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Chapter 1

Introduction

Using the PA Patient Safety Reporting System to improve healthcare safety and quality

Purpose

The purpose of this Training Manual and Users’ Guide is to help Pennsylvania healthcare facilities to improve the safety and quality of the care they provide to patients.

The Medical Care Availability and Reduction of Error Act of 2002—also known as “MCARE” or “Act 13 of 2002”—established the Patient Safety Authority (“the Authority”) as an independent agency of the Commonwealth. The Authority is charged with taking steps to reduce medical errors by identifying problems and recommending solutions that promote patient safety in Pennsylvania healthcare facilities.

MCARE required Pennsylvania hospitals, ambulatory surgery centers, behavioral health centers, and birthing centers to report to the Authority on the occurrence of “Serious Events” and “Incidents”. MCare also requires facilities to report Serious Events and “Infrastructure Failures” to the Department of Health (DOH). The Authority has developed the Pennsylvania Patient Safety Reporting System (PA-PSRS) to:

- Collect Serious Event, Incident, and Infrastructure Failure reports from MCARE-covered facilities
- Facilitate internal analysis and reporting of patient safety-related data within each facility
- Facilitate aggregate data analysis across facilities and development of preventive recommendations to improve patient safety
- Serve as an educational resource and quality improvement tool for healthcare provider organizations and their Patient Safety Committees

Reports are submitted to the Authority and the DOH as appropriate using a single interface. Note that:

- Reports of Incidents are submitted only to the Authority. They are not accessible to the DOH.
- Reports of Serious Events are submitted BOTH to the Authority and to the DOH for their respective statutory requirements.
• Reports of Infrastructure Failures are submitted only to the DOH. They are not accessible to the Authority.

### Organization

The Manual is organized into the following chapters and appendices:

- **Chapter 1: Introduction** explains the purpose of the Training Manual and Users’ Guide, presents an annotated outline of the manual, and discusses the scope of PA-PSRS.

- **Chapter 2: Getting Started** briefly outlines the major functions of the system and teaches you how to log on and navigate PA-PSRS.

- **Chapter 3: Facility Management** provides instructions for the Facility System Manager to perform their required activities.

- **Chapter 4: Event Reports** teaches you how to enter new reports, locate and amend submitted reports, and review report status.

- **Chapter 5: Report Coding** introduces several taxonomies or classification schemes used in PA-PSRS and teaches you how your coding of reports affects the usefulness of the data you can output from the system.

- **Chapter 6: Data Analysis** teaches you how to work with your facility’s data to generate meaningful reports to inform your patient safety and quality improvement activities. This chapter teaches you how to formulate and run data queries, as well as how to produce and save data tables and graphs.

- **Chapter 7: Communications** explains where to turn for technical assistance, provides necessary contact information, and discusses other types of communications you may receive from the Authority or its contractors.

- **Chapter 8: Falls Reporting Program** explains how to enroll in the hospital falls reporting program, collect detailed information related to falls, enter utilization data, and generate meaningful reports designed to assess the effectiveness of, and enhance hospital fall prevention programs, while benchmarking falls and falls with harm rates with other enrolled hospitals across the state.

- **Chapter 9: Pressure Injury Reporting** presents guidance on identifying and reporting Pressure Injury events, using the most current definitions.

- **Appendix A: Blank Forms** provides hardcopies of the portions of PA-PSRS used in reporting events, which may be useful in coding submitted reports.

- **Appendix B: Event Type Taxonomy** provides the complete list of event type codes used in PA-PSRS.

- **Appendix C: Selected Program Memoranda** provides policy guidance from the Patient Safety Authority.
The Scope of PA-PSRS

The PA Patient Safety Reporting System (PA-PSRS) is a mandatory, confidential, statewide information system for reporting of events, occurrences, or situations that have (or could have) resulted in unanticipated injury to a patient in an MCare-covered medical facility. Covered facilities include hospitals, ambulatory surgical centers, abortion facilities and birthing centers licensed as healthcare providers in the Commonwealth of Pennsylvania.

PA-PSRS will collect four general types of reports:

- Reports of Serious Events
- Reports of Incidents
- Reports of Infrastructure Failures.
- Reports of Other events

These terms are defined in MCare or in the latest guidance for reporting (see Figure 1-1).

“Serious Event.” An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an Incident.

“Incident.” An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a Serious Event.

“Infrastructure Failure.” An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

“Infrastructure.” Structures related to the physical plant and service delivery systems necessary for the provision of health care services in a medical facility.

“Other” event. An event for fulfilling the Centers for Medicare & Medicaid Services (CMS) requirement of hospitals to report any death in restraints or seclusion, or in which restraints or seclusion were used within 24 hours of death (other than soft wrist restraints).

Figure 1-1. Key Definitions

Important Note: As used in this manual or in the PA-PSRS software application, the word “event” is a generic term to describe any actual or potential patient safety-related occurrence. In this

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context, the word "event" is not to be confused with the MCare-defined term "Serious Event," which is defined much more narrowly.

In developing PA-PSRS, the Patient Safety Authority established several underlying principles:

- PA-PSRS must be comprehensive, understandable and easy to use.
- PA-PSRS must be user-friendly and respectful of the limited resources available to reporting facilities.
- Once established, PA-PSRS should not be redundant, duplicative or burdensome to reporting facilities.
- PA-PSRS must support two-way communications.

The PA-PSRS program will not only receive reports from reporting facilities, but will also provide feedback to facilities that they can use in their own patient safety and quality improvement activities. For example, facilities are able to generate statistical tables and graphs of their own data for internal use and analysis. (See Chapter 6, Data Analysis, for samples.) Facilities can also export data from PA-PSRS to perform customized analyses (see Section 6, Data Analysis).

System Confidentiality and Data Accessibility

PA-PSRS is a Web-based application with several layers of security, including Secure Socket Layer (SSL) encryption technology, automatic log-off after 15 minutes of idle time on a single report input screen, and intrusion detection systems. To help ensure security, the following steps are taken:

- Each user of the system must register once. Each user is associated with a single reporting facility.
- All information transmitted from the facility to the PA-PSRS application is encrypted, using industry-standard SSL technology.
- Users will be required to change their password every 60 days.
- PA-PSRS resides on the Commonwealth's system, and hence, has all the protection that the Commonwealth has for other secure applications, including intrusion detection systems.

The reports of Serious Events, Incidents, Infrastructure Failures, and Other events you submit to PA-PSRS are strictly confidential and will be available only to the parties and in the manner specified in MCare.

Data from the system will be accessible as follows:

- The Patient Safety Authority and its contractors will have access to all reports of Serious Events and Incidents. Although submitted reports will identify specific facilities, they will not contain any identifiable information, such as the names of individual healthcare workers or patients. While the Authority will produce analytical reports based on submitted data, these reports will include only aggregate, de-identified data representing multiple institutions.
Under no circumstances will the Authority release the details of specific event reports in a manner that allows a reporting facility to be identified.

- The Department of Health will have access to all reports of Serious Events, Infrastructure Failures and Other events. Although submitted reports will identify specific facilities, they will not contain any identifiable information, such as the names of individual healthcare workers or patients.

- Each facility that submits reports to PA-PSRS will have complete access to all of its own reports. Each facility will also have access to aggregate data gathered from reports submitted by other facilities, which could be useful for comparative purposes. However, no individual facility will be identifiable through the aggregate data reports.

MCAre specifically protects from disclosure reports submitted to the Authority through PA-PSRS. Section 311(a) of the Act states that any documents, materials, or information solely prepared or created for the purpose of complying with the Act’s patient safety reporting requirements “are confidential and shall not be discoverable or admissible as evidence in any civil or administrative action or proceeding.”

**HIPAA Concerns**

Under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (PL 104-191), all healthcare providers and their business associates are responsible for protecting the confidentiality of “protected health information” (PHI)—that is, individually identifiable health-related information.

The PA-PSRS program was specifically designed to prevent the collection of PHI. We have taken all reasonable steps to ensure that PA-PSRS does not request any information that can be used to match an event report in the database with a particular patient, such as a name, date of birth or medical record number. Further, the system does not request information that could be used to identify individual healthcare workers who may be involved in a reportable event (such as names, employee numbers or Social Security numbers).

Although there are no fields in the database that request PHI, it is still possible that system users could enter PHI—either intentionally or unintentionally—in free-text fields. We strongly encourage facilities to pay special attention to their HIPAA obligations.

PA-PSRS has established a principle that PSRS staff members may not modify or delete data submitted by a facility. Therefore, each PSO must be responsible for the integrity of their data.

See also “System Confidentiality” above.

**Impact of PA-PSRS on Reporting to Other Organizations**

PA-PSRS supports reporting to both the Patient Safety Authority and the Department of Health (DOH). Reporting through PA-PSRS does not relieve a healthcare facility of any obligations it may have to report to other federal, state or local government agencies, independent accrediting organizations or licensing boards.
Acknowledgements

The PA Patient Safety Reporting System (PA-PSRS) was developed and is maintained by ECRI Institute under contract to the Pennsylvania Patient Safety Authority. ECRI Institute is a Pennsylvania-based independent, non-profit health services research agency headquartered in Plymouth Meeting (Montgomery County). Its focus is healthcare technology, healthcare risk and quality management, and healthcare environmental management. ECRI Institute is a Collaborating Center of the World Health Organization and is designated an Evidence-based Practice Center (EPC) by the U.S. Agency for Healthcare Research and Quality (AHRQ).

Hewlett-Packard Company (HP), together with its subsidiaries, provides products, technologies, software, solutions, and services to individual consumers and small- and medium-sized businesses (SMBs), as well as to the government, health, and education sectors worldwide. HP was founded in 1939 and is headquartered in Palo Alto, California, with local offices in the Harrisburg area.

The Institute for Safe Medication Practices (ISMP), based in Horsham (Montgomery County), is providing analytical support and technical assistance to the PA-PSRS program. ISMP is a non-profit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention. The Institute provides an independent review of medication errors that have been voluntarily submitted by practitioners to a national Medication Errors Reporting Program (MERP) operated by the United States Pharmacopoeia (USP) in the USA.

The PA-PSRS software program was developed in part based on Patient Safety Net™, a proprietary patient safety reporting application developed and maintained by the University HealthSystem Consortium (UHC). UHC, based in Chicago, Illinois, is a non-profit alliance of the clinical enterprises of 87 academic health centers.

Diversified Data Systems (DDS), based in Mechanicsburg, PA, provided assistance in developing the PA-PSRS training program and this manual.

The Authority and ECRI Institute also wish to thank the Pennsylvania healthcare organizations who participated in the initial rollout of and subsequent enhancements to the PA-PSRS program. Their feedback and suggestions have helped to improve the usefulness of the system, and their ideas will continue to influence future enhancements. We appreciate their leadership and commitment to patient safety.
Getting Started
Key system functions and startup

Key System Functions

The system is designed around the following key functions:

1. System administration
2. Submitting reports of Serious Events, Incidents, Infrastructure Failures and Other events
3. Amending submitted reports
4. Data analysis of submitted reports

User Roles

Each facility will have three system “roles”:

- Facility System Manager
- PA-PSRS User
- Read-Only PA-PSRS User

Each role has unique responsibilities and separate User IDs and passwords.

The first role, the Facility System Manager, is responsible for:

- Assigning user IDs and passwords to other users in the facility and, conversely, removing user IDs and passwords.
- Establishing and maintaining “care areas” that will help define the location of events within a facility.
- Enrollment in the Falls Reporting Program

See the chapter Facility Management for steps the Facility System Manager must take before using the system for the first time.

The second role is that of a PA-PSRS User. One person may serve as both a PA-PSRS User and the FSM or a facility may designate a different person for each role. A PA-PSRS User is responsible for:

- Submitting reports.
- Amending reports.
• Viewing and printing reports.
• Analyzing data from the system.

Each MCare-covered facility designates its own Patient Safety Officer (PSO) in its Patient Safety Plan as submitted to the Department of Health under MCare. The PSO will be the primary point of contact responsible for interacting with PA-PSRS.

A facility may designate more than one individual to serve in the PA-PSRS User role. This will enable several people to submit reports directly to PA-PSRS on behalf of the facility. Please be advised, however, that the Patient Safety Officer identified in the facility’s MCare-required Patient Safety Plan is ultimately responsible for all reports submitted to the system. Therefore, be careful and exercise good judgment when deciding to whom you will grant this responsibility.

Nevertheless, we recommend that each facility designate at least one other individual with patient safety or quality management responsibilities to serve as a PA-PSRS User, particularly as a point of contact during periods when the primary PSO is unavailable. Each PSO (and each delegate they establish) will receive a unique ID and password for accessing the system.

Each facility must notify the Authority of any changes in its PSO. To do so, go to the Authority’s website, which is accessible via a button on the left side of the PA-PSRS sign-on screen. Click on the “Facility Reporting Information” link in the left-hand menu. There you will instructions for updating the name and contact information for your facility’s PSO.

The third role is that of the Read-only PA-PSRS User. Users who are assigned the Read-only user role are restricted from submitting or amending reports. This user role has access to the system for the following purposes:

• Viewing and printing reports.
• Analyzing data from the system.

Logging On

PA-PSRS is accessed via a secure, password-protected website via the Internet. You can access the system from any computer that meets the following specifications:

• Microsoft Internet Explorer 8 or later; Compatibility Mode may need to be activated
• Support for session cookies (non-persistent)
• Support for JavaScript
• Local administrative privileges during installation of ActiveX controls required to generate graphical reports
• Access to the internet
• e-Mail account
• Adobe Acrobat Reader V8.0 [You will be able to download Adobe Reader directly from the PA-PSRS main screen.]
To reach the PA-PSRS Home Page, direct your browser to the following URL:

http://www.papsrs.state.pa.us

To log on to the system, you will need your User ID and password, which is assigned by either the Patient Safety Authority or the Facility System Manager.

Log-on Steps:

1. From the PA-PSRS Home Page, enter your User ID and Password in the appropriate dialog boxes.

2. Press the button marked “Click here to Login.” This will bring you to the Main Menu where you will be able to perform several different functions. You can also bypass the Main Menu by checking a box to go directly to the reporting form if you want to submit a new event report.
Navigation

Once you log onto the system, the screen you see will depend on whether you have logged in as a PA-PSRS User, Read-Only PA-PSRS User, or the Facility System Manager (see User Roles, above).

If you have logged on as a PA-PSRS User or Read-Only PA-PSRS User, you will go directly to the PA-PSRS User Main Page (see below). The main page lists all the reports your facility has submitted.

Note the blue horizontal Navigation Bar on your screen that looks like the one shown below:

This Navigation Bar’s buttons (or selections) are used to move between the different system functions. You use the Navigation Bar by positioning your cursor over your selection. This will initiate a “pop up” menu of possible selections under that heading.

If you are a PA-PSRS User, positioning your mouse over “Event Report” in the Navigation Bar brings up a menu with three selections: Create New Event Report, Amend Event Report, or Retrieve Event Report By Report ID. To perform these functions, simply click on your selection.

If you are a Read-only user positioning your mouse over “Event Report” in the Navigation Bar brings up a menu with only one selection: Retrieve Event Report By Report ID. To perform this function, simply click on your selection.

This manual addresses the specifics of performing these tasks in later chapters. For now, familiarize yourself with the Navigation Bar and the available selections:
If you logged in as the **Facility System Manager**, your Navigation Bar will appear as shown below:

<table>
<thead>
<tr>
<th>Main Page</th>
<th>User Administration</th>
<th>Care Areas</th>
<th>Falls Program</th>
<th>Resources</th>
<th>Log Off</th>
</tr>
</thead>
</table>

As the Facility System Manager, the selections available from your Navigation Bar are:

- **Main Page**
- **User Administration**
  - Add New User
  - View/Edit User
- **Care Areas**
  - Add New Group
  - Edit/Delete Group
  - Add Care Area
Creating and Changing Passwords

As required for software hosted on Pennsylvania's computer network, the system will prompt you to change your password every 60 days for security reasons.

