



Revised Questions and Answers (June 5, 2009)

New information is highlighted in red.

The name of the program has been changed to “Adverse Events.”

Effective October 1, 2008, the eleven Adverse Events (three National Quality Forum and eight Centers for Medicare and Medicaid events) listed in Exhibit A still apply. In an attempt to clarify and limit the events that will be automatically added to the Hospital amendment, Blue Cross and Blue Shield of Alabama has revised the language to apply only to CMS-approved events after January 1, 2009.

Hospitals should strike the following language from the amendment:

Corporation may add or delete procedures (including those adopted by CMS), to Exhibit A with at least 90 days advance notice to the hospital.

The language should be replaced by:

Corporation may add CMS events to Exhibit A 90 days from the CMS adoption date.

Many Hospitals have expressed concern over discoverability. To clarify, in terms of our proposed web portal, we are requiring hospitals to report only the following information:

Name

DOB

Contract Number

The Serious Reportable Event

Date Event Occurred

All of the required fields are contained in the most basic medical record and otherwise discoverable in a malpractice lawsuit. We are not asking hospitals to report privileged or confidential information developed through the Peer Review Committee.

Throughout the process of amending our hospital contracts to exclude payment for Serious Adverse Events, we have gone to great lengths to set up a process that would not expose the hospital to additional malpractice liability. We have tried to balance the sometime competing concerns of our customers (increased transparency and provider accountability) and participating hospitals (increased liability). We believe the proposed amendment and related processes strike the appropriate balance.

Letter of Agreement for Adverse Events Questions and Answers

(Blue Cross and Blue Shield of Alabama's policy was developed based on the Alabama Hospital Association's Guidance on Adverse Events, the National Quality Forum and the Centers for Medicare and Medicaid Services.)

February 10, 2009

For a small number of pressure ulcers, staging is not possible at the time of admission. While this is very infrequent, how should this be coded?

There is currently no clear guidance from CMS related to this issue. The Alabama Hospital Association has submitted this issue has been sent to both CMS and to the Coding Clinic for national guidance. Once this info is available, Blue Cross and Blue Shield of Alabama intends to review the information and communicate a policy based on the national standards.

For patients admitted with stage 1 or 2 ulcers and while they are in the hospital the ulcers become stage 3 or 4, Blue Cross will be following Medicare's guidance not require that these to be reported.

October 7, 2008

Will Blue Advantage claims be included in the Adverse Events amendment?

Yes, Blue Advantage is part of this amendment.

Do we follow CMS claims filing guidelines for Blue Advantage claims?

Hospitals will follow the CMS guidelines in filing Blue Advantage claims, using the appropriate POA indicator on the claim.

If no claim is submitted for the event, or the event cannot be filed on a claim, then Blue Cross and Blue Shield of Alabama would expect to be notified via the web portal for both Blue Advantage and private business patients. Hospitals are not expected to report a single event on both the webportal and a claim. Submission via the web portal is only necessary in instances where no claim is submitted.

What is the policy for Blue Advantage for non-CMS events?

We ask the facility to report, via a secure form behind *ProviderAccess*, National Quality Forum Never Events that do not otherwise result in a claim being filed to Blue Cross. This requirement is consistent for both Blue Advantage and Blue Cross and Blue Shield of Alabama members.

The types of events and how to report are detailed in the chart below and include: Surgery performed on the wrong body part, surgery performed on the wrong patient, object left in the body after surgery, air embolism, blood incompatibility, hospital-acquired stage III and IV pressure ulcers, and death or disability associated with falls or trauma.

For the events that are both on the National Quality Forum and CMS, how should a hospital report this?

CMS events have corresponding ICD-9 diagnosis codes. Hospitals should use the POA indicator on claims for these events.

If no claim is submitted for the event or the event cannot be filed on a claim, then Blue Cross and Blue Shield of Alabama would expect to be notified via a secure form behind *ProviderAccess*.

Submission via the web portal is only necessary in instances where no claim is submitted. Please refer to the chart below for more information on reporting.

