISTORY VERSION

Bulletin Number:	RP-036		
Subject:	Preventable Serious Adverse Events		
Effective Date:	June 11, 2018	**End Date:**	
Issue Date:	January 1, 2024	**Revised Date:**	January 2024
Date Reviewed:	November 2023		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☒
Applicable Medicare Advantage Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY**	☒
Applicable Claim Type	**UB**	☒	**1500**	☒				

A checked box indicates the policy is applicable to that market either entirely, or partially, as indicated within the policy.

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this policy.

PURPOSE:

The National Quality Forum (NQF), an organization that aims to improve the quality of healthcare, published Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors [NQF Web Site, accessed January 15, 2014], which listed adverse events that were "serious, largely preventable and of concern to both the public and health care providers, Such events are referred to as "preventable serious adverse events or never events," and include "Wrong Surgery Events." For the purposes of this policy, such events are referred to as *Preventable Serious Adverse Events* (PSAEs). PSAEs shall also include "Hospital Acquired Conditions" as defined by the Centers for Medicaid & Medicare Services (CMS).

A Preventable Serious Adverse Event is a serious, identifiable, and unambiguous occurrence or error made by a provider that is preventable and should never occur. The NQF adopted and maintains a list of PSAEs. PSAEs include, but are not limited to:

- Certain surgical infections
- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- The wrong surgical procedure performed

This policy addresses general coverage guidelines on PSAEs as identified by the NQF. In addition to the list established by the NQF, this policy also includes any medical issues published by the Blue Cross Blue Shield Association (BCBSA) or the Federal Employee Program (FEP) as avoidable medical issues for which payment should not be made.

The Plan will monitor for compliance laws and guidance issued by state and federal governments as well as guidance issued by advisory organizations to include but not be limited to: Blue Cross Blue Sheild Association (BCBSA) policies and procedures; state and federal laws, regulations, and bulletins; and applicable advisory organizations' guidance and standards. Such guidance and standards will be incorporated by the Plan into its procedures and processes as appropriate and as they can be applied systemically. The Plan may also incorporate PSAEs into its' current Quality reimbursement and may give consideration for Blue's Distinction Awards and reserves the right to consider such information as part of any credentialing process.

COMMERICAL REIMBURSEMENT GUIDELINES:

Preventable Serious Adverse Events

The Plan will not provide reimbursement or allow providers to retain reimbursement for any care directly related to a PSAE and the Member shall not be liable for payment for any care resulting from PSAEs. In addition, a provider may not knowingly seek payment from The Plan or a member for a PSAE or for any services required to correct or treat problems created by a PSAE that occurred under the provider's control.

Subsequent services rendered by a *provider not involved with the initial PSAE will be considered for reimbursement. PSAEs include wrong surgical events (defined below). For a list of PSAEs see the *Appendix A* section of this policy. This list may be periodically revised.

***Note:** All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Wrong Surgery Events

A *Wrong Surgical Event* (WSE) is defined as a surgical or other invasive procedure that results when a practitioner erroneously performs:

- The wrong surgical or other invasive procedure on a patient
- A surgical or other invasive procedure on the wrong body part, **or**
- A surgical or other invasive procedure on the wrong patient.

A surgical or other invasive procedure is considered to be erroneously performed if it is not consistent with the correctly documented informed consent for that patient.

Emergent situations that occur during the course of surgery for which it is not possible to obtain informed consent are not considered a WSE. Also, a WSE is not intended to include changes in the plan that occurred upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

When a surgical or other invasive procedure is erroneously performed:

- All services provided in the operating room when an error occurs are considered related and therefore not covered.
- All providers in the operating room when the error occurs, who could bill individually for their services, are not eligible for payment.
- All related services provided during the same hospitalization in which the error occurred are not covered.

- All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Providers are required to append one of the following applicable HCPCS modifiers on each claim line related to the WSE. These will be denied as not covered and the member held harmless with no liability:

- Modifier PA: Surgery Wrong Body Part
- Modifier PB: Surgery Wrong Patient
- Modifier PC: Wrong Surgery on Patient

Note: The modifiers above are not applicable to *inpatient* claim submissions. However, the specific diagnosis codes for a wrong surgical event are required on the *inpatient* claim.

UB-04 Claim Provision

The Plan requires that all inpatient acute-care hospitals (including critical access hospitals and children's inpatient facilities) must populate Present on Admission data on all inpatient claims. This requirement is designed to identify and prevent additional reimbursement to the provider for situations in which specified conditions occur during the course of an inpatient stay but, were not present at the time of admission. This mechanism serves to implement Highmark's policy on hospital-acquired conditions in the inpatient acute-care hospital setting.

Although, the majority of such conditions are found on the NQF list, several are not. All of the HAC diagnoses, irrespective of this distinction, are embedded in the CMS Grouper algorithm The Plan employs when calculating DRG based reimbursement for inpatient acute-care hospital services. They are also a component of the separate process The Plan utilizes to review for potential hospital-acquired conditions occurring in inpatient acute-care hospitals reimbursed via methodologies other than those based on DRG. Under either DRG or non-DRG based reimbursement methods, if payment is reduced as a result of the presence of a HAC, the provider is not permitted to seek payment from the member for the difference between the reduced payment and the payment that might have been expected had the condition been present on admission. The member must be held harmless.

<u>Subsequent Services to Treat or Correct Problems Created by a HAC</u>

Providers are not permitted to seek payment for subsequent services required to treat or correct problems created by those hospital-acquired conditions that **appear** on the NQF list. Under The Plan's policy, the remaining hospital-acquired conditions that are recognized by CMS but **do not appear** on the NQF list are subject to CMS's rules on subsequent services. CMS permits billing of "reasonable and necessary services" following discharge, including services related to the HAC. The member must be held harmless for the corrective services, except for normal cost-sharing amounts required under the member's benefits.