Password Creation

When a new user is created, an email is sent with a link to a page to retrieve the User ID, create a password following the rules below, and setup the security challenge questions. When a password is reset, an email is sent with a link to a page to create a new password following the value requirements below.

When a password has expired, a prompt to change the password following the new requirements will be issued. If no security questions are yet defined, the selection of and answers to three (3) different questions will be prompted after the password update.

Password Validation Requirements

1. User password values must contain characters from all of the following four (4) classes:
   - Upper case letters (A-Z)
   - Lower case letters (a-z)
   - Westernized Arabic numerals (0-9)
   - These specific non-alphanumeric characters (', @', '#', '$', ',', ';', '-', _)

   Spaces are not permitted.

2. Examples of acceptable passwords using the 4 classes of characters are displayed on all password change screens. These sample values are not allowed to be used.

3. Passwords must be changed every sixty (60) days.

4. Passwords must contain at least eight (8) characters.
5. The previous ten (10) changed passwords are restricted from use.

6. Passwords may only change once every two (2) days. PA-PSRS help desk administrators can reset passwords at any time.

7. The password help documentation on the Change Password screen contains the new password policy.

8. Accounts will be locked out after eight (8) unsuccessful logon attempts. FSM users will have the ability to unlock their facility users from the current user administration screen via checkbox. All others must contact the helpdesk. When an account is locked out, a message to contact the Facility System Manager or the help desk to unlock the account will be presented on screen.

See Program Memorandum No. 2013-02 for more details about creating and changing passwords.
Facility Management
How to set up and maintain the system for your organization

Role of the Facility System Manager

The Facility System Manager is responsible for these functions in the system:

- Assigning user IDs and passwords to other users in the facility or, conversely, removing user IDs or passwords if, for example, a person is no longer employed by your facility.
- Establishing “care areas” and “care area groups” that will help define the location of events within the facility.
- Enrolling in the Falls Reporting Program (available to HOSPITALS only)

The Facility System Manager and PA-PSRS User both perform different functions; however, it is possible for an individual to maintain both roles under separate log in IDs. Recognizing that some organizations prefer to have different individuals handle these functions, we have defined a unique role for the Facility System Manager to offer this option.

There are separate User ID and password combinations for the Facility System Manager and a PA-PSRS User. Even if the same individual serves both roles, they will need to use the Facility System Manager login to perform administrative functions and the PA-PSRS User login to work with event reports and perform data analyses.

We recommend that both PA-PSRS Users and the Facility System Manager review the material in this chapter together. Each facility should decide:

- Who will be granted access to the system within the organization, and
- What care areas and care area groups are relevant to their facility?

Ideally, this should be done before you submit your first report to PA-PSRS.

User Administration

From the Main Page, when logged in as the Facility System Manager, click on "User Administration" to add a new user or to view/edit an existing user’s profile.

When a new facility is created in PA-PSRS two sets of User IDs and passwords are created: one for the Facility System Manager and one for a PA-PSRS User (for the facility’s legal Patient Safety Officer). Before ever accessing the system, these two roles will be established for you.
The first thing to do is to edit the profiles of these users to ensure that contact information and other details are correct.

Next, decide whether your facility wants more than one person to have the ability to submit reports to PA-PSRS. If you choose to allow anyone other than the PSO to submit reports to the system, the PSO must ultimately be responsible for the integrity of submitted reports.

If the PSO wishes to authorize other individuals to submit and amend reports on his or her behalf, you may add additional users by following these steps:

1. Click “User Administration” on the Navigation Bar
2. Click “Add New User” in the pop-up menu
3. Enter the information requested on the screen below and select “Yes” to the question “Can this user enter and amend PA-PSRS reports?”
4. Click “Save” when done

If the PSO wishes to authorize other individuals only to view and analyze reports on his or her behalf, you may add read-only users by following these steps:

1. Click “User Administration” on the Navigation Bar
2. Click “Add New User” in the pop-up menu
3. Enter the information requested on the screen below and select “No” to the question “Can this user enter and amend PA-PSRS reports?”
4. Click “Save” when done

An FSM has the ability to reset user passwords when needed. This can be done when editing a user profile, by clicking the “Rest Password” button and following the instructions on the screen. For convenience the user will be notified about how to obtain login information by means of email.
Care Area Administration

In PA-PSRS, each event report includes a question (Number 5) about where in your facility the event occurred. The PA-PSRS data analysis function allows you to analyze your facility’s reports by location and ask such questions as:

- What locations in our facility most frequently report medication errors?
- Do reported patient falls in some locations result in more serious injuries than falls in other locations?
- Two general patient floors have vastly different rates of reports of a certain type of Serious Event. Is one floor really safer than the other, or is staff on one floor more compliant about reporting events?

In order to help you identify the locations of events in your facility, PA-PSRS allows you to establish “care areas” for your facility. Establishing care areas simply involves:

- Developing a list of locations in your facility (e.g., Third Floor/ West Wing, or 3 West)
- Coding each care area for the area type (e.g., burn unit, pediatric unit, psychiatric unit – adolescent, med-surg, etc.)

Adding Care Areas

To establish your facility’s care areas, follow these steps:

1. While logged in as the Facility System Manager, click on “Care Areas” in the Navigation Bar.
2. Click on “Add Care Area” in the pop-up menu.
3. In the first dialog box (see screen below), enter the first location you wish to identify in your facility (e.g., 3 West).
4. In the second dialog box, if applicable, you can select a predefined care area group. Specifics of defining Care Area groups appears later in the chapter.
5. In the third dialog box, select the location type for that care area from the drop-down menu (e.g., Psychiatric Unit – All Ages).
6. Click “Save”.

Repeat these steps for each care area you wish to define in your facility. While this may take some time, especially for larger facilities, it is something you only need to do once. However, it will...
save you time in the long run and will greatly enhance the usefulness of the analyses you can generate with PA-PSRS in the future.

**Editing Care Areas**

Editing care area names or care area types will have an effect on analytic reports.

Changing the name of a **care area** will result in historical (i.e., existing) events reported for the care area being attributed to the new care area.

Example: The nursing unit 8 West is renamed 8 Harris thanks to the generosity of a hospital donor. The FSM changes the name of the care area in PA-PSRS to reflect the change on October 31. At the end of the year, a report of events occurring from January to December on 8 Harris will include any event reports or other information entered into PA-PSRS prior to October 31 when the unit was known as 8 West.

Changing the name of a **care area type** will result in historical (i.e., existing) events reported for the care area being attributed to the new care area type.

Example: The nursing unit 6 North has changed from a General Medical/Surgical Unit to an Inpatient Rehabilitation unit. The FSM changes the name of the care area type in PA-PSRS to reflect the change on June 30. At the end of the year, a report of events occurring from January to December for the Inpatient Rehabilitation care area will include any event reports or other information entered into PA-PSRS prior to June 30 when the unit was considered a General Medical/Surgical unit.

**Deleting Care Areas**

Deleting a care area will remove it from the list of care areas available for entering future event reports. Deleting a care area does not delete the events or utilization data previously reported for that care area. The events reported for that care area will remain in the PA-PSRS system, and any events or utilization data entered for that unit will be included in calculations for historical aggregate group event rates (e.g., facility-level falls rates).

Example: The Inpatient Psychiatric nursing unit 3 East has been permanently closed. The FSM deletes the care area in PA-PSRS on August 31. At the end of the year, a report of events occurring from January to December for the Inpatient Psychiatric care area type will include any event reports or other information entered into PA-PSRS for 3 East prior to August 31.

**Combining Care Areas**

When combining care areas, it is suggested to delete both existing care areas and create a new care area with a new name. If one of the care area names is changed and one is deleted, the new care area will contain events reported on the unit that changed names, but it will not include events that occurred on the deleted unit.
Care Area Group Administration

Under the menu item, Care Areas, the “Add New Group” and “Edit/Delete Group” items provide an option for facilities to specify care areas that can be grouped together for analytical reporting. One use for this feature is for a multi-facility system operating under a single license to group care areas by facility for analytical reports. This would allow you to generate reports by facility without reviewing a very large list to select care areas individually each time you generate a report. As another example, even in a single facility you could group clinically similar areas together as a group, such as all general med/surg floors.

To establish your facility’s Care Area Groups, follow these steps:

1. While logged in as the Facility System Manager, position your mouse over the “Care Areas” menu option.
2. Click on “Add Group” in the pop-up menu.
3. In the first dialog box, enter the group name.
4. Click “Save”.

Repeat these steps for each group you wish to define in your facility.

To update your facility’s Care Area Groups, follow these steps:

1. While logged in as the Facility System Manager, position your mouse over the “Care Areas” menu options.
2. Click on “Edit/Delete Group” in the pop-up menu.
3. Click the group name to be edited or deleted.
4. Change the group name or select care areas to be assigned to the group and click “Save” or click the “Delete” button to delete the group.
5. A confirmation box will be presented to confirm the delete option.
Falls Reporting Program Enrollment

Please read Chapter 8: Falls Reporting Program for complete instructions for enrollment, and a detailed explanation of the program.
Event Reports
Submitting new reports and searching/amending submitted reports

Reportable Events

What is a reportable event?

The PA-PSRS Program is designed to collect reports on four basic types of events:

- **Serious Events** are events, occurrences or situations involving the clinical care of a patient in a medical facility that either: a) results in death, or b) compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.

- **Incidents** are events, occurrences or situations involving the clinical care of a patient in a medical facility which could have injured the patient but neither: a) cause an unanticipated injury, nor b) require the delivery of additional health care services to the patient.

- **Infrastructure Failures** are: a) undesirable or unintended events, occurrences or situations that affect the infrastructure (i.e., physical plant and service delivery systems) of a medical facility, or b) the discontinuation or significant disruption of a service which could seriously compromise patient safety.

- **Other** events are: those which CMS requires hospitals to report to DOH a) any death in restraints or seclusion, or b) in which restraints or seclusion were used within 24 hours of death (other than soft wrist restraints).

Frequently Asked Questions

Are there any “rules of thumb” that can help us determine whether a report is a Serious Event, Incident, or Infrastructure Failure?

Facilities are responsible for coding reports. Patient Safety Officers should consult with their Patient Safety Committees and risk management staff in determining when an event is reportable and, if so, as what type. However, we can provide the following guidance:

1. If there was any harm to a patient, while the patient was receiving clinical care, the report should be coded as a **Serious Event** (with exceptions listed in number 2 below)
2. Reports in which a patient was harmed by a criminal, behavioral, and/or intentionally unsafe act should be coded as **Infrastructure Failures**. Please see PA-PSRS Program Memorandum #2005-03 (Reporting Crimes or Potentially Criminal Activity) in Appendix C.

3. Further guidance was detailed in the notice, titled “Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under the Medical Care Availability and Reduction of Error (MCARE) Act”, in The Pennsylvania Bulletin, dated September 27, 2014. Please see PA-PSRS Program Memorandum No. 2015-02 in Appendix C.

4. Use the Harm Score (see Chapter 5) to distinguish between **Serious Events** and **Incidents**. The Harm Score measures the extent to which a patient safety event “reached” the patient and the severity of the event outcome for the patient. In general, a Harm Score of D or below is consistent with an **Incident**, while a Harm Score of E or above suggests a **Serious Event**.

5. When in doubt about which of two or more harm scores is appropriate to a particular event, select the higher harm score that seems appropriate.

6. When in doubt about which of two or more event types is appropriate, select the one that seems most specific.

---

Can a single event ever be both a Serious Event and an Infrastructure Failure?

PA-PSRS treats Serious Events, Incidents and Infrastructure Failures as three mutually exclusive categories. In PA-PSRS, a report must be coded as only one of these three types of reports.

However, some events may not be easily defined. In these cases, the following rules will help to minimize the chance of miscoding:

<table>
<thead>
<tr>
<th>In cases where you are choosing between…</th>
<th>Choose…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Event and Incident</td>
<td>Serious Event</td>
</tr>
<tr>
<td>Serious Event and Infrastructure Failure</td>
<td>Serious Event</td>
</tr>
<tr>
<td>Incident and Infrastructure Failure</td>
<td>Infrastructure Failure</td>
</tr>
</tbody>
</table>

Should we report events in which a patient is injured by something other than a clinical process?

Facilities must use their own judgment in deciding how broadly to interpret the phrase “the clinical care of the patient,” which is a part of the definition of a Serious Event and an Incident.

Does PA-PSRS collect information on events that do or could compromise the safety of healthcare facility staff and/or visitors?

PA-PSRS only collects information related to the safety of patients. While healthcare worker and visitor safety are certainly important, they are beyond the scope of MCare and PA-PSRS.
Part of the definition of “Serious Event” relies on whether the event “compromised patient safety”? How do we know whether patient safety has been compromised?

This is another area where a facility must rely on the best judgment of its Patient Safety Officer, members of the Patient Safety Committee and risk management staff. However, some events and their consequences are sufficiently minor that they may not rise to the level of Serious Event, Incident, Infrastructure Failure or Other event and may not be necessary to report under MCare at all.

Part of the definitions of “Serious Events” and “Incidents” relies on whether a patient sustains an “unanticipated injury.” When is an injury unanticipated? What about adverse events that are not the results of a medical error?

You may sometimes question whether you should report adverse events that are not the result of a medical error and/or are seen as routine complications of care. Many adverse events are unpreventable complications of care. While this is true, MCare is not limited to preventable adverse events or medical errors. It encompasses patient safety more broadly.

The issue of whether or not an event is “unanticipated” is complex. Please see PA-PSRS Program Memorandum No. 2004-03 (Clarification Regarding Reportable Occurrences) in Appendix C.

Does the existence of a code in the “event type” taxonomy imply that this type of event is always reportable under MCare?

No, the decision about whether such cases are reportable is context-specific and depends on the details of each case.

Are all questions required to be answered for all types of reports (i.e., Serious Events, Incidents, and Infrastructure Failures)?

For Serious Events and Infrastructure Failures, all questions require a response. However, because MCare requires that Serious Events be reported within 24 hours of confirmation, in some cases you may have insufficient information to answer all questions at the time you are submitting a report. In these cases, you will have the option to select “To be determined” as the response for the initial report submission. When doing so, it is expected that you will amend the report before the 90-day amendment period expires. In addition, for certain questions related to Serious Events with lower levels of “harm score” as determined in Question 10, you will be able to check the box labeled “Based on harm score, no response is required.”

Some Infrastructure Failure reports (e.g., power failure) will not involve a particular patient. In such cases, you may answer questions such as patient age, admission date, and other patient-specific questions as “Not applicable.”
For reports of Incidents, only the first 12 questions are required. However, while Questions 13-21 are not required for report submission, we encourage you to answer as many of these questions as possible.

**Report Submission - Incidents and Serious Events**

To submit a new report to PA-PSRS, you must be logged onto the system as a PA-PSRS User (as opposed to the Facility System Manager or a Read-Only user). From any screen, follow these steps:

- Place your cursor over the “Event Report” box in the Navigation Bar. A drop-down menu will appear. Click on “Create New Event Report.”

**Screen 1:**

- The next screen that appears (see below) asks whether you are reporting a Serious Event, Incident, or Infrastructure Failure. Check the box next to the appropriate report type. Click “Definitions” for help identifying the report type.
- When you have selected the report type, click “Next Page” to proceed to the next screen.