Reportable Events	NQF	CMS	Web portal	Claim	Root Cause Analysis+
Surgery performed on the wrong body part	X		X		Yes
Surgery performed on the wrong patient	X		X		Yes
Wrong surgical procedure performed on a patient	X		X		Yes
Object left in the body after surgery	X	X	X	OR X	Yes
Air embolism	X	X	X	OR X	Yes
Blood incompatibility	X	X	X	OR X	Yes
Hospital-acquired pressure ulcers (decubitus ulcers) - stage three and four	X	X	X	OR X	N/A*
Falls and trauma (hospital-acquired) - fractures, dislocations, intracranial injuries, crushing injuries and burns	X	X	X	OR X	N/A*
Hospital-acquired catheter associated urinary tract infections		X		X	N/A*
Hospital-acquired vascular catheter -		X		X	N/A*

associated infection				
Hospital-acquired mediastinitis after coronary artery bypass surgery		X	X	N/A*

+Facilities will no longer be required to report if a root cause analysis was performed. While Blue Cross expects your facility to do a root cause analysis, you will not be required to notify us via the webportal. The optional information regarding outcomes has also been removed from the webportal

**Should a pattern develop, such as a large volume of UTIs on a single floor in a short time frame, Blue Cross and Blue Shield of Alabama would expect the facility to do a root cause analysis. It will not be necessary to report the specifics of the root cause analysis.*

September 16, 2008

Who at the facility level should be responsible for making the ultimate determination for the number of days, if any, to reduce?

Facilities are taking many different approaches to this process, but based on calls from the AlaHA Workgroup, most hospitals will be using a collaborative approach. Blue Cross will not be requiring any one way of making the final determination, allowing hospitals to decide what works best for their individual operational procedures.

Is there a timeframe in which we will need to report a Serious Adverse Event?

Blue Cross is recommending that the event be reported within 45 days of awareness of the event. We would encourage hospitals to report as soon as possible. If Blue Cross learns of an event that has not been reported by the hospital, an educational letter will be sent to the facility to let them know that Blue Cross is aware of the event and where the hospital can report the event, either via the webportal or filing of a claim.

Published August 15, 2008

What information will my facility have to report on the National Quality Forum Events?

Reporting will be done via *ProviderAccess*. No outcome information will be required, only the type of event and information on the patient to whom the event occurred will be required. Facilities will not be required to report if a root cause analysis was performed. While Blue Cross expects your facility to do a root cause analysis, you will not be required to notify us via the webportal. The optional information regarding outcomes has also been removed from the webportal.

What if a hospital does not sign the amendment by the August 15, 2008 deadline?

Hospitals that choose not to execute the amendment, or later choose not to add the National Quality Forum additional identified events, will be provided to customer groups upon request any time after August 15, 2008. In addition, non-execution of the Letter of Agreement will impact Hospital Tiered Network status for 2009. For 2010, the identified National Quality Forum events will be a part of the Hospital Tiered Network.

Does Blue Cross and Blue Shield of Alabama automatically assume that days will be reduced if one of the identified conditions was not present on admission?

Blue Cross realizes that not all conditions will result in additional days. When a condition does lead to an additional day, Blue Cross expects the hospital to make the clinical determination on how many days were added by the event.

Do facilities need to remove days, charges or both when they are incurred during event associated with an inpatient stay?

Facilities just need to non-cover the additional days (if there are any) associated with the event.

What happens if a patient falls and is subsequently injured, and the hospital does not believe it is responsible?

Blue Cross and Blue Shield of Alabama would expect that a claim would be filed with the correct POA code and the appropriate number of days for a typical stay for a similar diagnosis. However, if during the root cause analysis, after the claim is filed, it is determined that the hospital has observed and documented that patient safety measures were correctly followed, the hospital may determine that it was not responsible. At this point the hospital can refile the claim to include the total number of days for the patient stay; the hospital should be prepared to support the basis for the refiling. The hospital also has the option to hold the claim until the root cause analysis is finished, and the amount of additional days (if any) associated with the event is determined.

What if a facility receives a transfer patient with one of these Adverse Events? For example, a patient breaks his hip at one hospital and is transferred to a hospital with orthopedic capabilities.

The facility receiving the transfer would code the condition as present on admission and would file a claim for the entire length of stay.