<u>Preventable Serious Adverse Events Occurring in the Outpatient Facility Setting That Are Also Classified as Hospital-Acquired Conditions When They Occur in the Inpatient Acute-Care Setting</u>

As discussed above, certain preventable serious adverse events are classified as Hospital-Acquired Conditions and are treated as such when they occur in the **inpatient acute-care setting**. When such events occur in the **outpatient** facility setting, however, they are governed by Act 1. As required by Act 1, the provider is not permitted to seek payment for these services *from either The Plan or the member.*

When the existence of an outpatient preventable serious adverse event is recognized **before the patient is discharged**, the facility should "not seek payment" by not submitting a claim for the services to The Plan and not presenting a bill to the member. The member must be held harmless.

If the existence of an outpatient preventable serious adverse event is not recognized until **after the claim for the outpatient services has been submitted and/or payment has been received,** the provider should notify its Institutional Provider Relations representative so that payment can be prevented or retracted. The member must be held harmless.

If subsequent services are required to correct or treat problems created by the outpatient preventable serious adverse event, and the member chooses to have the corrective services performed by the provider under whose control the event occurred, that provider is not permitted to seek payment either from The Plan or from the member for such services. The member must be held harmless.

Claim Submissions for Wrong Surgical Events Occurring During an Inpatient Stay

If a wrong surgical event occurs during an inpatient stay, the provider must submit a **no-payment claim** (Type of Bill 110) for the non-covered services -- that is, those related to the wrong surgical event. The appropriate diagnosis code identifying the nature of the medical error must be reported.

If the provider believes that during the same stay it also provided other services that were not related to the wrong surgical event, it should submit two separate claims for the stay:

- A no-payment claim (Type of Bill 110) for the non-covered services (those related to the wrong surgical event); **and**
- An inpatient claim (Type of Bill 11X, excluding 110) for the covered services provided (those not related to the wrong surgical event).

In this situation, the hospital must report the same **Statement Covers From and Through Dates** on both the no-payment claim and the inpatient claim. The appropriate modifier from the list below must be reported ***on the no-payment claim only*** to identify the nature of the medical error. All other standard UB billing protocols apply to both the no-payment claim and the inpatient claim.

Note: Inpatient non-covered Type of Bill 0110 (no-pay claim), 2-digit surgical error codes entered in Form Locator 81 – Remarks (loop 2300):

- Modifier MX – for a wrong surgery on patient
- Modifier MY – for surgery on the wrong body part
- Modifier MZ – for surgery on the wrong patient

MEDICARE ADVANTAGE REIMBURSEMENT GUIDELINES:

Nationally Non-Covered Indications

A surgical or other invasive procedure is considered the “wrong procedure” if it is not consistent with the correctly documented and signed informed consent for the patient.

A surgical or other invasive procedure is considered to have been performed on the "wrong body part" if it is not consistent with the correctly documented and signed informed consent for the patient. This includes surgery on the right body *part*, but wrong location of the body.

A surgical or other invasive procedure is considered to have been performed on the "wrong patient" if the procedure is not consistent with the correctly documented and signed informed consent for the patient.

Note: Surgical and other invasive procedures are defined as operative procedures in which the skin or mucous membranes and connective tissue are incised, or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT).

Hospital Outpatient, Ambulatory Surgical Centers (ASC), and Practitioner Claims:

Providers are required to append one of the following applicable HCPCS modifiers to all lines when submitting a claim for the erroneous surgery(s):

- PA: Surgery Wrong Body Part
- PB: Surgery Wrong Patient
- PC: Wrong Surgery on Patient

COMMERCIAL REFERENCES:

- The Leapfrog Group: Leapfrog Group statement on never events. [Leapfrog Group Web site].
- National Quality Forum (NQF). Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors. [NQF Web Site].
- CMS Online Manual Pub. 100-2, Chapter 1, Sections 10 and 120
- CMS Online Manual Pub. 100-2, Chapter 16, Section 180
- CMS Online Manual Pub. 100-3, Chapter 1, Sections 140.6, 140.7, and 140.8
- CMS Online Manual Pub. 100-4, Chapter 32, Section 230
- Transmittal 102, CR 6405
- Transmittal 1816, CR 6634

Note: References Below are Applicable Only to Pennsylvania

- Preventable Serious Adverse Events Act-Enactment Act of June 10, 2009, P. L. 1, No. 1, Cl. 35. Pennsylvania General Assembly Web Site. http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2009&sessInd=0&act=1.

- Pennsylvania Act 1 of 2009, House Bill No. 84 http://www.pabulletin.com/secure/data/vol39/39-33/1474.html.

MEDICARE ADVANTAGE REFERENCES:

- National Quality Forum (NQF); Serious Reportable Events (SRE) Effective October 23, 2020
- Medicare Internet Only Manual (IOM); Pub 100-03, National Coverage Determinations (NCD)
- CMS Manual Chapter 1, Part 2, Section 140.6. Effective 01/15/2009

- Medicare Internet Only Manual (IOM), Pub 100-03, National Coverage Determinations (NCD)
- CMS Manual Chapter 1, Part 2, Section 140.7. Effective 01/15/2009.
- Medicare Internet Only Manual (IOM), Pub 100-03, National Coverage Determinations (NCD)
- CMS Manual Chapter 1, Part 2, Section 140.8. Effective 01/15/2009
- Medicare Learning Network MLN Matters; MM6405, Effective 1/15/2009

ADDITIONAL BILLING INFORMATION, REFERENCES AND GUIDELINES:

It is not an acceptable billing practice or process, for any reason, to refrain from submitting a claim because a PSAE or error occurred.