**Helpful Tip:** At any point during the report submission process, you can click on the “Help” link in the upper right-hand section of the screen. This will open a copy of this Training Manual in a new browser window.
Event Report

1. Report Submission Type: (Choose only one):
   - Serious Event definitions
   - Incident definitions
   - Infrastructure Failure definitions
   - Other definitions

Serious Event

An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident.

Remember: To be considered a “serious event,” the event, occurrence, or situation must meet all of the criteria under Column A or all of the criteria under Column B.

Column A OR Column B
- Involved the clinical care of a patient in a medical facility
- Resulted in the death of the patient
- Involved the clinical care of a patient in a medical facility
- Compromised patient safety
- Resulted in an unanticipated injury requiring additional healthcare services

Incident

An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event.

Remember: To be considered an “incident,” the event, occurrence, or situation must meet all of the following criteria:
- Involved the clinical care of a patient in a medical facility
- Could have injured the patient
- Did not cause an unanticipated injury requiring additional healthcare services to the patient

Infrastructure Failure

An undesirable or unintended event, occurrence or situation involving the infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

Remember: To be considered an “infrastructure failure”, a report must meet all of the criteria under Column A or all of the criteria under Column B.

Column A OR Column B
- An undesirable or unanticipated event
- Occurrence, or situation
- Involves the infrastructure of a medical facility
- Could seriously compromise patient safety
- An undesirable or unanticipated event
- Occurrence, or situation
- Involves discontinuation or significant disruption of a service
- Could seriously compromise patient safety

Other

CMS requires hospitals to report to DOH any death in restraints or seclusion or in which restraints or seclusion were used within 24 hours of death (other than soft wrist restraints). Deaths in which the restraints or seclusion are suspected of or confirmed as having played a role in the death should be reported as Serious Events (i.e., Serious Events J-A or J-5). Other deaths in which the restraint or seclusion use was incidental or not suspected should be reported under this “Other” category.
**Helpful Tip:** To move back and forth between screens, do not use your browser’s “Back” and “Forward” buttons. Use the hyperlinks to move between sections of the reporting form. If you accidentally use your browser’s buttons to navigate, you will need to hit the “refresh” button to continue.

**Screen 2 (Questions 1 through 4):**

- Answer each question by selecting the appropriate check boxes or entering the information requested into the dialog boxes.
- Click “Next Page” when finished to proceed to the next screen.
- Note the “Time remaining” box that appears in the upper right hand corner of the screen. You have 15 minutes to fill out the page (the timer resets for each page). If you allow the system to “time-out” the program will automatically close the session and your report will be lost. Click on “Reset Timer” at any time to reset the timer to 15 minutes.

<table>
<thead>
<tr>
<th>Event Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Report Submission Type: (Choose only one):</td>
</tr>
<tr>
<td>- Serious Event</td>
</tr>
<tr>
<td>- Incident</td>
</tr>
<tr>
<td>- Infrastructure Failure</td>
</tr>
<tr>
<td>- Other</td>
</tr>
<tr>
<td>2. How Was This Event Discovered (check all that apply):</td>
</tr>
<tr>
<td>- Witnessed/Involved</td>
</tr>
<tr>
<td>- Report by patient</td>
</tr>
<tr>
<td>- Report by family or visitors</td>
</tr>
<tr>
<td>- Report by staff member</td>
</tr>
<tr>
<td>- Report by resident, fellow, or student</td>
</tr>
<tr>
<td>- Assessment after event</td>
</tr>
<tr>
<td>- Review of record or chart</td>
</tr>
<tr>
<td>3. Gender Of Affected Patient (check one):</td>
</tr>
<tr>
<td>4. Age Of Affected Patient:</td>
</tr>
<tr>
<td>- Equal or greater than 2 years</td>
</tr>
<tr>
<td>- Under 2 years</td>
</tr>
<tr>
<td>- Under one month</td>
</tr>
</tbody>
</table>

**Helpful Tip:** Note that you can abort a report submission by hitting “Cancel.” Also, if you close your browser at any point before reaching the last screen or before clicking on “Submit Report,” this will also cancel your report submission.
Screen 3 (Questions 5 through 8):

- Answer each question by selecting the appropriate check boxes, entering the information requested into the dialog boxes, or using the pull-down menus. For questions 6 and 7, click on the calendar icon to get a pop-up calendar that can help you answer these questions.
- Question 6 includes sub-question 6a “Patient Status” with three patient status choices: Inpatient, Outpatient, and Unknown (see explanation below).
- Question 7 includes sub-questions 7a (date the event was confirmed) and 7b (explanation for any reports submitted more than 24 hours after confirmation).
- Question 8 asks you to identify the Event Type. (See Appendix B for more detailed information about the Event Type list.) To select the Event Type, first make a selection from three first drop-down box under the words Event Type, followed by a selection from the second drop-down box, then a selection from the third drop-down box if it is enabled. When no selection is needed from the third drop-down box it will be disabled.
- Click “Next Page” when finished to proceed to the next screen.
Helpful Tip: When filling out an event report, you can move back and forth through the screens by using the hyperlinks at the bottom right-hand corner of the screen. For example, after filling out the questions on the screen above, you can go back to previously completed parts of the form by clicking on the question numbers to which you want to return.

- Question 6a has three patient status choices. To understand the definitions for patient status, select the “Definitions” link located to the right of the field choices. When selected, a pop-up window with the patient status definitions will appear on the screen. To close this pop-up window, select the close link.

<table>
<thead>
<tr>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient</strong></td>
</tr>
<tr>
<td>Any admitted patient, including observational patients that receive care in a hospital unit (e.g. med/surg unit, critical care unit, pediatric unit, etc.) This includes any patient who is formally admitted while in the emergency room and is being held while waiting for a room.</td>
</tr>
</tbody>
</table>

| **Outpatient** |
| Any patient who receives care in the hospital without being admitted (e.g. emergency room, rehabilitation services, radiology) This definition includes emergency room patients prior to formal admission and emergency room observational patients. This EXCLUDES any patient who is formally admitted while in the emergency room and is being held while waiting for a room. It also includes patients who receive care in an ambulatory surgical facility, birthing center, and abortion facility. |

| **Unknown** |
| Patients designated as unknown are assumed to be either inpatient or outpatient based on the reported location where the event occurred, including falls, for the purpose of calculating falls rates. |

The patient status field is used in calculating falls rates reports. Limiting the use of the “Unknown” field will improve the accuracy of falls rates reports. For complete instructions for Fall Event reporting, please read Chapter 8: Falls Reporting Program.

- All reports from Ambulatory Surgical Facilities (ASFs), Birthing Centers (BCs), and Abortion Facilities (ABFs) will have this question auto-filled to outpatient and will not be visible.

Screens 3a-f (Detailed Questions):

- The next questions you see will depend on what Event Type you chose on the previous screen. For example, if you selected “Medication Error,” this screen will ask you about the drug, the dose, the route of administration, and other factors associated with medication errors. On the other hand, if you selected “Fall,” you would see a screen with detailed questions relating to patient falls. There are updates to two existing falls detail related
questions and three new falls detail related questions. For complete instructions for Fall Event reporting, please read **Chapter 8: Falls Reporting Program**. For complete details of all “Detailed Questions” screens, please refer to Appendix A.

- If you selected an event type that has no detailed questions (such as “Complications of a Procedure, Treatment, or Test”), the system will skip this screen.
- Click “Next Page” when finished.

**Screen 4 (Event Outcome, Questions 9-12):**

- This screen asks questions about the outcome of the event. In Question 9, you are asked to describe the event. When doing so, it may be helpful to start with the description the healthcare worker used when first reporting the event within your facility, and amending or adding to their description to reflect any follow-up investigation you may have performed. **NOTE: DO NOT INCLUDE THE NAME OF ANY PATIENT OR HEALTHCARE WORKER IN YOUR DESCRIPTION.**
- Question 10 asks you to select a **“harm score”**, which measures: a) the extent to which the event “reached” the patient, and b) the degree of harm the event caused to the patient. This harm score is adapted from a system developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). See Chapter 5 for more detailed discussion of the harm score and how to interpret it.
- Questions 11 and 12 ask you to identify the likelihood of the event’s reoccurrence and the likely severity of the event should it reoccur. These questions together form the basis of a **severity assessment index**—a tool for prioritizing reports for special attention or analysis. Help in answering these questions is available by clicking on “Definitions.” These questions and the criteria for answering them are based on the Severity Assessment Code system developed by the Veteran’s Administration’s National Center for Patient Safety. Please think carefully about the code that you use as these codes also help us to focus our attention on the most important reports.
- Click “Next Page” when finished.
Event Report

Please include all relevant information, including details on how or why the event occurred (maximum 1000 characters):

10. Harm Score (check one):

Unsafe conditions
□ A. Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.).

Event, No Harm
□ B1. An event occurred but it did not reach the individual ("near miss" or "close call") because of chance alone.
□ B2. An event occurred but it did not reach the individual ("near miss" or "close call") because of active recovery efforts by caregivers.
□ C. An event occurred that reached the individual but did not cause harm and did not require increased monitoring (an error of omission such as a missed medication dose does reach the individual).
□ D. An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.

Event, Harm
□ E. An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.
□ F. An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.
□ G. An event occurred that contributed to or resulted in permanent harm.
□ H. An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life).

Event, Death
□ I. An event occurred that contributed to or resulted in death.

Note: Modified from National Coordinating Council for Medication Error Reduction and Prevention (NCC-MERP)

11. Likelihood Of Event Recurrence: [ ] Definitions

12. Severity Of Effect Resulting From Recurrence Of Event: [ ] Definitions

Next Page | Top of Page | Cancel
Return to Questions: 1-4 | 5-8
Screen 5 (Health IT, Question 13)

- Question 13 asks you whether Health IT caused or contributed to the event.
- Click “Next Page” when finished.

If “Yes” is selected, a series of follow-up questions will be presented.

The follow-up questions record information specifically related to events where health IT was indicated as a contributing factor. The Health IT follow-up questions include the following:

1. **Which Health IT system(s) caused or contributed to the event? (check all that apply)**
   A. Values - Use multiple response categories from [AHRQ Common Formats, V1.2 Question 21 - 23.](V2_commonformats.html)
      - For each question include an option for **Unknown** and **Other (Please Specify)** if they are not already indicated by the question in the source document.
   B. At least one question response is required for all events.

2. **HIT Contributing Factors (check all that apply)**
   A. Values - Use categories taken from [AHRQ Common Formats, V1.2 Questions 24 - 26.](V2_commonformats.html)
      - For each question include an option for **Unknown** and **Other (Please Specify)** if they are not already indicated by the question in the source document.
   B. At least one question response is required for all events.

3. **System identifiers**
   A. Values:
      - **Device/Application Name** (e.g., Powerchart)
      - **Manufacturer** (e.g., Cerner)
      - **Unknown**
   B. Both Device/Application Name and Manufacturer values are required unless Unknown is checked.
Event Report

Health IT Questions

13. Did Health IT cause or contribute to this event?
   [ ] Yes [ ] No [ ] Unknown

A. Which Health IT Systems Caused or Contributed to the Event? (check all that apply)
   - Administrative/Billing/Practice Management System
     a. Massive patient index
     b. Registration/appointment scheduling system
     c. Coding/patient billing
     d. Unknown
     e. Other (Please Specify)

   - Electronic health record (EHR) or component of EHR
     a. Computerized provider order entry (CPOE) system
     b. Pharmacy system
     c. Electronic medication administration record (eMAR)
     d. Clinical documentation system (e.g., progress notes)
     e. Clinical decision support (CDS) system
     f. Unknown
     g. Other (Please Specify)

   - Miscellaneous
     a. Automated dispensing system
     b. Human interface device (e.g., keyboard, mouse, touchscreens, speech recognition systems, monitors, display, printers)
     c. Laboratory information system (LIS), including radiology, and pathology systems
     d. Radiology/diagnostic imaging systems, including picture archiving and communication systems (PACS)
     e. Other (Please Specify)

B. HIT Contributing Factors (check all that apply)
   - Equipment/Device Function
     a. Loss or delay of data
     b. System returns or stores data that does not match patient
     c. Image misalignment/complex issue
     d. Image orientation incorrect
     e. Incorrect test results
     f. Incorrect software/programming malfunction
     g. Incorrect or inappropriate dose
     h. Other (Please Specify)

   - Ergonomics, including human/device interface issues
     a. Hardware location (e.g., allowed placement for use)
     b. Data entry or selection (e.g., entry or selection of wrong patient, wrong provider, wrong drug, wrong dose)
     c. Information display or interpretation (e.g., font size, color of font, location of information in display screen)
     d. Alert function alarm
     e. Other (Please Specify)

   - Miscellaneous
     a. Incompatibility between devices
     b. Equipment/Device maintenance
     c. Hardware failure or problem
     d. Network failure or problem
     e. Security, virus, or other malware issue
     f. Unexpected software design issue
     g. Unknown
     h. Other (Please Specify)

C. Device Identifier(s)
   [ ] Unknown

Device/Application Name
Manufacturer

Next Page | Top of Page | Cancel
Return to Questions: 3.4 | 5.11 Event Details | 5.32

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Screen 6 (Recommendations and Disposition, Questions 14-15):

- Question 14 allows you to describe any changes you are making in your facility or “lessons learned” to prevent this type of event from reoccurring. These can include the development of new policies and procedures, changes in operations or staffing patterns, or even facility modifications. **NOTE: DO NOT INCLUDE THE NAME OF ANY PATIENT OR HEALTHCARE WORKER IN YOUR DESCRIPTION**
- Question 15 asks you to identify the disposition of the event.
- Click “Next Page” when finished.
Exhibit 4-1. Elements of a Good Narrative

**Question 9** asks you to “Describe the event.” Please provide as much detail as necessary in your narrative description to convey the clinical context for the case. In describing the case, include the following elements, if known and applicable:

<table>
<thead>
<tr>
<th>Critical elements</th>
<th>Example (Patient Fall)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who (<strong>GENERIC</strong> patient descriptor)*</td>
<td>Post-op surgical patient…</td>
</tr>
<tr>
<td>What (event)</td>
<td>…was discovered on the floor of her room…</td>
</tr>
<tr>
<td>Who (<strong>GENERIC</strong> provider roles)*</td>
<td>…by a nurse’s aide…</td>
</tr>
<tr>
<td>Where (type of site)*</td>
<td>…on general med/surg floor…</td>
</tr>
<tr>
<td>When (in context)</td>
<td>…six hours after leaving recovery following a scheduled hysterectomy.</td>
</tr>
<tr>
<td>How (in context)</td>
<td>Patient reported she was attempting to get to the bathroom.</td>
</tr>
<tr>
<td>Recovery attempts/opportunities</td>
<td>The bedrails were up.</td>
</tr>
<tr>
<td>Why</td>
<td>Possible explanations include dehydration, vertigo from anesthesia, or overuse of patient-controlled analgesia.</td>
</tr>
</tbody>
</table>

*Include only generic descriptors of persons and places. Never include identifying information.