Does this policy apply to outpatient or inpatient?

This policy applies only to inpatient admissions. Following CMS guidelines, emergency room visits, observation beds, and outpatient surgeries are all considered outpatient and do not apply to this amendment.

What is the impact on physicians?

The impact to physicians has yet to be established. In the coming months, we will be examining, with the help of the Alabama Hospital Association and the Medical Association for the State of Alabama, the role of physicians in these events and possible impacts to physicians.

How does a hospital determine how many days to delete from the bill for an adverse event?

The hospital would make the determination that the condition was in fact hospital-acquired. If the event is determined to be hospital-acquired, then the hospital must decide if an adjustment should be made in the days billed (e.g., if the hospital-acquired condition added to the length of stay, the hospital should not bill for the additional days).

In making the determination, the hospital could consider many clinical factors, including but not limited to, the following:

- The age of the person, comorbidities and other relevant issues
- The acceptable range of a normal length of stay for hospital patients with similar medical conditions

The determination process will be hospital specific, due to the differences among patients, facilities, and conditions.

Published August 6, 2008

When is the Letter of Agreement due to Blue Cross?

The Letter of Agreement must be postmarked no later than **August 15, 2008**. For Hospital Tiered Network Criteria, hospitals will receive tiering points if they sign and return the Letter of Agreement by the due date.

What does the hospital commit to when it signs this amendment?

Signing the hospital amendment commits the hospital to non-billing and reporting of the eight Centers for Medicare and Medicaid (CMS) events and the three National Quality Forum events. The amendment also states that the corporation will add CMS adopted events 90 days from the CMS adoption date.

Is Blue Cross planning to expand the list of Adverse Events?

Yes, Blue Cross will expand the list to include applicable remaining items on the National Quality Forum list as well as future CMS adopted events. Your facility needs to be aware that Blue Cross intends to extend the list to include the applicable National Quality Forum events shown below during contract renewals on or after January 1, 2009.

The additional National Quality Forum events are:

- Surgical Events
 - Post-operative death in normal healthy patient
 - Implantation of wrong egg or sperm
- Product or Device Events
 - Death/disability associated with use of contaminated drugs, devices or biologics
 - Death/disability associated with use of device other than as intended
- Care Management Event
 - Death/disability associated with medication error
 - Maternal death/disability with low-risk delivery
 - Death/disability associated with hypoglycemia
 - Death/disability associated with hyperbilirubinemia in neonates
 - Death/disability due to spinal manipulative therapy
- Environmental Events
 - Death/disability associated with use of restraints within facility
 - Death/disability due to wrong oxygen or gas

What definition will be used in consideration of “disability”?

A serious disability is defined as a major loss of function that endures for more than 30 days, is not present at the time services were sought and is not related to the presenting condition.

Who at the hospital is responsible for reporting?

Hospitals should have effective and non-punitive methods for identifying Adverse Events and learning from them so as to not repeat them in the future. Blue Cross recognizes that all hospitals have unique operational procedures. The hospital will be responsible for implementing

a work flow process and designating a reporting contact to work with Blue Cross.

Who determines the amount of days that were incurred due to an event?

Hospitals will have the responsibility for determining any days caused by a Serious Adverse Event, and making the appropriate change to the claim.

What happens if a patient falls and is subsequently injured, and the hospital does not believe it is responsible?

Blue Cross and Blue Shield of Alabama would expect that a claim would be filed with the correct POA code and the appropriate number of days for a typical stay for a similar diagnosis. However, if during the root cause analysis, after the claim is filed, it is determined that the hospital has observed and documented that patient safety measures were correctly followed, the hospital may determine that it was not responsible. At this point the hospital can refile the claim to include the total number of days for the patient stay; the hospital should be prepared to support the basis for the refiling.

Given that the Adverse Events program is new to all parties involved, how will Blue Cross and/or hospitals address areas of concern, matters in dispute, or problems with implementation?

With any new process, there is a level of trust and cooperation required for successful operations. Blue Cross will continue to rely upon feedback through the Alabama Hospital Association's Quality Task Force and Association leadership. In addition, a steering committee will be appointed to provide guidance and leadership on this and other endeavors. This committee will be comprised of three hospital CEOs, three physicians, three business leaders and BCBS representatives.