RELATED POLICIES:

Refer to the following Reimbursement Policies for additional information:

- RP-035 Correct Coding Guidelines

APPENDIX A:

LIST OF PREVENTABLE SERIOUS ADVERSE EVENTS

Surgical Events	a. Surgery performed on the wrong body part. b. Surgery performed on the wrong patient. c. Wrong surgical procedure performed on a patient. d. Unintended retention of a foreign object in a patient after surgery or other procedure. e. Intraoperative or immediately postoperative death in an ASA Class I patient.
Product or Device Events	a. Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility. b. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. c. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.
Patient Protection Events	a. Infant discharged to the wrong person. b. Patient death or serious disability associated with patient elopement (disappearance). c. Patient suicide or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

Care Management Events	a. Patient death or serious disability associated with a medication error (such as, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration). b. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products. c. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility. d. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility. e. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates. f. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility. g. Patient death or serious disability due to spinal manipulative therapy. h. Artificial insemination with the wrong donor sperm or wrong egg.
Environmental Events	a. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility. b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances. c. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility. d. Patient death or serious disability associated with a fall while being cared for in a healthcare facility. e. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.
Criminal Events	a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider. b. Abduction of a patient of any age. c. Sexual assault on a patient within or on the grounds of a healthcare facility. d. Death or significant injury of a patient or staff member from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility.

POLICY UPDATE HISTORY INFORMATION:

6 / 2018	Implementation
11 / 2021	Added NY region applicable to the policy
6 / 2022	Removed N-67 MP Reference Added RP Reference MRP-006
1 / 2024	Added Medicare Advantage section merged from MRP-006

Highmark Reimbursement Policy Bulletin

HISTORY VERSION

Bulletin Number:	RP-036		
Subject:	Preventable Serious Adverse Events		
Effective Date:	June 11, 2018	**End Date:**	
Issue Date:	July 18, 2022	**Revised Date:**	July 2022
Date Reviewed:	July 2022		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☒
Applicable Medicare Advantage Market	**PA**	☐	**WV**	☐	**DE**	☐	**NY** ☐
Applicable Claim Type	**UB**	☒	**1500**	☒			

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PURPOSE:

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This policy addresses general coverage guidelines on PSAEs as identified by the NQF. In addition to the list established by the NQF, this policy also includes any medical issues published by the Blue Cross Blue Shield Association (BCBSA) or the Federal Employee Program (FEP) as avoidable medical issues for which payment should not be made.

The Plan will monitor for compliance laws and guidance issued by state and federal governments as well as guidance issued by advisory organizations to include but not be limited to:, BCBSA policies and

procedures; state and federal laws, regulations, and bulletins; and applicable advisory organizations' guidance and standards. Such guidance and standards will be incorporated by the Plan into its procedures and processes as appropriate and as they can be applied systemically. The Plan may also incorporate PSAEs into its' current Quality reimbursement and may give consideration for Blue's Distinction Awards and reserves the right to consider such information as part of any credentialing process.

REIMBURSEMENT GUIDELINES:

Preventable Serious Adverse Events

The Plan will not provide reimbursement or allow providers to retain reimbursement for any care directly related to a PSAE and the Member shall not be liable for payment for any care resulting from PSAEs. In addition, a provider may not knowingly seek payment from The Plan or a member for a PSAE or for any services required to correct or treat problems created by a PSAE that occurred under the provider's control.

Subsequent services rendered by a ***provider** not involved with the initial PSAE will be considered for reimbursement. PSAEs include wrong surgical events (defined below). For a list of PSAEs see the *Appendix A* section of this policy. This list may be periodically revised.

***Note:** All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Wrong Surgery Events

A *Wrong Surgical Event* (WSE) is defined as a surgical or other invasive procedure that results when a practitioner erroneously performs:

- The wrong surgical or other invasive procedure on a patient
- A surgical or other invasive procedure on the wrong body part, **or**
- A surgical or other invasive procedure on the wrong patient.

A surgical or other invasive procedure is considered to be erroneously performed if it is not consistent with the correctly documented informed consent for that patient.

Emergent situations that occur during the course of surgery for which it is not possible to obtain informed consent are not considered a WSE. Also, a WSE is not intended to include changes in the plan that occurred upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

When a surgical or other invasive procedure is erroneously performed:

- All services provided in the operating room when an error occurs are considered related and therefore not covered.
- All providers in the operating room when the error occurs, who could bill individually for their services, are not eligible for payment.
- All related services provided during the same hospitalization in which the error occurred are not covered.
- All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Providers are required to append one of the following applicable HCPCS modifiers on each claim line related to the WSE. These will be denied as not covered and the member held harmless with no liability:

- Modifier PA: Surgery Wrong Body Part
- Modifier PB: Surgery Wrong Patient
- Modifier PC: Wrong Surgery on Patient

Note: The modifiers above are not applicable to *inpatient* claim submissions. However, the specific diagnosis codes for a wrong surgical event are required on the *inpatient* claim.

UB-04 Claim Provision

The Plan requires that all inpatient acute-care hospitals (including critical access hospitals and children's inpatient facilities) must populate Present on Admission data on all inpatient claims. This requirement is designed to identify and prevent additional reimbursement to the provider for situations in which specified conditions occur during the course of an inpatient stay but, were not present at the time of admission. This mechanism serves to implement Highmark's policy on hospital-acquired conditions in the inpatient acute-care hospital setting.

Although, the majority of such conditions are found on the NQF list, several are not. All of the HAC diagnoses, irrespective of this distinction, are embedded in the CMS Grouper algorithm The Plan employs when calculating DRG based reimbursement for inpatient acute-care hospital services. They are also a component of the separate process The Plan utilizes to review for potential hospital-acquired conditions occurring in inpatient acute-care hospitals reimbursed via methodologies other than those based on DRG. Under either DRG or non-DRG based reimbursement methods, if payment is reduced as a result of the presence of a HAC, the provider is not permitted to seek payment from the member for the difference between the reduced payment and the payment that might have been expected had the condition been present on admission. The member must be held harmless.