Other elements to include are:

- Relevant diagnoses
- Indication(s) for admission or ambulatory encounter
- Relevant comorbidities or risk factors
- Procedures involved

**Question 14** asks for “Recommendations for system improvement to prevent recurrence.” Providing specific recommendations for prevention or mitigation will help PA-PSRS to develop useful information for other Pennsylvania healthcare organizations. Please include the following elements in your description(s):

<table>
<thead>
<tr>
<th>Critical elements</th>
<th>Example (Drug Administered to Wrong Patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who (<strong>GENERIC</strong> provider roles)*</td>
<td>Nurses and nurse’s aides…</td>
</tr>
<tr>
<td>What (action plan)</td>
<td>…will verify patient identity…</td>
</tr>
<tr>
<td>Where (types of sites)*</td>
<td>…at all locations in the facility…</td>
</tr>
<tr>
<td>When (in context)</td>
<td>…before each medication administration…</td>
</tr>
<tr>
<td>How (method)</td>
<td>…by comparing the medication administration order with the patient’s arm band.</td>
</tr>
<tr>
<td>Why (lesson learned)</td>
<td>Multiple independent system safeguards must be in place from the physician’s order to the pharmacy to the bedside.</td>
</tr>
</tbody>
</table>

*Include only generic descriptors of persons and places. Never include identifying information.
Screen 7 (Follow-up Questions, Questions 16-22):

- In many cases, you may not be able to answer with certainty the Follow-up Questions at the time you are completing an initial report. When this is the case, provide answers that best represent your current understanding of the event. You can amend the report or provide additional information for up to 90 days after submitting your initial report. (Later in this chapter we provide instructions on how to amend an existing report.)

- You may revise your responses to these questions after additional investigation, ranging from simply discussing the event with the individual who reported it through your facility’s internal reporting system, all the way up to a formal root cause analysis or other investigative technique. PA-PSRS allows you to record and analyze the results of your own investigations.
e. Patient Characteristics:  □ Based on Harm Score selected, no response is needed
   □ Lack of patient compliance/adherence
   □ Lack of patient understanding
   □ Language barrier
   □ Lack of family member cooperation
   □ None
   □ To be determined

f. Organizational Management:  □ Based on Harm Score selected, no response is needed
   □ No 24 hour pharmacy
   □ Inadequate bed availability
   □ Presence of boarder patient/different service  Definitions
   □ Presence of observation patient
   □ Lack of policies and procedures
   □ Unclear or ambiguous policies and procedures
   □ Procedures not followed
   □ None
   □ To be determined

g.  □ Other, please specify any additional information  (maximum 500 characters)

17. What Was Done To Remedy The Situation Or Reduce Its Likelihood For Recurrence? (check all that apply)
   □ Based on Harm Score selected, no response is needed
   □ Talked with patient/family
   □ Arranged for support of staff member involved
   □ Discussed the event with the involved healthcare worker
   □ Discussion with staff of unsafe practices
   □ Physically removed equipment or supplies
   □ Staff orientation process
   □ Review/revised policies and procedures
   □ Education or training of staff
   □ Documentation procedures
   □ Modified staffing pattern or workflow
   □ Referred issue to another department (Identify):

   □ Referred issue to medical leadership or administrative leadership
   □ Requested assistance from quality improvement in conducting analysis of event
   □ No actions necessary
   □ To be determined
   □ Other (specify, maximum 250 characters):
18. Does event qualify as a JCAHO defined Sentinel Event? **Definitions**
   - [ ] Yes
   - [ ] No
   - [ ] Based on Harm Score selected, no response is needed
   - [ ] To be determined

19. If root cause analysis performed, select root causes: **Definitions**
   (select up to 3 causes that contribute most to event) (other specify, maximum 250 characters)
   - [ ] Based on Harm Score selected, no response is needed
   - [ ] No root cause analysis performed
   - [ ] To be determined
   *Other (specify):*

20. Causal code (Einthoven Classification Model - Medical Version): **Definitions**
   - [ ] Based on Harm Score selected, no response is needed
   - [ ] None
   - [ ] To be determined

21. Assessment of Additional Costs incurred (check all that apply):
   - [ ] Based on Harm Score selected, no response is needed
   - [ ] No additional cost
   - [ ] Patient discomfort or inconvenience
   - [ ] Additional laboratory testing or diagnostic imaging
   - [ ] Other additional diagnostic testing
   - [ ] Additional patient monitoring in current location
   - [ ] Visit to Emergency department
   - [ ] Hospital admission
   - [ ] Transfer to more intensive level of care
   - [ ] Increased length of stay
   - [ ] Minor surgery
   - [ ] Major surgery
   - [ ] System or processes delay care to a patient
   - [ ] To be determined
   *Other (specify): (maximum 250 characters)*

22. Other Comments: (maximum 250 characters)

- Answer these questions by following the directions on the screen, using the check boxes and menus provided.
- When you are finished with this screen you may click on “Submit Report”. When you click “Submit Report,” you are filing a report as defined by MCare.
If the report is a Serious Event, it is submitted to the Patient Safety Authority and the Department of Health.

If the report is an Incident, it is submitted to the Patient Safety Authority.

If the report is an Infrastructure Failure or Other event, it is submitted to the Department of Health.

If you fail to click “Submit Report” from this screen, or if you stop entering information at any point before reaching this screen, the report will not be submitted and your data will not be stored in PA-PSRS.

When you click “Submit Report” you will see the screen below, which asks you to attest that the information in the report is accurate and complete and to confirm that you are ready to submit the report. Press “OK” to submit the report.
Once you submit your report, you will see the following screen, which confirms that your report has been received. The report will be assigned a unique Report Number, which you can record. You will also have the option to print out a summary of the report you just submitted or to immediately begin to enter a new report.

The submission process has been successfully completed.

This report has been submitted to the Patient Safety Authority. In addition, due to the nature of the report, a copy will also be sent to the PA Department of Health.

For your records, the Report Identifier associated with this submission is 49511.

Thank you.

What would you like to do next?

• Print This Report
• Add another Event Report
• Return to Main Page
• Logoff
Submitting Infrastructure Failure reports follows the same format as the submission of Incident and Serious Event reports. You must be logged onto the system as a PA-PSRS User (as opposed to the Facility System Manager and Read-Only User). Pay attention to the screens as they are NOT identical to the screens for Incidents and Serious Events. **RESPONSES ARE REQUIRED FOR ALL QUESTIONS**, though “Not Applicable” is an acceptable response for certain questions. There are no “event detail” questions associated with reports of Infrastructure Failures.

**Screen 1:**

- Select "Infrastructure Failure" by checking the box next to this report type. Click “Definitions” for help identifying the report type.
- Click “Next Page” to proceed to the next screen.
Screen 2 (Questions 1 through 4):

- Answer each question by selecting the appropriate check boxes or entering the information requested into the dialog boxes.
- For questions 3 and 4, you may use the response “Not Applicable” for Infrastructure Failures that do not affect particular patients (e.g., power failure).
- Click “Next Page” when finished to proceed to the next screen.
Screen 3 (Questions 5 through 8):

- Answer each question by selecting the appropriate check boxes, entering the information requested into the dialog boxes, or using the pull-down menus. For questions 6, 7a and 7b, click on the calendar icon to get a pop-up calendar that can help you answer these questions.

- Note that question 6 permits the response “Not Applicable” and that Question 7 includes sub-questions 7a (date the event was confirmed) and 7b (explanation for any reports submitted more than 24 hours after confirmation).

- Question 8 asks you to identify the event type using the taxonomy for Infrastructure Failures. (See Appendix B for more detailed information about the Event Type list.) To choose the event type, position your cursor over the words “Point here.” This will bring up a tiered menu of possible selections. If you select “Other” as the event type, you must type in a brief description of the event (up to 250 characters) in the dialog box to the right labeled “Other: specify:"

- Click “Next Page” when finished to proceed to the next screen.
There are follow-up questions associated with Event Type W - Capacity. The two (2) new questions are:

- Where are patients receiving care as a result of the capacity problem (e.g., ED, PACU, hallway)?
  - The response will be free form text.
- How many patients were affected by this event over the one-day period covered by this report?
  - The response will be a 2-digit number.
Screen 4 (Event Outcome, Questions 9-12):

- This screen asks questions about the outcome of the event. In Question 9, you are asked to describe the event. **NOTE: DO NOT INCLUDE THE NAME OF ANY PATIENT OR HEALTHCARE WORKER IN YOUR DESCRIPTION.**

- Question 10 asks you to select a “harm score”, which measures: a) the extent to which the event “reached” the patient, and b) the degree of harm the event caused to the patient. This harm score is adapted from a system developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). See Chapter 5 for more detailed discussion of the harm score and how to interpret it.

- Questions 11 and 12 ask you to identify the likelihood of the event’s reoccurrence and the likely severity of the event should it reoccur. These questions together form the basis of a severity assessment index—a tool for prioritizing reports for special attention or analysis. Help in answering these questions is available by clicking on “Definitions.” These questions and the criteria for answering them are based on the Severity Assessment Code system developed by the Veteran’s Administration’s National Center for Patient Safety.

- Click “Next Page” when finished.
Screen 5 (Health IT, Question 13)

- Question 13 asks you whether Health IT caused or contributed to the event.
- Click "Next Page" when finished.
Screen 7 (Follow-up Questions, Questions 16-22):

- In many cases, you may not be able to answer with certainty the Follow-up Questions at the time you are completing an initial report. When this is the case, provide answers that best represent your current understanding of the event. You can amend the report or provide additional information for up to 90 days after submitting your initial report. (Later in this chapter we provide instructions on how to amend an existing report.)

- You may revise your responses to these questions after additional investigation, ranging from simply discussing the event with the individual who reported it through your facility's internal reporting system, all the way up to a formal root cause analysis or other investigative technique. PA-PSRS allows you to record and analyze the results of your own investigations.
e. Patient Characteristics: ☐ Based on Harm Score selected, no response is needed
☐ Lack of patient compliance/adherence
☐ Lack of patient understanding
☐ Language barrier
☐ Lack of family member cooperation
☐ None
☐ To be determined

f. Organizational Management: ☐ Based on Harm Score selected, no response is needed
☐ No 24 hour pharmacy
☐ Inadequate bed availability
☐ Presence of boarder patient/different service (Definitions)
☐ Presence of observation patient
☐ Lack of policies and procedures
☐ Unclear or ambiguous policies and procedures
☐ Procedures not followed
☐ None
☐ To be determined

9. ☐ Other, please specify any additional information (maximum 500 characters)

17. What Was Done To Remedy The Situation Or Reduce Its Likelihood For Recurrence? (check all that apply)
☐ Based on Harm Score selected, no response is needed
☐ Talked with patient/family
☐ Arranged for support of staff member involved
☐ Discussed the event with the involved healthcare worker
☐ Discussion with staff of unsafe practices
☐ Physically removed equipment or supplies
☐ Staff orientation process
☐ Review/revised policies and procedures
☐ Education or training of staff
☐ Documentation procedures
☐ Modified staffing pattern or workflow
☐ Referred issue to another department (identify):

☐ Referred issue to medical leadership or administrative leadership
☐ Requested assistance from quality improvement in conducting analysis of event
☐ No actions necessary
☐ To be determined
☐ Other (specify, maximum 250 characters): 
Answer these questions by following the directions on the screen, using the check boxes and menus provided.

When you are finished with this screen you may click on “Submit Report”. When you click “Submit Report,” you are filing a report as defined by MCare.
If the report is a Serious Event, it is submitted to the Patient Safety Authority and the Department of Health.

If the report is an Incident, it is submitted to the Patient Safety Authority.

If the report is an Infrastructure Failure or Other event, it is submitted to the Department of Health.

If you fail to click “Submit Report” from this screen, or if you stop entering information at any point before reaching this screen, the report will not be submitted and your data will not be stored in PA-PSRS.

When you do click “Submit Report,” you will see the screen shown below, which asks you to confirm that you are ready to submit the report.

![Microsoft Internet Explorer](Microsoft Internet Explorer.png)

This Infrastructure Failure event will be reported to the PA Department of Health.

By submitting this report, you attest that the information provided is accurate and complete to the best of your knowledge.

Do you wish to submit this report at this time?

[OK] [Cancel]

When you do click “OK,” you will see the screen shown below, which confirms that your report has been submitted. The report will be assigned a unique Report Number, which you can record. You will also have the option to print out a summary of the report you just submitted or immediately begin to enter a new event report.

The submission process has been successfully completed.

This report has been sent to the PA Department of Health.

For your records, the Report Identifier associated with this submission is 49530.

Thank you.

What would you like to do next?

- Print This Report
- Add another Event Report
- Return to Main Page
- Logout
Report Submission – Other Events

CMS requires hospitals to report any death in restraints or seclusion, or in which restraints or seclusion were used within 24 hours of death (other than soft wrist restraints). Submitting Other reports follows the same format as the submission of Infrastructure Failure reports. You must be logged onto the system as a PA-PSRS User (as opposed to the Facility System Manager and Read-Only User). The screens are NOT identical to the screens for Incidents and Serious Events. **RESPONSES ARE REQUIRED FOR ALL QUESTIONS**, though “Not Applicable” is an acceptable response for certain questions. There are no “event detail” questions associated with reports of Infrastructure Failures.

Screen 1:

- Select “Other” by checking the box next to this report type. Click “Definitions” for help identifying the report type.
- Click “Next Page” to proceed to the next screen.
Screen 2 (Questions 1 through 4):

- Answer each question by selecting the appropriate check boxes or entering the information requested into the dialog boxes.
- For questions 3 and 4, you may use the response “Not Applicable” for Infrastructure Failures that do not affect particular patients (e.g., power failure).
- Click “Next Page” when finished to proceed to the next screen.
Screen 3 (Questions 5 through 8):

- Answer each question by selecting the appropriate check boxes, entering the information requested into the dialog boxes, or using the pull-down menus. For questions 6, 7a and 7b, click on the calendar icon to get a pop-up calendar that can help you answer these questions.

- Note that question 6 permits the response “Not Applicable” and that Question 7 includes sub-questions 7a (date the event was confirmed) and 7b (explanation for any reports submitted more than 24 hours after confirmation).

- Question 8 asks you to identify the event type using the taxonomy for Other events. The only event type available is Z. Restraints and seclusion. To choose the event sub-type, position your cursor over the words “Point here.” This will bring up a menu of possible selections.

- Click "Next Page" when finished to proceed to the next screen.
Screen 4 (Event Outcome, Questions 9-12):

- This screen asks questions about the outcome of the event. In Question 9, you are asked to describe the event. **NOTE: DO NOT INCLUDE THE NAME OF ANY PATIENT OR HEALTHCARE WORKER IN YOUR DESCRIPTION.**
- Question 10 asks you to select a "harm score"; the only allowable score allowed is B2, since any report of this type would be seen as the active recovery efforts by caregivers to prevent a safety event.
- Questions 11 and 12 ask you to identify the likelihood of the event’s reoccurrence and the likely severity of the event should it reoccur. These questions together form the basis of a **severity assessment index**—a tool for prioritizing reports for special attention or analysis. Help in answering these questions is available by clicking on "Definitions." These questions and the criteria for answering them are based on the Severity Assessment Code system developed by the Veteran’s Administration’s National Center for Patient Safety.
- Click “Next Page” when finished.

Screen 5 (Health IT, Question 13)

- Question 13 asks you whether Health IT caused or contributed to the event.
- Click “Next Page” when finished.
Screen 7 (Follow-up Questions, Questions 16-22):

- In many cases, you may not be able to answer with certainty the Follow-up Questions at the time you are completing an initial report. When this is the case, provide answers that best represent your current understanding of the event. You can amend the report or provide additional information for up to 90 days after submitting your initial report. (Later in this chapter we provide instructions on how to amend an existing report.)