If there is no claim associated with the event (for example: surgery on the wrong body part), what is the purpose for reporting the event?

This policy was designed in such a way that allows hospitals to determine when the event has taken place and to therefore not bill us for the event. Self reporting via the web portal will provide us with an audit trail to this policy to validate/verify that no payment was made for the event and that the patient was not billed for the event. In addition, even though there would be no claim associated with the event, our customers expect that we report the number of events for their specific group.

What is the reason for instituting this amendment for Adverse Events?

We realize Alabama's hospitals are committed to providing the highest quality care possible for all patients. However, there are times when, despite best efforts, events occur that could have been prevented. We agree with our customer groups and with other national insurers that patients and insurers should not have to pay for Adverse Events. By working with the Alabama Hospital Association, we were able to generate a list of events that should generally be preventable through the application of evidence-based guidelines.

What does it mean to "waive all costs directly related to a Serious Adverse Event"?

The hospital should not submit a claim or bill the patient for any of the three surgical Never Events. Hospital-acquired conditions will be reviewed on a case-by-case basis by the hospital, and the hospital will not bill Blue Cross or the patient for any days that were the direct result of a Serious Adverse Event.

Here are some examples:

- A patient enters the hospital for surgery on the left knee, but the right knee is operated on in error. The entire hospital stay associated with operation on the incorrect knee should not be billed to Blue Cross or the patient.
- A patient enters the hospital for surgery and develops a stage-four pressure ulcer. This event prolongs the patient's hospital stay by two days. Blue Cross would cover the typical length of stay for similar surgeries, but would not be expected to pay for the additional two days. Neither would the patient be held financially accountable for those two days.

Published July 2, 2008

What are the current criteria?

The policy includes 11 Adverse Events (or hospital-acquired conditions). Eight events are from the Centers for Medicare & Medicaid Services' (CMS) Inpatient Prospective Payment Policy for hospitals for 2008 and are hospital-acquired conditions. Following are the eight events:

- Object left in the body after surgery - Unintended retention of a foreign object in a patient after surgery or other procedure
- Air embolism - Patient death or serious disability directly attributable to an intravascular air embolism that occurs while being cared for in a healthcare facility
- Blood incompatibility - Patient death or serious disability directly attributable to a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- Hospital-acquired pressure ulcers (decubitus ulcers) - stage three and four
- Hospital-acquired catheter-associated urinary tract infections
- Hospital-acquired vascular catheter - associated infection
- Hospital-acquired mediastinitis after coronary artery bypass surgery
- Falls and trauma (hospital-acquired) - fractures, dislocations, intracranial injuries, crushing injuries and burns

In addition to the above CMS events, Blue Cross and Blue Shield of Alabama has included three surgical Never Events from the National Quality Forum's list. These Never Events are provided below:

- Surgery performed on the wrong body part
- Surgery performed on the wrong patient

- Wrong surgical procedure performed on a patient

What is the difference between a Never Event and a hospital-acquired condition?

The National Quality Forum defines Never Events as serious and costly errors that ideally should *never* happen in a hospital setting and for which practices should be adopted to prevent their occurrence. Hospital-acquired conditions should be rare and generally preventable through the application of evidence-based guidelines.

How is this policy different from the CMS policy?

The Blue Cross and Blue Shield of Alabama policy is based on the CMS policy on Adverse Events, but Blue Cross has added three additional events to the list of non-covered services. Blue Cross and Blue Shield of Alabama's Adverse Events Policy applies to all Participating Hospitals, regardless of type.

What types of hospitals are impacted by this policy?

The Letter of Agreement applies to all inpatient hospitals in Alabama and contiguous counties that Blue Cross directly contracts with for its local network. This includes general acute care hospitals, long-term care hospitals, rehabilitation hospitals, Children's Hospital, and Veteran Administration Hospitals.

Is this policy being implemented to save money?

Blue Cross and Blue Shield of Alabama supports the programs initiated by CMS and NQF. While we expect the incidence rate of these events to be low, it is important for hospitals in our network to support a culture of quality, which should ultimately lower costs and enhance patient safety/care.