Subsequent Services to Treat or Correct Problems Created by a HAC

Providers are not permitted to seek payment for subsequent services required to treat or correct problems created by those hospital-acquired conditions that **appear** on the NQF list. Under The Plan's policy, the remaining hospital-acquired conditions that are recognized by CMS but **do not appear** on the NQF list are subject to CMS's rules on subsequent services. CMS permits billing of "reasonable and necessary services" following discharge, including services related to the HAC. The member must be held harmless for the corrective services, except for normal cost-sharing amounts required under the member's benefits.

Preventable Serious Adverse Events Occurring in the Outpatient Facility Setting That Are Also Classified as Hospital-Acquired Conditions When They Occur in the Inpatient Acute-Care Setting

As discussed above, certain preventable serious adverse events are classified as Hospital-Acquired Conditions and are treated as such when they occur in the **inpatient acute-care setting**. When such events occur in the **outpatient** facility setting, however, they are governed by Act 1. As required by Act 1, the provider is not permitted to seek payment for these services *from either The Plan or the member.*

When the existence of an outpatient preventable serious adverse event is recognized **before the patient is discharged**, the facility should "not seek payment" by not submitting a claim for the services to The Plan and not presenting a bill to the member. The member must be held harmless.

If the existence of an outpatient preventable serious adverse event is not recognized until **after the claim for the outpatient services has been submitted and/or payment has been received,** the provider should notify its Institutional Provider Relations representative so that payment can be prevented or retracted. The member must be held harmless.

If subsequent services are required to correct or treat problems created by the outpatient preventable serious adverse event, and the member chooses to have the corrective services performed by the provider under whose control the event occurred, that provider is not permitted to seek payment either from The Plan or from the member for such services. The member must be held harmless.

Claim Submissions for Wrong Surgical Events Occurring During an Inpatient Stay

If a wrong surgical event occurs during an inpatient stay, the provider must submit a **no-payment claim** (Type of Bill 110) for the non-covered services -- that is, those related to the wrong surgical event. The appropriate diagnosis code identifying the nature of the medical error must be reported.

If the provider believes that during the same stay it also provided other services that were not related to the wrong surgical event, it should submit two separate claims for the stay:

- A no-payment claim (Type of Bill 110) for the non-covered services (those related to the wrong surgical event); **and**
- An inpatient claim (Type of Bill 11X, excluding 110) for the covered services provided (those not related to the wrong surgical event).

In this situation, the hospital must report the same **Statement Covers From and Through Dates** on both the no-payment claim and the inpatient claim. The appropriate diagnosis code from the list below must be reported ***on the no-payment claim only*** to identify the nature of the medical error. All other standard UB billing protocols apply to both the no-payment claim and the inpatient claim.

Note: Inpatient non-covered Type of Bill 0110 (no-pay claim), 2-digit surgical error codes entered in Form Locator 81 – Remarks (loop 2300):

- Modifier MX – for a wrong surgery on patient;
- Modifier MY – for surgery on the wrong body part; or
- Modifier MZ – for surgery on the wrong patient

REFERENCES:

- The Leapfrog Group. Leapfrog Group position statement on never events. [Leapfrog Group Web site]. Retrieved from http://www.leapfroggroup.org/for_hospitals/leapfrog_hospital_quality_and_safety_survey_copy/never_events. Accessed January 15, 2014.

- National Quality Forum (NQF). Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors. [NQF Web Site]. Retrieved from http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp. Accessed January 15, 2014.

- CMS Online Manual Pub. 100-2, Chapter 1, Sections 10 and 120
- CMS Online Manual Pub. 100-2, Chapter 16, Section 180
- CMS Online Manual Pub. 100-3, Chapter 1, Sections 140.6, 140.7, and 140.8

- CMS Online Manual Pub. 100-4, Chapter 32, Section 230
- Transmittal 102, CR 6405
- Transmittal 1816, CR 6634

Note: References Below are Applicable Only to Pennsylvania

- Preventable Serious Adverse Events Act-Enactment Act of June 10, 2009, P. L. 1, No. 1, Cl. 35. Pennsylvania General Assembly Web Site. Retrieved from http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2009&sessInd=0&act=1. Accessed January 15, 2014.

- Pennsylvania Act 1 of 2009, House Bill No. 84 http://www.pabulletin.com/secure/data/vol39/39-33/1474.html.

ADDITIONAL BILLING INFORMATION, REFERENCES AND GUIDELINES:

It is not an acceptable billing practice or process, for any reason, to refrain from submitting a claim because a PSAE or error occurred.

RELATED HIGHMARK POLICIES:

Refer to the following Medicare Advantage Reimbursement Policies for additional information:

- MRP-006 Wrong Surgery

APPENDIX A:

LIST OF PREVENTABLE SERIOUS ADVERSE EVENTS

Surgical Events	a. Surgery performed on the wrong body part. b. Surgery performed on the wrong patient. c. Wrong surgical procedure performed on a patient. d. Unintended retention of a foreign object in a patient after surgery or other procedure. e. Intraoperative or immediately postoperative death in an ASA Class I patient.
Product or Device Events	a. Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility. b. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. c. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.
Patient Protection Events	a. Infant discharged to the wrong person.

b. Patient death or serious disability associated with patient elopement (disappearance).
c. Patient suicide or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

Care Management Events

a. Patient death or serious disability associated with a medication error (such as, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).
b. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.
c. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.
d. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
e. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.
f. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
g. Patient death or serious disability due to spinal manipulative therapy.
h. Artificial insemination with the wrong donor sperm or wrong egg.