- You may revise your responses to these questions after additional investigation, ranging from simply discussing the event with the individual who reported it through your facility’s internal reporting system, all the way up to a formal root cause analysis or other investigative technique. PA-PSRS allows you to record and analyze the results of your own investigations.
e. Patient Characteristics:  
☐ Based on Harm Score selected, no response is needed
☐ Lack of patient compliance/adherence
☐ Lack of patient understanding
☐ Language barrier
☐ Lack of family member cooperation
☐ None
☐ To be determined

f. Organizational Management:  
☐ Based on Harm Score selected, no response is needed
☐ No 24 hour pharmacy
☐ Inadequate bed availability
☐ Presence of boarded patient/different service  
Definition:
☐ Presence of observation patient
☐ Lack of policies and procedures
☐ Unclear or ambiguous policies and procedures
☐ Procedures not followed
☐ None
☐ To be determined

g. ☐ Other, please specify any additional information  
(maximum 500 characters)

17. What Was Done To Remedy The Situation Or Reduce Its Likelihood For Recurrence? (check all that apply)
☐ Based on Harm Score selected, no response is needed
☐ Talked with patient/family
☐ Arranged for support of staff member involved
☐ Discussed the event with the involved healthcare worker
☐ Discussion with staff of unsafe practices
☐ Physically removed equipment or supplies
☐ Staff orientation process
☐ Review/revised policies and procedures
☐ Education or training of staff
☐ Documentation procedures
☐ Modified staffing pattern or workflow
☐ Referred issue to another department (Identify):

☐ Referred issue to medical leadership or administrative leadership
☐ Requested assistance from quality improvement in conducting analysis of event
☐ No actions necessary
☐ To be determined
☐ Other (specify, maximum 250 characters):
• Answer these questions by following the directions on the screen, using the check boxes and menus provided.

• When you are finished with this screen you may click on “Submit Report”.

When you click “Submit Report,” you are filing a report as defined by MCare.
If the report is a Serious Event, it is submitted to the Patient Safety Authority and the Department of Health.
If the report is an Incident, it is submitted to the Patient Safety Authority.
If the report is an Infrastructure Failure or Other event, it is submitted to the Department of Health.
If you fail to click “Submit Report” from this screen, or if you stop entering information at any point before reaching this screen, the report will not be submitted and your data will not be stored in PA-PSRS.

When you do click “Submit Report,” you will see the screen shown below, which asks you to confirm that you are ready to submit the report.

![Microsoft Internet Explorer alert](image)

When you do click “OK,” you will see the screen shown below, which confirms that your report has been submitted. The report will be assigned a unique Report Number, which you can record. You will also have the option to print out a summary of the report you just submitted or immediately begin to enter a new event report.

**Managing Submitted Reports**

You can manage your reports from the main page—the first page you see when you log on (see below).
From this page, you can sort your reports by several criteria simply by clicking on the blue “up” and “down” arrows beneath the column headings. For instance:

- If you want to view your most recent reports, clicking on the down arrow in the column labeled “Date & Time Report Submitted” will sort your reports in reverse chronological order.
- If you want to focus on your reports with the most significant harm score, click on the down arrow beneath the column heading “Harm Score.”
- If you want to see all reports of medication errors at once, click the up arrow under the column heading “Event Type.”
- On each screen, 10 reports are shown. To screen through more reports, click “Next” or click on a specific page number.

Helpful Tip: The column “TBD” displays a red flag to denote any report with “To be determined” selected as a response to one or more questions. When a submitted report is viewed or printed, the following message will appear in the header section near the top of the report: “This report has one or more fields marked ‘To Be Determined.’”. You can sort the list of reports by this column to easily identify those reports requiring attention.

By default, this screen shows reports submitted in the past 90 days. To filter this list for a shorter timeframe, click on “New Date Range” just below the menu bar, as shown below.

https://psrs.psu.edu/admin/report/

To find a specific report when you already know the ID number, select “Event Report” from the menu bar; then select “Retrieve Event Report by Report ID.” This will take you to the screen shown below. Enter the Report ID and press “Retrieve Report.”
Amending a Submitted Report

After you submit a report to PA-PSRS, the report may be amended for up to 90 days. It may be appropriate to amend reports to correct details that upon further investigation turned out to be incorrect, to augment reports with the results of an investigation or root cause analysis, or to update reports as circumstances change. You can see how many days remain to amend a report from the Main Page; refer to the column “Days Remaining to Amend.”

After a period of 90 days from original submission, each report is “locked down” in the system and may no longer be amended. Such reports may still be viewed and printed.

To amend a submitted report, follow these steps:

1. From the Main Page, enter the Report ID in the dialog box in the upper right of your screen labeled “Selected Report ID”. Rather than type in the Report ID, clicking on an ID number in the first column will enter it for you.


3. Click on “Amend Event Report” in the pop-up menu.

4. Move the cursor through the questions, just as you would when originally submitting a report, until you reach the question you want to amend. Make the necessary corrections.
When you have made all the changes you wish, to save your amended version of this report, you must go to the last page and click on the hyperlink that reads “Submit Report.” Otherwise, your changes will not be saved. Please note that an Amended Report will be assigned a modified Report Number to distinguish it from the original report (see Report History later in this Chapter for details).

**Viewing and Printing Reports**

You may view or print an event report at any time after it has been submitted to PA-PSRS. Please be careful, however, about the security protections you put in place within your own facility regarding printed reports. Since the information you submit to PA-PSRS is confidential and sensitive, consider how frequently you want to create printed versions of your PA-PSRS reports. Be sure to treat any printouts with the appropriate level of security.

To view or print a report:

- From the Main Page, enter the Report ID in the dialog box in the upper right of your screen labeled “Selected Report ID”. Rather than type in the Report ID, clicking on a Report ID number in the left column will enter it for you.

- Click on “View/Print” in the Navigation Bar.

- Click on either “view” or “print” in the pop-up menu.

- By default, the system will present a summary version of the report for viewing or printing. In a summary view, only items that were entered or checked will be shown.

- Alternately, clicking “Full View” will present the entire report, including all the items and check boxes that were not used in the report.

Notice in the screen shot below, when viewing or printing a report, the information displayed includes the Report ID, current amendment number (where applicable), the original submission date and time, the User ID of the individual who submitted the original report, date and time of last update (where applicable), and the User ID of the individual who made the latest amendment. In addition, if any field on the report has been marked “To Be Determined,” a statement indicating this is displayed as a reminder to the facility.
Report History

You can also use PA-PSRS to generate a “report history.” A report history is essentially a report that shows you what changes have been made to an event report since it was originally submitted as well as who made each change. This feature will be more significant for facilities where the PSO has authorized multiple individuals to submit reports to PA-PSRS.

You will know if a report has been amended by looking at the Report ID number (see screen below). If a Report ID ends in a hyphen followed by a two-digit suffix (e.g., 0123456-01), this indicates that the report has been amended since its original submission. The two-digit suffix indicates the number of times the initial report has been revised. (e.g., 0123456-01 indicates that there has been one amendment to the original report, 0123456-02 indicates that there have been two amendments, 0123456-05 indicates that there have been five amendments, etc.)
To see a report history for a particular event report, follow these steps:

1. From the Main Page, enter the Report ID in the dialog box in the upper right of your screen labeled “Selected Report ID”. Rather than type in the Report ID, clicking on a Report ID number in the left column will enter it for you.
2. Click on “View/Print” in the Navigation Bar.
3. Click on “Report Amendments” in the pop-up menu.
4. The selected report opens in a new browser window. When you are done viewing the report, simply close the browser window.
Blank Forms

You can print copies of blank forms that contain all of the questions and possible selections for PA-PSRS event reports. These may be useful as checklists when conducting interviews with healthcare workers who report events internally, or you may even choose to incorporate blank forms into your facility's internal reporting system.

To access the blank forms, click on “Blank Forms” from the Navigation bar, then select which form(s) you want from the pop-up menu.

All forms are provided in Adobe Acrobat format. Viewing and printing these files requires Adobe Acrobat Reader, a free software application available from Adobe Systems Incorporated. To obtain this software, under the “Blank Forms” pop-up menu, select “Download Adobe Acrobat” and follow the instructions on the screen.

Anonymous Reports

Under MCare, healthcare workers may submit anonymous reports of Serious Events directly to the Patient Safety Authority if they have previously complied with section 308 (a) of the Act. The availability of Anonymous Report forms offers additional opportunities to promote patient safety, and you are encouraged to print and distribute copies of the form in your facility. The form is available via the Authority’s website, as well as through the PA-PSRS program.

Resources

You can access training materials and system update information on-line while logged in to PA-PSRS. These may be used as reference material and/or training aides. To access system resources, click on “Resources” from the Navigation bar, then select which resource you want to access from the pop-up menu.
Chapter 5

Report Coding
How to get the most from your facility’s data

Classification Systems

PA-PSRS uses several taxonomies—or classification systems—for coding the data you submit in your reports. The benefits of using such systems are:

- By using checklists or drop-down menus, they allow you to submit more detailed reports much faster than you could if you had to type everything in manually.
- They facilitate faster database searching.
- They make it possible for you to perform more advanced analyses of your own data by supporting more sophisticated database queries.
- They make it possible for you to develop meaningful comparisons of your facility’s data to aggregate, de-identified data from other facilities.

Some of the taxonomies used in PA-PSRS, which we will discuss in more detail throughout this chapter, include systems for classifying data about:

- Severity of a Serious Event, Incident or Infrastructure Failure
- Event type (e.g., medication error, fall, etc.)
- Root cause analysis

Report Severity

In any patient safety reporting system, some reports are more significant than others. For example, a report of an unexpected patient death is generally considered more significant than a report of a minor bruise. The level of follow-up by the Patient Safety Authority will also likely relate to the significance ascribed to the report. A Patient Safety Officer will no doubt spend a considerable amount of effort investigating the cause of an unexpected death, whereas a minor bruise that seems like an isolated occurrence may not warrant as much attention.

Two systems are currently in wide use around the country for classifying the severity of a patient safety report: the harm score taxonomy developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) and the severity assessment code system developed by the Veterans’ Administration (VA) National Center for Patient Safety. PA-PSRS has adapted both of these systems to meet the requirements of MCare and incorporated them into the PA-PSRS software application.

After your facility has used PA-PSRS for a while and developed a sizeable database, you will be able to produce data tables, charts and graphs that show the number or percentage of events by
severity. For example, one way to demonstrate progress toward your goal of improving patient safety might be to show that during a period when the overall number of reports is increasing, the overall severity of those reports is decreasing. This could suggest that more potential events are being caught in time to either prevent or minimize harm to patients.

Report severity can also be used to prioritize reports within your institution for follow-up by or discussion among your Patient Safety Committee. For example, your facility may decide to institute a policy where all reports of a certain severity score or higher should receive a certain level of investigation (such as a root cause analysis or failure mode-and-effects analysis).

**Harm Score**

The harm score is requested in Question 10. The harm score measures: a) the extent to which the event "reached" the patient, and b) the degree of harm the event caused to the patient (see Table 5-1). There are 10 categories in the harm score taxonomy, labeled from A through I. Events closer to category "A" resulted in less harm to the patient than events closer to category "I".

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unsafe Conditions</strong></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.)</td>
</tr>
<tr>
<td><strong>Event, No Harm</strong></td>
<td></td>
</tr>
<tr>
<td>B1</td>
<td>An event occurred but it did not reach the individual (&quot;near miss&quot; or &quot;close call&quot;) because of chance alone.</td>
</tr>
<tr>
<td>B2</td>
<td>An event occurred but it did not reach the individual (&quot;near miss&quot; or &quot;close call&quot;) because of active recovery efforts by caregivers.</td>
</tr>
<tr>
<td>C</td>
<td>An event occurred that reached the individual but did not cause harm and did not require increased monitoring (an error of omission such as a missed medication dose does reach the individual).</td>
</tr>
<tr>
<td>D</td>
<td>An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.</td>
</tr>
<tr>
<td><strong>Event, Harm</strong></td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.</td>
</tr>
<tr>
<td>F</td>
<td>An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.</td>
</tr>
<tr>
<td>G</td>
<td>An event occurred that contributed to or resulted in permanent harm.</td>
</tr>
<tr>
<td>H</td>
<td>An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life).</td>
</tr>
<tr>
<td><strong>Event, Death</strong></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>An event occurred that contributed to or resulted in death.</td>
</tr>
</tbody>
</table>

Source: Adapted from the National Coordinating Council on Medication Error Reporting and Prevention.
Helpful Hint: Use the Harm Score to distinguish between Serious Events and Incidents. The Harm Score measures the extent to which a patient safety event “reached” the patient and also the severity of the consequences of the event for the patient. In PA-PSRS, a Harm Score of D or below is consistent with an Incident, while a Harm Score of E or above defines a Serious Event.

Severity Assessment Code

The Severity Assessment Code (SAC) system for coding patient safety reports is incorporated in PA-PSRS as Questions 11 and 12, which ask you to estimate the:

- Likelihood of event’s reoccurrence
- Severity of effect resulting from reoccurrence of event

Therefore, this system rates a report by both its frequency and its severity. The frequency (or likelihood of reoccurrence) is rated in four categories from frequent to remote, while severity is rated from catastrophic to minor. The significance of a report is determined by finding the intersection of these two ratings in the matrix shown below in Table 5-2. The number in the appropriate cell is the severity “score.” The higher the score, the more significant the report.

<table>
<thead>
<tr>
<th>Probability of reoccurrence</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Occasional</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Uncommon</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Remote</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Source: Garthwaite TL. VHA National Patient Safety Improvement handbook 1050.1. Washington (DC): Veterans Health Administration, Department of Veterans Affairs; 2002 Jan 30. various p.

For example, when reviewing a report of a blood transfusion error in which a patient is given blood of the wrong type, you might rate such a report as “remote” in terms of its likelihood of reoccurrence, but “catastrophic” in terms of its severity if it should reoccur. Though this type of error happens very infrequently, the results can be devastating (often involving the death of the patient) when such errors do occur. Therefore, this type of report (a “3”) is more likely to deserve a more thorough investigation and analysis than a report reflecting situations coded “1”.

In the VA’s SAC method, each patient safety event (i.e., a Serious Event or Incident) can be assigned a risk assessment score, which is derived by locating the intersection of the severity and frequency estimates. The higher the score, the greater is the risk associated with the event. An advantage of this system, developed by the VA’s National Center for Patient Safety, over the NCC MERP system, is that it recognizes that some “near misses” are more significant than some actual events. For example, nearly administering a drug to which a patient has a known serious allergy is more significant than actually failing to administer a Tylenol.

When answering Questions 11 and 12, clicking on “Definitions” will bring up guidance on how to choose among the categories available for each question (see Figure 5-1).
Figure 5-1. Definitions for VA Severity Assessment Code (Questions 11 and 12)

**Likelihood**

- **Frequent:** Likely to occur immediately or within a short period of time (may happen several times in 1 year).
- **Occasional:** Probably will occur in time (may happen several times in 1 to 2 years).
- **Uncommon:** Possible to occur in time (may happen sometime in 2 to 5 years).
- **Remote:** Unlikely to occur (may happen sometime in 5 to 30 years).

**Severity**

- **Catastrophic:**
  - Patients with actual or potential
  - Death or major permanent loss of function (sensory, motor, physiologic or intellectual) not related to the natural course of the patient's illness or underlying condition (i.e., acts of commission or omission).
  - Suicide (inpatient or outpatient)
  - Hemolytic transfusion reaction
  - Surgery/Procedure on the wrong patient or wrong body part
  - Infant abduction or infant discharge to the wrong family
  - Death or major permanent loss of function that is a direct result of injuries sustained in a fall, or associated with an unauthorized departure from an around-the-clock treatment setting, or the result of an assault or other crime

- **Major:**
  - Patients with actual or potential
  - Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (i.e., acts of commission or omission).
  - Disfigurement
  - Surgical intervention required
  - Increased length of stay for 3 or more days
  - Increased level of care for 3 or more days

- **Moderate:**
  - Patients with actual or potential
  - Increased length of stay for up to three days, or increased level of care for up to three days

- **Minor:**
  - No increased length of stay or increased level of care

*Note: Adopted from the Veterans Health Administration Vol 1050.1*
Event Type

The Event Type taxonomy helps you to classify each report so that similar cases can be grouped and analyzed together. The taxonomy has up to three levels, with each level becoming more specific.