What happens if, through error or mistake, Blue Cross is billed and payment is made to a hospital for a Serious Adverse Event?

In this situation, the hospital will be required to refund the money for such payment or submit a corrected bill as appropriate. The patient will be held financially harmless. In the event of an increased length of stay, level of care or significant intervention, the facility will do its best to "split out" those additional charges.

Will the claims process change?

Yes, the claims process will change slightly to accommodate the reporting of a valid Present on Admission (POA) indicator. Our goal is to mirror the Medicare requirements for POA indicator, as closely as possible. A valid POA will be required for diagnosis codes that indicate one of the eight Adverse Events.

What is Present on Admission (POA)?

CMS defines Present on Admission as a set of specified conditions that are present at the time the order for inpatient admission occurs. Conditions that develop during an outpatient encounter, including the emergency room, observation, or outpatient surgery, are considered Present on Admission.

What are the POA Indicators and what do they mean?

Y = Yes. Diagnosis was present at time of inpatient admission.

N = No. Diagnosis was not present at time of inpatient admission.

U = No information in the record. Documentation insufficient to determine if the condition was present at the time of inpatient admission.

W = Clinically undetermined. Provider unable to clinically determine whether the condition was present at the time of inpatient admission.

1 = Unreported/Not used. Exempt from POA reporting. This code is equivalent to a blank on the UB-04; however, it was determined that blanks are undesirable when submitting this data via the 4010A

What are the current diagnosis codes for the hospital acquired conditions?

(As of July 1, 2008)

- International Classification of Diseases (ICD-9) codes 998.4 and 998.7 - Unintended retention of a foreign object in a patient after surgery or other procedure
- 999.1 - Patient death or serious disability directly attributable to an intravascular air embolism that occurs while being cared for in a healthcare facility
- 999.6 - Patient death or serious disability directly attributable to a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- 707.23 and 707.24 - Hospital-acquired pressure ulcers (decubitus ulcers) - stage three and four
- 996.64 - Hospital-acquired catheter associated urinary tract infections
 - *Note:* 996.64 would not need to be coded as POA if one of the following codes is present on the claim, also: 112.2, 590.10, 590.11, 590.2, 590.3, 590.80, 590.81, 595, 597, 599
- 999.31 - Hospital-acquired vascular catheter-associated infection
- 519.2 and one of the following procedure codes 36.10-36.19 - Hospital-acquired mediastinitis after coronary artery bypass surgery
- 800-829, 830-839, 850-854, 925-929, 940-949, 991-994 - Falls and trauma (hospital acquired) - fractures, dislocations, intracranial injuries, crushing injuries and burns

Will Blue Cross be moving toward Diagnosis Related Group (DRG) reimbursement?

For private business, Blue Cross will continue to reimburse on a per diem basis.

When does the Serious Adverse Event protocol become effective?

October 1, 2008

What is the Alabama Hospital Association's opinion on Adverse Events?

Blue Cross has worked closely with AlaHA and solicited input from the hospital community during this process. AlaHA members are supportive of initiatives to promote the highest quality

care possible for all patients. They have issued a guidance paper to hospitals to assist them in discussing this issue with their boards, medical staff and employees, as well as to provide a resource in developing internal policies related to these events. Blue Cross will continue its commitment to maintain communication with AlaHA and the hospital community as program development progresses.

Where can I learn more about Adverse Events?

Blue Cross and Blue Shield of Alabama used the following three main sources in creating our policy:

- Alabama Hospital Association’s Guidance on Adverse Events (www.alaha.org)
- Centers for Medicare and Medicaid Services (www.cms.gov)
- National Quality Forum (www.qualityforum.org)

These documents will be available via the Blue Cross and Blue Shield of Alabama web site (www.bcbsal.com).

Who should we contact at Blue Cross with questions about Adverse Events?

Questions can be submitted to NetworkAnalysis@bcbsal.org. Program information can be obtained on the Blue Cross and Blue Shield of Alabama web site www.bcbsal.com and through your Provider Network Services Representative. This Question and Answer document will be updated on a regular basis and is available on the Blue Cross and Blue Shield of Alabama web site.