Environmental Events

a. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.
b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
c. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.
d. Patient death or serious disability associated with a fall while being cared for in a healthcare facility.
e. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

Criminal Events

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
b. Abduction of a patient of any age.
c. Sexual assault on a patient within or on the grounds of a healthcare facility.
d. Death or significant injury of a patient or staff member from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility.

POLICY UPDATE HISTORY INFORMATION:

6 / 2018	Implementation
11 / 2021	Added NY region applicable to the policy
6 / 2022	Removed N-67 MP Reference Added RP Reference MRP-006

Highmark Reimbursement Policy Bulletin

HISTORY VERSION

Bulletin Number:	RP-036		
Subject:	Preventable Serious Adverse Events		
Effective Date:	June 11, 2018	**End Date:**	
Issue Date:	November 1, 2021	**Revised Date:**	July 2021
Date Reviewed:	July 2021		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA**	☒	**WV**	☒	**DE**	☒	**NY** ☒
Applicable Medicare Advantage Market	**PA**	☐	**WV**	☐	**DE**	☐	**NY** ☐
Applicable Claim Type	**UB**	☒	**1500**	☒			

Reimbursement Policy designation of Professional or Facility application is based on how the provider is contracted with the Plan. This Policy supersedes direction provided in Bulletins prior to the effective date of this Policy.

PURPOSE:

The National Quality Forum (NQF), an organization that aims to improve the quality of healthcare, published Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors [NQF Web Site, accessed January 15, 2014], which listed adverse events that were "serious, largely preventable and of concern to both the public and health care providers, Such events are referred to as "preventable serious adverse events or never events," and include "Wrong Surgery Events." For the purposes of this policy, such events are referred to as *Preventable Serious Adverse Events* (PSAEs). PSAEs shall also include "Hospital Acquired Conditions" as defined by the Centers for Medicaid & Medicare Services (CMS).

A Preventable Serious Adverse Event is a serious, identifiable, and unambiguous occurrence or error made by a provider that is preventable and should never occur. The NQF adopted and maintains a list of PSAEs. PSAEs include, but are not limited to:

- Certain surgical infections
- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- The wrong surgical procedure performed

This policy addresses general coverage guidelines on PSAEs as identified by the NQF. In addition to the list established by the NQF, this policy also includes any medical issues published by the Blue Cross Blue Shield Association (BCBSA) or the Federal Employee Program (FEP) as avoidable medical issues for which payment should not be made.

The Plan will monitor for compliance laws and guidance issued by state and federal governments as well as guidance issued by advisory organizations to include but not be limited to:, BCBSA policies and

procedures; state and federal laws, regulations, and bulletins; and applicable advisory organizations' guidance and standards. Such guidance and standards will be incorporated by the Plan into its procedures and processes as appropriate and as they can be applied systemically. The Plan may also incorporate PSAEs into its' current Quality reimbursement and may give consideration for Blue's Distinction Awards and reserves the right to consider such information as part of any credentialing process.

REIMBURSEMENT GUIDELINES:

Preventable Serious Adverse Events

The Plan will not provide reimbursement or allow providers to retain reimbursement for any care directly related to a PSAE and the Member shall not be liable for payment for any care resulting from PSAEs. In addition, a provider may not knowingly seek payment from The Plan or a member for a PSAE or for any services required to correct or treat problems created by a PSAE that occurred under the provider's control.

Subsequent services rendered by a *provider not involved with the initial PSAE will be considered for reimbursement. PSAEs include wrong surgical events (defined below). For a list of PSAEs see the *Appendix A* section of this policy. This list may be periodically revised.

***Note:** All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Wrong Surgery Events

A *Wrong Surgical Event* (WSE) is defined as a surgical or other invasive procedure that results when a practitioner erroneously performs:

- The wrong surgical or other invasive procedure on a patient
- A surgical or other invasive procedure on the wrong body part, **or**
- A surgical or other invasive procedure on the wrong patient.

A surgical or other invasive procedure is considered to be erroneously performed if it is not consistent with the correctly documented informed consent for that patient.

Emergent situations that occur during the course of surgery for which it is not possible to obtain informed consent are not considered a WSE. Also, a WSE is not intended to include changes in the plan that occurred upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

When a surgical or other invasive procedure is erroneously performed:

- All services provided in the operating room when an error occurs are considered related and therefore not covered.
- All providers in the operating room when the error occurs, who could bill individually for their services, are not eligible for payment.
- All related services provided during the same hospitalization in which the error occurred are not covered.
- All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Providers are required to append one of the following applicable HCPCS modifiers on each claim line related to the WSE. These will be denied as not covered and the member held harmless with no liability:

- Modifier PA: Surgery Wrong Body Part
- Modifier PB: Surgery Wrong Patient
- Modifier PC: Wrong Surgery on Patient

Note: The modifiers above are not applicable to *inpatient* claim submissions. However, the specific diagnosis codes for a wrong surgical event are required on the *inpatient* claim.

UB-04 Claim Provision

The Plan requires that all inpatient acute-care hospitals (including critical access hospitals and children's inpatient facilities) must populate Present on Admission data on all inpatient claims. This requirement is designed to identify and prevent additional reimbursement to the provider for situations in which specified conditions occur during the course of an inpatient stay but, were not present at the time of admission. This mechanism serves to implement Highmark's policy on hospital-acquired conditions in the inpatient acute-care hospital setting.

Although, the majority of such conditions are found on the NQF list, several are not. All of the HAC diagnoses, irrespective of this distinction, are embedded in the CMS Grouper algorithm The Plan employs when calculating DRG based reimbursement for inpatient acute-care hospital services. They are also a component of the separate process The Plan utilizes to review for potential hospital-acquired conditions occurring in inpatient acute-care hospitals reimbursed via methodologies other than those based on DRG. Under either DRG or non-DRG based reimbursement methods, if payment is reduced as a result of the presence of a HAC, the provider is not permitted to seek payment from the member for the difference between the reduced payment and the payment that might have been expected had the condition been present on admission. The member must be held harmless.