For example, a report may be of a…

*Medication Error (Level 1)*

…involving what kind of medication error?...

*Monitoring error (Level 2)*

…where the specific error was…

*Documented allergy (Level 3)*

This would be the Event Type for reporting a case where a patient received (or nearly received) a medication to which they had a documented allergy, assuming it otherwise met the definition of a Serious Event or Incident.

At the highest level (Level 1), there are 16 Event Types (labeled A through X):

A. Medication Error  
B. Adverse Drug Reaction (not a medication error)  
C. Equipment/Supplies/Devices  
D. Fall  
E. Error Related to Procedure/Treatment/Test  
F. Complication of Procedure/Treatment/Test  
G. Transfusion  
H. Skin Integrity  
I. Patient Self-Harm  
J. Other/Miscellaneous  
R. Emergency Services/Response  
S. Physical Plant/Utilities/Service Disruption  
T. Administration/Management  
V. Criminal/Potentially Criminal or Illegal Activity  
W. Capacity  
X. Other Infrastructure Failure

Event Types A through I may apply to both Serious Events and Incidents. Event Types R through X are reserved for Infrastructure Failures.

The complete Event Type taxonomy is presented in Appendix B.

Categories A and E use the word “error.” The use of this word is not meant to convey blame or guilt associated with these events. The use of the word “error” in these categories is simply meant to distinguish these event types from those that immediately follow them. For example, under “Medication Error,” administering a dose of medication to the wrong patient is clearly an error.
Whereas, an “Adverse Drug Reaction” (Category B)—while of interest from a patient safety perspective—is not necessarily the result of an error.

Another important point to note: you should not assume that, simply because an event type code exists in PA-PSRS, that this type of event is always required to be reported under MCare.

**Root Cause Analysis**

Questions 18 and 19 in the PA-PSRS reporting forms provide tools that can be used for conducting a root cause analysis (RCA).

In Question 18, the system prompts you to select up to three “root causes” from a defined list based on the Joint Commission guidance document: “Minimum Scope of Root Cause Analysis for Specific Types of Sentinel Events.” The full list of codes for Question 18 is shown in Figure 5-2.

A second method of coding reports for the results of an RCA is based on the Eindhoven Classification Scheme – Medical Version originally developed by Van der Schaaf et al. and popularized by the Medical Event Reporting System for Transfusion Medicine (MERS-TM), developed in the mid-1990s.

Though the MERS-TM program remains focused on errors related to blood transfusion, the Eindhoven model is widely applicable throughout medicine for coding and classifying the root causes of errors and near misses that are the final output of a formal root cause analysis. Figure 5-3 presents the list of Eindhoven model codes and their definitions.

---

### Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral assessment process</td>
<td>Assessment for the special needs of patients receiving treatment for emotional or behavioral disorders. Includes assessment of patients’ risk to self (and to others, in cases of assault, rape, or homicide where a patient is the assailant).</td>
</tr>
<tr>
<td>Physical assessment process ‡</td>
<td>Assessment used to determine care based on the patient’s physiological, psychosocial needs and the setting in which the care is provided. Includes search for counterfeit.</td>
</tr>
<tr>
<td>Patient identification process</td>
<td>Process used to identify patients and assure that the right test, treatment, medication is given to the right patient.</td>
</tr>
<tr>
<td>Patient observation procedures</td>
<td>Process used to monitor the patient based upon the assessment and reassessment of a patient.</td>
</tr>
<tr>
<td>Care planning process</td>
<td>Process of defining how care will be provided based on an assessment/reassessment of the patient. This includes monitoring, modifying or compelling care based on assessment/reassessments, and coordinating follow-up.</td>
</tr>
<tr>
<td>Staffing levels</td>
<td>The number of staff, staff’s qualifications and competencies provided based on the volume and acuity of patients.</td>
</tr>
<tr>
<td>Orientation &amp; training of staff</td>
<td>The organization’s overall plan to orient and train staff based on job requirements. The individualized plan for the involved employee based on the employee’s experience, education, and abilities. Modifications made to the plan based on the employee’s performance.</td>
</tr>
<tr>
<td>Competency assessment / credentialing</td>
<td>Ongoing, periodic evaluation of staff member’s and physician’s continuing abilities to perform their duties. This includes data on qualifications such as license and training or experience, and data on actual performance that is collected and assessed initially and on an ongoing basis.</td>
</tr>
<tr>
<td>Supervision of staff</td>
<td>Processes in place to monitor staff’s performance and actions taken to hold staff accountable for their performance. Processes the medical staff uses to assure that a LHI with clinical privileges supervises each participant in a professional graduate education program in patient care responsibilities.</td>
</tr>
<tr>
<td>Communication with patient/family</td>
<td>The process of relaying information between hospital and patient/family. The patient/family needs to be involved in all aspects of their care and care decisions. This includes patient/family education.</td>
</tr>
<tr>
<td>Communication among staff members</td>
<td>The process of how information is communicated amongst care providers so that optimal patient care is provided. This includes interdisciplinary, intra-discipline, inter-department and intra-department.</td>
</tr>
<tr>
<td>Availability of information</td>
<td>The care provider has all information needed available in a useful format for patient care. The organization has access to information in a useful aggregated format so that patient outcomes can be improved. This includes individual and hospital performance in patient care, governance, management and support processes.</td>
</tr>
<tr>
<td>Adequacy of technological support</td>
<td>The adequacy of how technological support is used when commercially available to provide optimal patient care and minimize errors associated with human failures.</td>
</tr>
<tr>
<td>Equipment maintenance / management</td>
<td>The hospital’s plan to maintain equipment was followed and is an effective plan to promote the safe and effective use of equipment.</td>
</tr>
<tr>
<td>Physical environment §</td>
<td>The physical environment is free of hazards. This includes furnishings, hardware (e.g., bars, hooks, railings), lighting, distractions. The adequacy of the process for effectively conducting a risk assessment and taking actions based on evaluation of the impact of buildings, grounds, equipment, occupancy, and external physical systems on patients and public safety.</td>
</tr>
<tr>
<td>Security systems and processes</td>
<td>The processes to manage the environment of care including processes and activities, which will prevent patient, staff and visitor accidents and injuries, as well as, maintain an environment, which is sensitive to patient, needs for comfort, social interaction, positive distraction and self-control.</td>
</tr>
<tr>
<td>Control of medications: storage/access</td>
<td>The processes in place that support safe medication use. This includes formulary management, storage, control, dispensing, administration, and distribution of prepackaged medications obtained from outside sources.</td>
</tr>
<tr>
<td>Labeling of medications</td>
<td>All medications dispensed to inpatients or outpatients are appropriate and safely labeled using a standardized method.</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Latent errors</td>
<td>Errors resulting from underlying system failures.</td>
</tr>
<tr>
<td>Technical factors</td>
<td>Refers to physical items, such as equipment, physical installations, software, materials, labels, and forms.</td>
</tr>
<tr>
<td>External</td>
<td>Technical failures beyond the control and responsibility of the investigating organization.</td>
</tr>
<tr>
<td>Design</td>
<td>Failures due to poor design of equipment, software, labels, or forms.</td>
</tr>
<tr>
<td>Construction</td>
<td>Correct design was not followed accurately during construction.</td>
</tr>
<tr>
<td>Materials</td>
<td>Material defects not classified under TD or TC.</td>
</tr>
<tr>
<td>Organizational factors</td>
<td>Refers to the context of the workplace, such as SOPs, culture, and management.</td>
</tr>
<tr>
<td>External</td>
<td>Failures at an organizational level beyond the control and responsibility of the investigating organization.</td>
</tr>
<tr>
<td>Transfer of knowledge</td>
<td>Failures resulting from inadequate measures taken to ensure that situational or domain-specific knowledge or information are transferred to all new or inexperienced staff.</td>
</tr>
<tr>
<td>Protocols/procedures</td>
<td>Failures related to the quality and availability of protocols with the department (too complicated, inaccurate, unrealistic, absent, or poorly presented).</td>
</tr>
<tr>
<td>Management priorities</td>
<td>Internal management decisions in which safety is relegated to an inferior position in the face of conflicting demands or objectives. This is a conflict between production needs and safety (e.g., decisions about staffing levels).</td>
</tr>
<tr>
<td>Culture</td>
<td>Failures resulting from collective approach to risk and attendant modes of behavior in the investigating organization.</td>
</tr>
<tr>
<td>Active errors (human)</td>
<td>Errors or failures resulting from human behavior.</td>
</tr>
<tr>
<td>Knowledge-based behaviors</td>
<td></td>
</tr>
<tr>
<td>Knowledge-based errors</td>
<td>The inability of an individual to apply existing knowledge to a novel situation.</td>
</tr>
<tr>
<td>Rule-based behaviors</td>
<td></td>
</tr>
<tr>
<td>Qualifications</td>
<td>Incorrect fit between an individual’s qualifications, training, or education and a particular task.</td>
</tr>
<tr>
<td>Coordination</td>
<td>Lack of task coordination within a healthcare team in an organization.</td>
</tr>
<tr>
<td>Verification</td>
<td>Failures in the correct and complete assessment of a situation, including relevant conditions of the patient and materials to be used, before starting the intervention.</td>
</tr>
<tr>
<td>Intervention</td>
<td>Failures that result from faulty task planning (selecting the wrong protocol) and/or execution (selecting the right protocol but carrying it out incorrectly).</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Failures during monitoring of process or patient status during or after intervention.</td>
</tr>
<tr>
<td>Skill-based behaviors</td>
<td></td>
</tr>
<tr>
<td>Slips</td>
<td>Failures in performance of fine motor skills.</td>
</tr>
<tr>
<td>Tripping</td>
<td>Failures in whole body movements.</td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Patient-related factor</td>
<td>Failures related to patient characteristics or conditions that influence treatment and are beyond the control of staff.</td>
</tr>
<tr>
<td>Unclassifiable</td>
<td>Failures that cannot be classified in any other category.</td>
</tr>
</tbody>
</table>

Chapter 6

Data Analysis

Introduction

PA-PSRS allows you to analyze data from your own facility. Using this analytical feature, you can:

- Generate **data tables** from your own facility’s submitted reports.
- Produce **pie charts and graphs** that track the number and types of reports submitted by your facility over time in different categories (e.g., by harm score, by event type, etc.).
- **Query** the database to look for **patterns or trends**.
- **Download** data tables and graphics for use in presentations and reports to your Board, your Patient Safety Committee, or others.

You will not be able to view specific information related to individual facilities, and other facilities will not be able to view your facility’s reports or data. In some cases, you will be able to compare your facility’s experience with other facilities, but only using aggregate, de-identified data.

You can also download your facility’s data from PA-PSRS and import it to a database or spreadsheet application to perform custom analyses on your own. Refer to the Standard Data Export and Advanced Data Export topics at the end of this section.
Accessing Available Reports

To access available reports, select “Analytical Data Tools” from the menu bar; then select “Event Report Data Analysis.” This will take you to the main Report Selection screen (see below), where you can select which analytical report you wish to create.

The following reports are available to all hospitals:

- Summary of Submitted Reports by Type
- Harm Score Trends by Month
- Harm Score Distribution
- Event Detail by Harm Score
- Distribution of Subcategories
- Top 3 Event Types by Care Area
- High Alert Medications and Steps in the Medication Process
- Medications Contributing to Risk for Fall
- Details Related to Falls
- Distribution of Potential Contributing Factors

Additional reports are available to hospitals enrolled in the falls reporting program (see Chapter 8: Falls Reporting Program):

- Falls Rates Reports
- Falls Risk and Strategy Process Measure
- Falls Dashboard
- Falls Tracking Groups Rates Reports
- Falls Utilization Data Reports

Simply select which report you want by clicking on the name, and then by clicking on the “Generate Report” button in the bottom right corner of the page. Alternatively, you can set other parameters for your report by clicking on the “Additional Criteria” hyperlink.
Types of Analytical Reports

Summary of Submitted Reports by Type

This report presents a simple table showing the number of Serious Event, Incident, and Infrastructure Failure reports submitted by your facility, compared with the total number of each type of report submitted by facilities statewide. The default timeframe for this report is to calculate all data for the current year. By clicking on "Additional Criteria" you can adjust the timeframe by years, months, and quarters.

<table>
<thead>
<tr>
<th>Report Submission Type</th>
<th>#</th>
<th>Facility %</th>
<th>PA-PSRS Statewide Aggregate %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Event</td>
<td>23</td>
<td>11.3</td>
<td>11.3</td>
</tr>
<tr>
<td>Incident</td>
<td>188</td>
<td>83.3</td>
<td>83.3</td>
</tr>
<tr>
<td>Infrastructure Failure</td>
<td>11</td>
<td>5.4</td>
<td>5.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>203</strong></td>
<td><strong>100%</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
Harm Score Trends by Month

This report presents, either as a line graph or table, a time series showing the total number of reports submitted over a series of months by harm score. The reports stratify the harm scores into the following five clusters:

- All (includes all reports of any harm score)
- Unsafe Conditions (Harm Score A)
- Event, No Harm (Harm Scores B1 through D)
- Event, Harm (Harm Scores E through H)
- Event, Death (Harm Score I)

From the main report selection page, you can choose to show any combination of report types (Serious Event, Incident, or Infrastructure Failure). By selecting "Additional Criteria" you can modify the report by event date, gender or age of affected patients, care area, or event type. In addition to showing your facility’s data, this report also presents aggregate statewide data for comparison.
Harm Score Distribution

This report presents, either as a pie chart or table, the number or percentage of reports by harm score among all reports submitted.

From the main report selection page, you can choose to show any combination of report types (Serious Event, Incident, or Infrastructure Failure). By selecting “Additional Criteria” you can modify the report by event date, gender or age of affected patients, care area, or event type. In addition to showing your facility’s data, this report also presents aggregate statewide data for comparison.
Event Detail by Harm Score

This report presents, either as a series of pie charts or as a table, the number or percentage of reports by event type (e.g., falls, adverse drug reactions, etc.) among all reports submitted, according to the following harm score clusters:

- Unsafe Conditions (Harm Score A)
- Event, No Harm (Harm Scores B1 through D)
- Event, Harm (Harm Scores E through H)
- Event, Death (Harm Score I)

From the main report selection page, you can choose to show any combination of report types (Serious Event, Incident, or Infrastructure Failure). By selecting “Additional Criteria” you can modify the report by event date, gender or age of affected patients, care area, or event type. In addition to showing your facility’s data, this report also presents aggregate statewide data for comparison.
**Distribution of Subcategories**

This report presents, either as a series of pie charts or tables, the distribution of second-level event types for each event type category, as well as the distribution of harm scores among those reports. For example, under the event type “Skin Integrity,” this report presents: a) how many or what proportion of reports relate to pressure injuries, rashes, lacerations, and burns, etc., and b) how many or what proportion of skin integrity reports fall into each harm score category.

To see the subcategory distributions for different first-level event types (e.g., medication error, skin integrity, etc.), after generating the report, select different “Event Types” using the dialog box above the graph or chart area.

From the main report selection page, you can choose to show any combination of report types (Serious Event, Incident, or Infrastructure Failure). By selecting “Additional Criteria” you can modify the report by event date, gender or age of affected patients, care area, or event type. In addition to showing your facility’s data, this report also presents aggregate statewide data for comparison.
Top 3 Event Types by Care Area

This report presents a series of three tables that correspond with the three most frequently reported event types in your facility. For each of these event types, these tables will show you where in your facility (by care area) they are most frequently reported.