Subsequent Services to Treat or Correct Problems Created by a HAC

Providers are not permitted to seek payment for subsequent services required to treat or correct problems created by those hospital-acquired conditions that **appear** on the NQF list. Under The Plan's policy, the remaining hospital-acquired conditions that are recognized by CMS but **do not appear** on the NQF list are subject to CMS's rules on subsequent services. CMS permits billing of "reasonable and necessary services" following discharge, including services related to the HAC. The member must be held harmless for the corrective services, except for normal cost-sharing amounts required under the member's benefits.

Preventable Serious Adverse Events Occurring in the Outpatient Facility Setting That Are Also Classified as Hospital-Acquired Conditions When They Occur in the Inpatient Acute-Care Setting

As discussed above, certain preventable serious adverse events are classified as Hospital-Acquired Conditions and are treated as such when they occur in the **inpatient acute-care setting**. When such events occur in the **outpatient** facility setting, however, they are governed by Act 1. As required by Act 1, the provider is not permitted to seek payment for these services *from either The Plan or the member.*

When the existence of an outpatient preventable serious adverse event is recognized **before the patient is discharged**, the facility should "not seek payment" by not submitting a claim for the services to The Plan and not presenting a bill to the member. The member must be held harmless.

If the existence of an outpatient preventable serious adverse event is not recognized until **after the claim for the outpatient services has been submitted and/or payment has been received,** the provider should notify its Institutional Provider Relations representative so that payment can be prevented or retracted. The member must be held harmless.

If subsequent services are required to correct or treat problems created by the outpatient preventable serious adverse event, and the member chooses to have the corrective services performed by the provider under whose control the event occurred, that provider is not permitted to seek payment either from The Plan or from the member for such services. The member must be held harmless.

Claim Submissions for Wrong Surgical Events Occurring During an Inpatient Stay

If a wrong surgical event occurs during an inpatient stay, the provider must submit a **no-payment claim** (Type of Bill 110) for the non-covered services -- that is, those related to the wrong surgical event. The appropriate diagnosis code identifying the nature of the medical error must be reported.

If the provider believes that during the same stay it also provided other services that were not related to the wrong surgical event, it should submit two separate claims for the stay:

- A no-payment claim (Type of Bill 110) for the non-covered services (those related to the wrong surgical event); **and**
- An inpatient claim (Type of Bill 11X, excluding 110) for the covered services provided (those not related to the wrong surgical event).

In this situation, the hospital must report the same **Statement Covers From and Through Dates** on both the no-payment claim and the inpatient claim. The appropriate diagnosis code from the list below must be reported ***on the no-payment claim only*** to identify the nature of the medical error. All other standard UB billing protocols apply to both the no-payment claim and the inpatient claim.

Note: Inpatient non-covered Type of Bill 0110 (no-pay claim), 2-digit surgical error codes entered in Form Locator 81 – Remarks (loop 2300):

- Modifier MX – for a wrong surgery on patient;
- Modifier MY – for surgery on the wrong body part; or
- Modifier MZ – for surgery on the wrong patient

REFERENCES:

- The Leapfrog Group. Leapfrog Group position statement on never events. [Leapfrog Group Web site]. Retrieved from http://www.leapfroggroup.org/for_hospitals/leapfrog_hospital_quality_and_safety_survey_copy/never_events. Accessed January 15, 2014.

- National Quality Forum (NQF). Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors. [NQF Web Site]. Retrieved from http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp. Accessed January 15, 2014.

- CMS Online Manual Pub. 100-2, Chapter 1, Sections 10 and 120
- CMS Online Manual Pub. 100-2, Chapter 16, Section 180
- CMS Online Manual Pub. 100-3, Chapter 1, Sections 140.6, 140.7, and 140.8

- CMS Online Manual Pub. 100-4, Chapter 32, Section 230
- Transmittal 102, CR 6405
- Transmittal 1816, CR 6634

Note: References Below are Applicable Only to Pennsylvania

- Preventable Serious Adverse Events Act-Enactment Act of June 10, 2009, P. L. 1, No. 1, Cl. 35. Pennsylvania General Assembly Web Site. Retrieved from http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2009&sessInd=0&act=1. Accessed January 15, 2014.

- Pennsylvania Act 1 of 2009, House Bill No. 84 http://www.pabulletin.com/secure/data/vol39/39-33/1474.html.

ADDITIONAL BILLING INFORMATION, REFERENCES AND GUIDELINES:

It is not an acceptable billing practice or process, for any reason, to refrain from submitting a claim because a PSAE or error occurred.

RELATED HIGHMARK POLICIES:

Refer to the following Medicare Advantage Medical Policies for additional information:

- N-67: Wrong Surgery – NCDs 140.6, 140.7, 140.8

APPENDIX A:

LIST OF PREVENTABLE SERIOUS ADVERSE EVENTS

Surgical Events	a. Surgery performed on the wrong body part. b. Surgery performed on the wrong patient. c. Wrong surgical procedure performed on a patient. d. Unintended retention of a foreign object in a patient after surgery or other procedure. e. Intraoperative or immediately postoperative death in an ASA Class I patient.
Product or Device Events	a. Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility. b. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. c. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.
Patient Protection Events	a. Infant discharged to the wrong person.

b. Patient death or serious disability associated with patient elopement (disappearance).
c. Patient suicide or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.

Care Management Events

a. Patient death or serious disability associated with a medication error (such as, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration).
b. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products.
c. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.
d. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
e. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.
f. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
g. Patient death or serious disability due to spinal manipulative therapy.
h. Artificial insemination with the wrong donor sperm or wrong egg.

Environmental Events

a. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility.
b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
c. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.
d. Patient death or serious disability associated with a fall while being cared for in a healthcare facility.
e. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.

Criminal Events

a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider.
b. Abduction of a patient of any age.
c. Sexual assault on a patient within or on the grounds of a healthcare facility.
d. Death or significant injury of a patient or staff member from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility.

POLICY UPDATE HISTORY INFORMATION:

6 / 2018	Implementation
11 / 2021	Added NY region applicable to the policy

Highmark Reimbursement Policy Bulletin

Bulletin Number:	RP-036		
Subject:	Preventable Serious Adverse Events		
Effective Date:	June 11, 2018	**End Date:**	
Issue Date:	June 11, 2018		
Source:	Reimbursement Policy		

Applicable Commercial Market	**PA** ☒	**WV** ☒	**DE** ☒
Applicable Medicare Advantage Market	**PA** ☐	**WV** ☐	
Applicable Claim Type	**UB** ☒	**1500** ☒	

PURPOSE:

The National Quality Forum (NQF), an organization that aims to improve the quality of healthcare, published Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors [NQF Web Site, accessed January 15, 2014], which listed adverse events that were "serious, largely preventable and of concern to both the public and health care providers, Such events are referred to as "preventable serious adverse events or never events," and include "Wrong Surgery Events." For the purposes of this policy, such events are referred to as *Preventable Serious Adverse Events* (PSAEs). PSAEs shall also include "Hospital Acquired Conditions" as defined by the Centers for Medicaid & Medicare Services (CMS).

A Preventable Serious Adverse Event is a serious, identifiable, and unambiguous occurrence or error made by a provider that is preventable and should never occur. The NQF adopted and maintains a list of PSAEs. PSAEs include, but are not limited to:

- Certain surgical infections
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This policy addresses general coverage guidelines on PSAEs as identified by the NQF. In addition to the list established by the NQF, this policy also includes any medical issues published by the Blue Cross Blue Shield Association (BCBSA) or the Federal Employee Program (FEP) as avoidable medical issues for which payment should not be made.

The Plan will monitor for compliance laws and guidance issued by state and federal governments as well as guidance issued by advisory organizations to include but not be limited to:, BCBSA policies and procedures; state and federal laws, regulations, and bulletins; and applicable advisory organizations' guidance and standards. Such guidance and standards will be incorporated by the Plan into its procedures and processes as appropriate and as they can be applied systemically. The Plan may also

incorporate PSAEs into its' current Quality reimbursement and may give consideration for Blue's Distinction Awards and reserves the right to consider such information as part of any credentialing process.

REIMBURSEMENT GUIDELINES:

Preventable Serious Adverse Events

The Plan will not provide reimbursement or allow providers to retain reimbursement for any care directly related to a PSAE and the Member shall not be liable for payment for any care resulting from PSAEs. In addition, a provider may not knowingly seek payment from The Plan or a member for a PSAE or for any services required to correct or treat problems created by a PSAE that occurred under the provider's control.

Subsequent services rendered by a *provider not involved with the initial PSAE will be considered for reimbursement. PSAEs include wrong surgical events (defined below). For a list of PSAEs see the *Appendix A* section of this policy. This list may be periodically revised.

***Note:** All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Wrong Surgery Events

A *Wrong Surgical Event* (WSE) is defined as a surgical or other invasive procedure that results when a practitioner erroneously performs:

- The wrong surgical or other invasive procedure on a patient
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- A surgical or other invasive procedure on the wrong patient.

A surgical or other invasive procedure is considered to be erroneously performed if it is not consistent with the correctly documented informed consent for that patient.

Emergent situations that occur during the course of surgery for which it is not possible to obtain informed consent are not considered a WSE. Also, a WSE is not intended to include changes in the plan that occurred upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

When a surgical or other invasive procedure is erroneously performed:

- All services provided in the operating room when an error occurs are considered related and therefore not covered.
- All providers in the operating room when the error occurs, who could bill individually for their services, are not eligible for payment.
- All related services provided during the same hospitalization in which the error occurred are not covered.
- All providers in the same Group, employed by, or associated with the provider(s) who caused or created the PSAE or error, which could bill or may receive reimbursement for services to correct the error, are not eligible for payment.

Providers are required to append one of the following applicable HCPCS modifiers on each claim line related to the WSE. These will be denied as not covered and the member held harmless with no liability:

- Modifier PA: Surgery Wrong Body Part
- Modifier PB: Surgery Wrong Patient
- Modifier PC: Wrong Surgery on Patient

Note: The modifiers above are not applicable to *inpatient* claim submissions. However, the specific diagnosis codes for a wrong surgical event are required on the *inpatient* claim.

UB-04 Claim Provision

The Plan requires that all inpatient acute-care hospitals (including critical access hospitals and children's inpatient facilities) must populate Present on Admission data on all inpatient claims. This requirement is designed to identify and prevent additional reimbursement to the provider for situations in which specified conditions occur during the course of an inpatient stay but, were not present at the time of admission. This mechanism serves to implement Highmark's policy on hospital-acquired conditions in the inpatient acute-care hospital setting.

Although, the majority of such conditions are found on the NQF list, several are not. All of the HAC diagnoses, irrespective of this distinction, are embedded in the CMS Grouper algorithm The Plan employs when calculating DRG based reimbursement for inpatient acute-care hospital services. They are also a component of the separate process The Plan utilizes to review for potential hospital-acquired conditions occurring in inpatient acute-care hospitals reimbursed via methodologies other than those based on DRG. Under either DRG or non-DRG based reimbursement methods, if payment is reduced as a result of the presence of a HAC, the provider is not permitted to seek payment from the member for the difference between the reduced payment and the payment that might have been expected had the condition been present on admission. The member must be held harmless.