By selecting "Additional Criteria" you can modify the report by report type, event date, gender or age of affected patients.

<table>
<thead>
<tr>
<th>S. Physical Plant / Utilities / Service Disruption</th>
<th>T. Administration / Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Area Name</td>
<td>#</td>
</tr>
<tr>
<td>Test Care Area 15</td>
<td>1</td>
</tr>
<tr>
<td>Test Care Area 18</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>V. Criminal / Potentially Criminal or Illegal Activity</th>
<th>All Other Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Area Name</td>
<td>#</td>
</tr>
<tr>
<td>Test Care Area 15</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
</tr>
</tbody>
</table>
High Alert Medications and Steps in the Medication Process

This report presents, either as a series of pie charts or tables, the distribution of high-alert medications (e.g., warfarin, IV potassium, etc.) associated with submitted medication error reports and also the distribution of steps in the medication process (e.g., prescribing, administration, etc.) associated with all medication error reports.

From the main report selection page, you can select report type (Serious Event and/or Incident). By selecting “Additional Criteria” you can modify the report by event date, or by gender or age of affected patients.
Medications Contributing to Risk for Fall

This report presents, either as a series of pie charts or tables, the distribution of medications (e.g., anti-seizure, diuretics, etc.) associated with submitted reports of patient falls. (This report is available to all hospitals reporting to PA-PSRS. For additional reports available to hospitals enrolled in the falls reporting program, see Chapter 8).

From the main report selection page, you can select report type (e.g., Serious Event, Incident). By selecting “Additional Criteria” you can modify the report by event date, gender or age of affected patients, or care area.
Details Related to Falls

This report is available to all hospitals reporting to PA-PSRS. For additional reports available to hospitals enrolled in the falls reporting program, see Chapter 8: Falls Reporting Program.

Available either as a bar chart or table, this report presents the responses to detailed questions about reports of patient falls. Examples of these detailed questions include the following:

- Whether a falls risk assessment was completed
- Whether a sitter was in place
- Whether the patient lost consciousness

From the main report selection page, select report type (e.g., Serious Event, Incident). By selecting “Additional Criteria” you can modify the report by event date, gender or age of affected patients, harm score cluster, or care area.

Report Style: [Chart]
Report Submission Type: [✓] Serious Event [✓] Incident
Event Date: Current Year
Gender: All
Age: All
Harm Score: All
Care Area: All

Select New Criteria | Choose New Report | Return to Main Page
**Distribution of Potential Contributing Factors**

This report presents, either as a pie chart or table, the distribution of factors contributing to submitted reports. These factors are based on the following categories:

- Team factors
- Work environment
- Task factors
- Staff factors
- Patient characteristics
- Organizational/Management factors
- Other

The default setting for this report is to look at all event types, but by choosing specific event types (e.g., medication errors, complications of a procedure/treatment/test, etc.) you can study whether different event types are characterized by different contributing factors.

From the main report selection page, you can select report type (Serious Event, Incident, or Infrastructure Failure). By selecting “Additional Criteria” you can modify the report by event date, event type, gender or age of affected patients or care areas.
Saving Analytical Reports

PA-PSRS supports saving the graphs or tables from any report you generate using the system. You can then paste these graphs and tables into word processing documents, use them in reports you make to your facility’s Patient Safety Committee, or to support your own analyses.

To save a graph or chart, select “File” in the gray toolbar at the top of the image you want to save, then select “Save Chart.” This will open a “Save as” dialog box where you must select a filename and file type.

To save files for use in word processing applications, we recommend saving the chart as a Windows metafile. To do this, from the “Save as” dialog box, click on “Save as type”, then choose “metafile” from the menu. This will save the document in a form that can be read by most Windows applications.

To save data tables, use your mouse to highlight all the rows and columns of the table you want to save. When the area you wish to capture is highlighted, press CTRL-C on your keyboard to copy. Next, open a new, blank file in your word processing or spreadsheet program and press CTRL-V on your keyboard to paste.
Searching Reports

PA-PSRS includes a search facility that lets you identify all submitted reports matching a variety of criteria you may set and modify. To access the search screen, while logged in as a PS-PSRS User or Read-only PA-PSRS User, select “Analytical Data Tools” from the main screen menu bar, then select “Search Submitted Event Reports.” This will take you to the following search interface.

1. **Selection Criteria**
   - **Select a Facility:** [Dropdown]
   - **Report Submission Type:** [Required] [ ] Serious Event [ ] Incident
   - **Date:** [Previous] [ ] Event Date [ ] Admit Date [ ] Submit Date
     - From: [ ] To: [ ] [ ] 03/14/2005
   - **Event Time:** [Optional] [ ] Unknown Time
   - **Day(s) of the Week:** [Optional] [ ] All [ ] Mon [ ] Tue [ ] Wed [ ] Thu [ ] Fri [ ] Sat [ ] Sun
   - **Gender:** [Optional] [ ] All [ ] Female [ ] Male
   - **Age:** [Optional]
     - [ ] Or
     - [ ] Years [ ] Months [ ] Days
     - From: [ ] To: [ ]
   - **Care Area:** [Optional] [ ] All [ ] Specify a care area and select a facility
   - ** Harm Score:** [Optional]
     - [ ] All [ ] [Definitions]
   - **Event Type:** [Optional]
     - [ ] All [ ] Add/Change Event Type Criteria

[Clear Criteria] [Generate Report]

[Go To Main Page]
From this page you may specify the criteria for the reports you wish to view. These criteria include:

- Report type (Serious Event, Incident, or Infrastructure Failure)
- Date (either by date of event or date of admission)
- Event time of day and day of the week
- Age and gender of affected patients
- Care area
- Harm Score category
- Event type (adverse drug reaction, fall, etc.)

After selecting the criteria for the reports you wish to retrieve, click on “Generate Report” in the lower right hand corner of the page. The resulting data set will be displayed in a format similar to that used in managing your current reports (see Chapter 2).

**Standard Data Export**

You can download data elements from reports you have submitted to PA-PSRS using the “Export Data” and the “Advanced Data Export” function.

The “Export Data” function will create a comma-delimited file containing key report elements which can then be imported to Microsoft Excel or another spreadsheet program.

To use this feature, take the following steps:

1. Select “Analytical Data Tools” from the menu bar on the main screen; then select “Export Data.” This will take you to the screen shown below.

**Export Data**

This utility will export a list of submitted reports to a text file suitable for import into a database or Excel spreadsheet. Files over 3000 rows are limited to 21 day intervals. Please enter the criteria.

- Export data based on: 
  - Event Date
  - Submit Date

  Start Date: [mm/dd/yyyy]

  End Date: [mm/dd/yyyy]

  Export

Go To: Main Page
2. Enter a date range for the reports you wish to download. (Note: Date ranges may be no larger than one month for each file you create with this feature. To create spreadsheets with longer date ranges, you will need to perform multiple downloads.)

3. Press the “Export” button.

4. You will be presented with a choice to save the download file to your computer or to open the file (see below). To save the file, press “Save” and select a location and filename using the dialog boxes presented. To open the file, press “Open.” For the file to open properly, you must have a spreadsheet program (such as Microsoft Excel) already on your computer.

The following data elements will be included in the downloaded file:

- Report ID
- Submission type (i.e., Serious Event, Incident, or Infrastructure Failure)
- Person submitting the report
- Event location (i.e., care area)
- Event type (e.g., medication error, fall, etc.)
- Harm score
- Event date
- Event time
- Likelihood of recurrence
- Frequency of recurrence
- Days remaining to amend report
- Date of last report update
- Date of report original submission
Advanced Data Export

“Advanced Data Export” allows a user to export either all or just some of the elements that make up a PA-PSRS report. Select which data elements to export by choosing individual question numbers. If a question is selected for export, all data associated with that question will be exported. For example, if the user wishes to include Harm Score in the data export, simply make sure question 10, Harm Score is checked off on the criteria selection screen. To include data related to where in the facility the event occurred, the user would check question 5, Care Area, when selecting which data fields to export (see below).

In addition to selecting which data elements to export, you must select a date range. You have the option of choosing either all reports which were submitted to PA-PSRS during that particular date range or all reports where the event date falls within the date range. Regardless of the date type selected, a facility may request up to 6 months’ worth of data at one time. If the date range selected spans more than 31 days, the data is separated over multiple files based on month. For example, if the user selects the date range January 15 – March 15, three files will be generated. The first file will cover the dates 1/15 – 1/31, the second file will start on February 1 and cover a full month, while the third file will start on March 1 and go through March 15.
“Advanced Data Export” processes all requests by generating one or more XML files. XML is the standard by which PA-PSRS exchanges data with facilities.

Helpful Tip: For a more detailed explanation on the “Advanced Data Export” feature see the PA-PSRS Advanced Data Export Users Guide located under the Resources tab within PA-PSRS.
Communications

Report Follow-up

A member of the PA-PSRS Program and/or Department of Health (DOH) staff may contact you to follow up on individual reports submitted to the system. For example:

- When a report may represent a new or emerging threat to patient safety.
- When program staff would like to request more detail than is contained in the report.
- To provide the facility with relevant feedback from PA-PSRS or from other authoritative sources of patient safety information.
- When there is the possibility of immediate patient jeopardy.

In addition, if a report contains individually identifying information, you may receive a message from PA-PSRS staff notifying you of this error.

When the Authority receives an anonymous report of a Serious Event from a healthcare worker, PA-PSRS will notify you of the receipt of the report and request the results of your investigation pursuant to MCare.

Patient Safety Advisories

The Patient Safety Authority and the PA-PSRS Program staff issue Patient Safety Advisories, with supplements as necessary, to facilities and providers. Based on actual reports submitted through PA-PSRS, Advisory articles include clinical guidance that will be useful as part of your ongoing quality improvement and patient safety activities. The Advisories are distributed electronically to all PA-PSRS users and are also available on the Patient Safety Authority website at http://www.patientsafetyauthority.org. Click on “Advisories” in the left-hand navigation menu.

Patient Safety Recommendations

The Patient Safety Authority may periodically issue recommendations to facilities, consistent with MCare, with the approval by the DOH. These recommendations may be made on a facility-specific or statewide basis for the purpose of reducing the number and severity of Serious Events and Incidents.
**Program Announcements and System Administration**

The PA-PSRS Program periodically distributes program announcements via e-mail and via posting on the Authority website ([http://www.patientsafetyauthority.org](http://www.patientsafetyauthority.org)) concerning items of general interest, such as upcoming training sessions and the introduction of system improvements and enhancements. Some correspondence is in the form of program memoranda. Program Memoranda can be located within PA-PSRS under the ‘Resources’ tab. Five program memoranda are included in Appendix C of this manual.

**Help Desk**

If you encounter any problems or difficulties using the PA-PSRS system, first refer to this Manual to see if the task you are trying to perform is addressed. The Manual is available online at the PA-PSRS website ([http://www.papsrs.state.pa.us](http://www.papsrs.state.pa.us)). You will need to log onto the system to access the Manual. The Manual will periodically be updated by issuing Program Memoranda to reflect incremental changes to the system.

If the Manual does not address your problem or question, contact the PA-PSRS Help Desk to answer questions regarding Incidents or Serious Events during business hours (9:00 a.m. – 5:00 p.m., Monday-Friday, exclusive of holidays) via toll-free telephone (866-316-1070), Fax (610-567-1114) or e-mail (Support_papsrs@pa.gov).

For questions about Infrastructure Failures, please contact the DOH surveyor for your facility. Your surveyor may also be able to assist you with questions regarding Serious Events. Please note that the Help Desk will not be able to advise you on whether to classify individual reports as Serious Events, Incidents, Infrastructure Failures or Other events. See Frequently Asked Questions in Chapter 4.
Falls Reporting Program

Enrollment, data entry and using report functions

Program Overview

The Falls Reporting Program is available to **HOSPITALS ONLY**. Participating hospitals agree to standardize their facility’s definitions and reporting of falls and to provide monthly utilization data through PA-PSRS. This will allow for unit-level and/or facility-level detailed reports of the rates of falls and falls with harm, as well as statewide benchmarking.

Program Enrollment

The Facility System Manager is responsible for enrolling in the Falls Reporting Program.

When the Facility System Manager logs in to PA-PSRS, the blue horizontal Navigation Bar will appear as below.

To access the Falls Reporting Enrollment screen, select “Falls Program” from the Navigation bar. (See below).

At the top of the screen, there is a link to the Program Memorandum. Click on this link to read a more thorough description of the program, what the benefits and responsibilities are for participating hospitals, including definitions to be adopted.
The Enrollment Options screen will display three falls reporting program participation options from which to select:

1. **Unit-level monthly data**
   Yes, I agree to standardize my facility's definitions and reporting of falls and to provide monthly utilization data (i.e., patient days and patient encounters) at the Unit-level; this will allow for unit-level and facility-level detailed reports of the rates of falls and falls with harm.

2. **Facility-level monthly data only (no unit-level)**
   Yes, I agree to standardize my facility's definitions and reporting of falls and to provide monthly utilization data (i.e., patient days) at the Facility-level; this will allow for facility-level detailed reports of the rates of falls and falls with harm. I understand that I will NOT be able to generate unit-level reports.

3. **No enrollment**
   No, I choose not to participate in the standardized reporting of falls; I understand that I will NOT be able to generate reports of the rates of falls and falls with harm.

To save your enrollment selection, click the “Save” button at the bottom of the screen; a pop-up window with an enrollment confirmation message will confirm your selection. To confirm this selection, click the “OK” button. To change the selection identified in the enrollment confirmation pop-up window, click on the “Cancel” button to return to the Enrollment Options screen and select a different enrollment option.

To cancel the current falls program enrollment selection and default to the last saved enrollment option choice, select the “Cancel” button on the enrollment screen.

To change your enrollment status at any time, please follow the program enrollment steps on the previous page.

**NOTE:** If your facility chooses to “un-enroll” from the program, you will still have access to any data you entered during the time of enrollment.

To see the assignment of facility care areas to PA-PSRS care areas and falls tracking groups, click on the “Falls Units” button. The falls unit care area list that will appear on the screen can be printed by clicking on the “Print” button at the bottom of the screen.
Care Areas (Units) for Falls Tracking

Inpatient Care Areas

<table>
<thead>
<tr>
<th>Care Area</th>
<th>Care Area Type</th>
<th>Falls Tracking Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1AOrtho</td>
<td>Medical/Surgical Unit</td>
<td>General Medical/Surgical Units</td>
</tr>
<tr>
<td>CardiacCareUnit</td>
<td>Cardiac ICU</td>
<td>Critical Care</td>
</tr>
<tr>
<td>ChestPainEvaluationCenter</td>
<td>Cardiac Intermediate Unit</td>
<td>Intermediate Unit</td>
</tr>
<tr>
<td>InpatientPT</td>
<td>Renal Unit</td>
<td>Specialty Units</td>
</tr>
<tr>
<td>IntensiveCareUnit</td>
<td>Medical/Surgical ICU</td>
<td>Critical Care</td>
</tr>
<tr>
<td>CardiacCareUnit</td>
<td>Cardiac ICU</td>
<td>Critical Care</td>
</tr>
</tbody>
</table>

Outpatient Care Areas

<table>
<thead>
<tr>
<th>Care Area</th>
<th>Care Area Type</th>
<th>Falls Tracking Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Medicine</td>
<td>Physician Practice</td>
<td>Outpatient Clinics</td>
</tr>
<tr>
<td>Department of Surgery</td>
<td>Physician Practice</td>
<td>Outpatient Clinics</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>Emergency Department</td>
<td>Emergency Department</td>
</tr>
<tr>
<td>Nuclear Medicine</td>
<td>Imaging - Nuclear Medicine</td>
<td>Radiology Services</td>
</tr>
<tr>
<td>Occupational Therapy</td>
<td>Rehab - Occ Therapy</td>
<td>Rehabilitation Services</td>
</tr>
<tr>
<td>OP-PT</td>
<td>Rehab - Phys Therapy</td>
<td>Rehabilitation Services</td>
</tr>
<tr>
<td>Outpatient Chemotherapy</td>
<td>OIP Oncology Clinic</td>
<td>Outpatient Clinics</td>
</tr>
</tbody>
</table>

To view a history of your enrollment choices, including the date, time, and person who made the changes, select the “Show History” button at the bottom of the enrollment screen.