Subsequent Services to Treat or Correct Problems Created by a HAC

Providers are not permitted to seek payment for subsequent services required to treat or correct problems created by those hospital-acquired conditions that **appear** on the NQF list. Under The Plan's policy, the remaining hospital-acquired conditions that are recognized by CMS but **do not appear** on the NQF list are subject to CMS's rules on subsequent services. CMS permits billing of "reasonable and necessary services" following discharge, including services related to the HAC. The member must be held harmless for the corrective services, except for normal cost-sharing amounts required under the member's benefits.

Preventable Serious Adverse Events Occurring in the Outpatient Facility Setting That Are Also Classified as Hospital-Acquired Conditions When They Occur in the Inpatient Acute-Care Setting

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When the existence of an outpatient preventable serious adverse event is recognized **before the patient is discharged**, the facility should "not seek payment" by not submitting a claim for the services to The Plan and not presenting a bill to the member. The member must be held harmless.

If the existence of an outpatient preventable serious adverse event is not recognized until **after the claim for the outpatient services has been submitted and/or payment has been received,** the provider should notify its Institutional Provider Relations representative so that payment can be prevented or retracted. The member must be held harmless.

If subsequent services are required to correct or treat problems created by the outpatient preventable serious adverse event, and the member chooses to have the corrective services performed by the provider under whose control the event occurred, that provider is not permitted to seek payment either from The Plan or from the member for such services. The member must be held harmless.

Claim Submissions for Wrong Surgical Events Occurring During an Inpatient Stay

If a wrong surgical event occurs during an inpatient stay, the provider must submit a **no-payment claim** (Type of Bill 110) for the non-covered services -- that is, those related to the wrong surgical event. The appropriate diagnosis code identifying the nature of the medical error must be reported.

If the provider believes that during the same stay it also provided other services that were not related to the wrong surgical event, it should submit two separate claims for the stay:

- A no-payment claim (Type of Bill 110) for the non-covered services (those related to the wrong surgical event); **and**
- An inpatient claim (Type of Bill 11X, excluding 110) for the covered services provided (those not related to the wrong surgical event).

In this situation, the hospital must report the same **Statement Covers From and Through Dates** on both the no-payment claim and the inpatient claim. The appropriate diagnosis code from the list below must be reported ***on the no-payment claim only*** to identify the nature of the medical error. All other standard UB billing protocols apply to both the no-payment claim and the inpatient claim.

Note: Inpatient non-covered Type of Bill 0110 (no-pay claim), 2-digit surgical error codes entered in Form Locator 81 – Remarks (loop 2300):

- MX – for a wrong surgery on patient;
- MY – for surgery on the wrong body part; or
- MZ – for surgery on the wrong patient

REFERENCES:

- The Leapfrog Group. Leapfrog Group position statement on never events. [Leapfrog Group Web site]. Retrieved from http://www.leapfroggroup.org/for_hospitals/leapfrog_hospital_quality_and_safety_survey_copy/never_events. Accessed January 15, 2014.

- National Quality Forum (NQF). Fact Sheet: Serious reportable events transparency & accountability are critical to reducing medical errors. [NQF Web Site]. Retrieved from http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp. Accessed January 15, 2014.

- CMS Online Manual Pub. 100-2, Chapter 1, Sections 10 and 120
- CMS Online Manual Pub. 100-2, Chapter 16, Section 180
- CMS Online Manual Pub. 100-3, Chapter 1, Sections 140.6, 140.7, and 140.8
- CMS Online Manual Pub. 100-4, Chapter 32, Section 230
- Transmittal 102, CR 6405
- Transmittal 1816, CR 6634

Note: References Below are Applicable Only to Pennsylvania

- Preventable Serious Adverse Events Act-Enactment Act of June 10, 2009, P. L. 1, No. 1, Cl. 35. Pennsylvania General Assembly Web Site. Retrieved from http://www.legis.state.pa.us/cfdocs/legis/li/uconsCheck.cfm?yr=2009&sessInd=0&act=1. Accessed January 15, 2014.

- Pennsylvania Act 1 of 2009, House Bill No. 84 http://www.pabulletin.com/secure/data/vol39/39-33/1474.html.

ADDITIONAL BILLING INFORMATION, REFERENCES AND GUIDELINES:

It is not an acceptable billing practice or process, for any reason, to refrain from submitting a claim because a PSAE or error occurred.

RELATED HIGHMARK POLICIES:

Refer to the following Medical Policies for additional information:

- Medicare Advantage Medical Policy N-67: Wrong Surgery – NCDs 140.6, 140.7, 140.8

APPENDIX A: List of Preventable Serious Adverse Events

Surgical Events	a. Surgery performed on the wrong body part. b. Surgery performed on the wrong patient. c. Wrong surgical procedure performed on a patient. d. Unintended retention of a foreign object in a patient after surgery or other procedure. e. Intraoperative or immediately postoperative death in an ASA Class I patient.
Product or Device Events	a. Patient death or serious disability associated with the use of contaminated drugs, devices or biologics provided by the healthcare facility. b. Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. c. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility.

Patient Protection Events	a. Infant discharged to the wrong person. b. Patient death or serious disability associated with patient elopement (disappearance). c. Patient suicide or attempted suicide, resulting in serious disability while being cared for in a healthcare facility.
Care Management Events	a. Patient death or serious disability associated with a medication error (such as, errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration). b. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products. c. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility. d. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility. e. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates. f. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility. g. Patient death or serious disability due to spinal manipulative therapy. h. Artificial insemination with the wrong donor sperm or wrong egg.
Environmental Events	a. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility. b. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances. c. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility. d. Patient death or serious disability associated with a fall while being cared for in a healthcare facility. e. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility.
Criminal Events	a. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider. b. Abduction of a patient of any age. c. Sexual assault on a patient within or on the grounds of a healthcare facility. d. Death or significant injury of a patient or staff member from a physical assault (that is, battery) that occurs within or on the grounds of a healthcare facility.