Definitions

The Falls Reporting Program uses the standardized falls definitions adopted by the Pennsylvania Patient Safety Authority’s (Authority) Southeast Regional Falls Reporting Initiative and consistent with the National Quality Forum endorsed National Database of Nursing Quality Indicators (NDNQI) patient fall measures.

Your participation in the Falls Reporting Program requires adherence to these definitions.

**Fall:** any unplanned descent to the floor (or other horizontal surface such as a chair or table), with or without injury to the patient.
The definition of falls includes:
- Assisted falls, in which a caregiver sees a patient about to fall and intervenes, lowering them to a bed or floor
- Therapeutic falls, in which a patient falls during a physical therapy session with a caregiver present specifically to catch the patient in case of a fall
- Physiologic falls, in which a patient falls as a result of a seizure or syncope

The definition excludes failures to rise, in which a patient attempts but fails to rise from a sitting or reclining position.

**Falls with harm:** Any fall that requires more than first-aid care. Treatment beyond first-aid care includes a laceration that requires physician intervention (e.g., sutures), more serious injury (e.g., fracture), or death. (This definition does not include the use of steri-strips.)

**Patient Days:** A house-wide census conducted and recorded each day that counts the number of occupied beds in each unit (i.e. Care Areas defined in PA-PSRS). The daily census should be performed at the same time of day at a time decided by the facility. The daily census should INCLUDE all occupied beds and EXCLUDE unoccupied beds. A bed is considered occupied if a patient is assigned to that bed at the time the census is conducted.

**Patient Encounters:** A count of the total number of patients who receive services for that day in outpatient care areas defined in PA-PSRS (e.g., emergency room, rehabilitation services, radiology, etc.). The daily count should INCLUDE inpatients and outpatients who receive services in these areas.

Utilization Data Entry

PA-PSRS Users are responsible for submitting utilization data. (If you are a Read-Only User you will be unable to submit data or reports. The Facility System Manager is responsible for assigning User versus Read-Only rights).

When the PA-PSRS User logs in to PA-PSRS, the blue horizontal Navigation Bar will appear as below.

To access the utilization data entry screen, select the “Utilization Data” menu option from the Navigation bar. If you are enrolled in the unit-level falls reporting program, the unit-level utilization data screen will appear. If you are enrolled in the facility-level falls reporting program, the facility-level utilization data entry screen will appear.

Both the unit-level and facility-level utilization data entry screens have the same two links: a help link and a definitions link (see utilization data screens below). The “Help” link is located in the upper right hand corner of the screen. It will open to this section of the PA-PSRS user manual that pertains to entering utilization data.

The “Definitions” link is also located in the upper right hand corner of the screen. This link will provide an informational pop-up screen with the definitions for Patient Days and Patient Encounters.
Utilization Data Entry

Unit-Level Utilization Data Entry:

When the Utilization Data menu option is selected, a screen titled, "Enter Unit-level Utilization Data for [Month, Year]" will be displayed.

The unit-level utilization data entry screen has two tables. The top table is for reporting inpatient utilization data (patient days). The bottom table is for reporting outpatient utilization (patient encounters).

Both tables have three columns. The first two columns are titled “Care Areas” and “Care Area Types.” Care areas are inpatient and outpatient units as defined by your institution. The care area type column consists of general PA-PSRS category unit designations (e.g., medical/surgical, intermediary unit, inpatient psychiatric) assigned to each facility care area by PA-PSRS. (NOTE: if there are problems with this information, or missing care areas, contact PA-PSRS to make the appropriate corrections). The third column has boxes to enter in patient day data and patient encounter data for each unit or care area.

The PA-PSRS care areas for patient day data include:

- General medical/surgical units
- Intermediate units (e.g., telemetry units, step-down units)
- Inpatient psychiatric units
Inpatient rehabilitation units
Pediatric care units
Specialty units (e.g., oncology units, orthopedic units)
Critical care units

The PA-PSRS care areas for patient encounter data include:
- Emergency Department
- Radiology
- Rehabilitation Services
- Outpatient Clinics

**Inpatient (Patient Days)**

In the third column of the first table titled, “Patient Days,” enter the number of patient days for the month in the box next to each of your institution’s designated facility care areas.

It will also be required to enter in your institution’s number of total facility-level patient days data. It is suggested to collaborate with your finance department to obtain this number. At the bottom of the inpatient table, there is a line titled, “Total Facility-level Patient Days.” Place the total number of facility-level patient days in the box at the right. The total facility-level patient days will often be higher than the sum of the patient days entered for the individual units. This is because there are inpatient days occurring on units that are not part of the falls reporting program tracking groups (e.g. women’s health, mother-baby). The total facility-level patient days will equal the sum of the units in smaller hospitals where all inpatient days occur on units that are part of the falls reporting program tracking groups.

Notice two shaded rows, “Patient Days Subtotal (sum of patient days from units above)” and “Patient Days from Other Units (calculated as difference between Facility-Level Patient Days and Unit-Level Patient Days Subtotal).” The PA-PSRS system will automatically calculate this data.

**Outpatient (Patient Encounters)**

In the third column of the second table, titled, “Patient Encounters,” enter the number of patient encounters for the month in the box next to each of your institution’s designated facility outpatient care areas.

Notice the shaded row, “Total Patient Encounters (Selected Units Above).” The PA-PSRS system will automatically calculate this data.

**NOTE:** The facility-level OUTPATIENT fall rate will be based SOLELY on those units where there is denominator data. Falls that occur in any outpatient units not being monitored for utilization data will be excluded from the falls rates reports.

When finished entering the utilization data, click the “Save” button at the bottom of the screen.

To print a hard copy of the utilization, click the “Print” button.

If the “Reset” button is selected before the “Save” button, any currently entered utilization data will not be saved.

To close the utilization data screen, click the “Close” button which will prompt the user to save the data if there are changes and then close the screen.
Amending Unit-level Utilization Data:

Participating hospitals have the ability to amend their Utilization Data for the previous 3 months. To amend utilization data, return to the “Navigational Bar” screen where you will see a drop-down box with menu choices. Select “Edit Utilization Data” from the Utilization Data menu.

The amending utilization data screen will be the same as the data entry utilization data screen, except there will be drop-down menus for the year and month. Data for the most recent month will be displayed. To edit data for a different month, select the month for the data that you wish to modify from the drop-down menus.
Facility-level Utilization Data Entry:

When the Utilization Data menu option is selected, a screen titled, "Enter Facility-level Utilization Data for [Month, Year]" will be displayed.
The facility-level utilization data entry screen has one row titled, “Total Facility-level Patient Days.” Enter your facility’s total monthly patient days in the box at the end of this row.

Once the utilization data has been entered, click the “Save” button at the bottom of the screen.

Print a hard copy of the utilization data page by clicking the “Print” button.

If the “Reset” button is selected before pressing the “Save” button, any currently entered data will not be saved.

To close the utilization data screen, click the “Close” button which will prompt the user to save the data if there are changes and then close the screen.

**Amending Facility-level Utilization Data:**

Participating hospitals have the ability to amend their Utilization Data for the previous 3 months. To amend utilization data, return to the “Navigational Bar” screen where you will see a drop-down box with menu choices. Select “Edit Utilization Data” from the Utilization Data menu.

The amending utilization data screen will be the same as the data entry utilization data screen, except there will be drop-down menus for the year and month. Data for the most recent month will be displayed. To edit data for a different month, select the month for the data to be modified from the drop-down menus.

The amending utilization data screen will be the same as the data entry utilization data screen, except there will be drop-down menus for the year and month.

Data for the most recent month will be displayed. To edit data for a different month, select the month for the data to be modified from the drop-down menus.
Submiting Falls Reports

Refer to Chapter 4: Event Reports for instructions and frequently asked questions applicable to all event reporting. The following information applies specifically to falls reporting.

Patient Status

For HOSPITALS: Regardless of enrollment status, the system provides a mandatory data field on the first page of the Serious Event/Incident/Infrastructure Failure PA-PSRS report entry form labeled “Patient Status”. 
To understand the definitions for patient status, select the “Definitions” link located to the right of the field choices. When selected, a pop-up window with the patient status definitions will appear on the screen. To close this pop-up window, select the close link.

### Definitions

**Inpatient**
- Any admitted patient, including observational patients that receive care in a hospital unit (e.g., medical/surgical unit, critical care unit, pediatric unit, etc.) This includes any patient who is formally admitted while in the emergency room and is being held while waiting for a room.

**Outpatient**
- Any patient who receives care in the hospital without being admitted (e.g., emergency room, rehabilitation services, radiology). This definition includes emergency room patients prior to formal admission and emergency room observational patients. This EXCLUDES any patient who is formally admitted while in the emergency room and is being held while waiting for a room. It also includes patients who receive care in an ambulatory surgical facility, birthing center, and abortion facility.

**Unknown**
- Patients designated as unknown are assumed to be either inpatient or outpatient based on the reported location where the event occurred, including falls, for the purpose of calculating falls rates.

There are three patient status choices. The patient status field is used in calculating falls rates reports. Limiting the use of the "Unknown" field will improve the accuracy of falls rates reports.

- **Inpatient**: any admitted patient, including observational patients that receive care in a hospital unit (e.g., medical/surgical unit, critical care unit, pediatric unit, etc.) This includes any patient who is formally admitted while in the emergency room and is being held while waiting for a room.

- **Outpatient**: any patient who receives care in the hospital without being admitted (e.g., emergency room, rehabilitation services, radiology). This definition includes emergency room patients prior to formal admission and emergency room observational patients. This EXCLUDES any patient who is formally admitted while in the emergency room and is being held while waiting for a room. It also includes patients who receive care in an ambulatory surgical facility, birthing center, and abortion facility.

- **Unknown**: Patients designated as unknown are assumed to be either inpatient or outpatient based on the reported location where the event occurred, including falls, for the purpose of calculating falls rates.

- All reports from Ambulatory Surgical Facilities (ASFs), Birthing Centers (BCs), and Abortion Facilities (ABFs) will have this question auto-filled to outpatient without the opportunity to change this designation. This field will be disabled (but visible) for ASFs, BCs and ABFs.
Fall Event Details

When entering event reports for falls, the Fall Event Details screen has revisions to two existing questions and three new questions. Each question has the same three responses: yes, no, and unknown. A falls event decision tree was developed to provide a systematic approach to evaluate the circumstances surrounding falls and to standardize falls reporting and is located at: http://patientsafety.pa.govpst/Pages/Falls/algorithm.aspx.

The first question to be revised is Question H: Fall precaution/protocol in place. This question has 8 identifiable falls prevention strategies. If there are no falls prevention strategies indicated or it is unknown, chose one of these options and then move to the next question. When yes is chosen, select at least one of the 8 fall prevention strategies. The last prevention strategy listed is “other” and is a free text field. Enter any fall prevention strategy that is not currently listed. The eight fall prevention strategies include:

- Patient risk identifiers (e.g. wrist bands, visual cues on the walls or charts)
- Patient and family education
- Hourly (or more frequent) comfort and toileting rounds
- Nurse call system
- Alarms present: bed exit or chair
- Appropriate footwear/clothing
- Equipment used: bedrails up, high-low beds, fall mats
- Other (specific) [text field, limit 50 characters]

Question K is also revised. The question originally read, “Drug-induced.” The question now asks, “Was fall drug-induced?”

- K. Was fall drug-induced?  ☐ Yes  ☐ No  ☐ Unknown
The three new questions are:

Question P: Does patient have history of visual impairment (this includes patients who wear corrective lenses)?
Question Q: Does patient have history of hearing impairment?
Question R: Does patient have prior history of falls in the past 12 months?

P. Does patient have recent history of visual impairment?

☐ Yes  ☐ No  ☐ Unknown

Q. Does patient have recent history of hearing impairment?

☐ Yes  ☐ No  ☐ Unknown

R. Does patient have prior history of falls in the past 12 months?

☐ Yes  ☐ No  ☐ Unknown

After completing the Fall Event Details, return to questions 9 through 21 of the Event Report Including: Event Outcome, Recommendations and Disposition, and Follow-up Questions as explained in Chapter 4: Event Reports, pages 24-30.

Once all the questions have been answered, click Submit Report and follow the instructions on the screen. These final steps are explained in Chapter 4: Event Reports, pages 30-32.

Falls Analytic Reports

Hospitals enrolled in the Falls Reporting Program have access to analytic reports in addition to the existing falls reports which remain available to all hospitals as described in Chapter 6: Data Analysis.

The Falls Reporting Program analytic reports include:

- Falls Rates Reports
  - Falls and Falls with harm per 1,000 patient days
  - Falls and Falls with harm per 1,000 patient encounters
  - Falls and Falls with harm per 1,000 adjusted patient days
- Falls Risk and Strategy Process Measure
- Falls Dashboard
Periodic Falls Rate  
Facility Level Patient Days Falls Rates Quartiles  
Falls Risk Assessment  
Falls Details  
Falls Prevention Strategies in Place  
  • Falls Tracking Groups Rates Reports  
    Inpatient falls tracking groups  
    Outpatient falls tracking groups  
  • Falls Utilization Data Reports  
    Monthly compliance summary  
    Unit-level compliance details

To access available reports, select “Analytical Data Tools” from the Navigation Bar; then select “Event Report Data Analysis” from the drop-down menu.

This will take you to the main Report Selection screen (see below), where you can select which analytical report you wish to create.

The report screen where the PA-PSRS user can select a report will be determined by enrollment status:

- **Facility-level enrolled hospitals** will have access to the falls rates facility report, falls risk and strategy process measures report, falls dashboard, and falls utilization data report.

- **Unit-level enrolled hospitals** will have access to the falls rates report, falls rates report for inpatient vs. outpatient care areas, falls risk and strategy process measure report, falls dashboard, falls tracking group rates report, and falls utilization data report.
Configurable Options

The reports have configurable options that vary according to the type of falls report and enrollment level. If a report is selected and the “Generate Report” button is clicked, the default settings for that report will apply. If a customized report is desired, click on the “Additional Criteria” link (as shown below) before clicking the “Generate Report” button.

The program enrollment level and type of report selection will determine the list of configurable options.

ALL FALLS REPORTS (except the utilization data report) include the following configurable options:

- **Report submission type**
  - Falls report/rate report – includes Incident and Serious Events - default
  - Falls with harm report/rate report – includes Serious Events only

- **Periodicity (time period)**
  - Monthly – default
  - Quarterly
  - Yearly

- **Time Frame**
  - Select the time in months for each report. No dates may be selected prior to the month and year the facility enrolled in the falls program.
FALLS RATES REPORTS include the following configurable options:

**Report Style**
- Chart - default
- Tabular

**Time Format**
- Time-series (i.e., trend line) - default
- Cross-section (i.e., bar chart)

**Comparison Group** (see section on Benchmarking, following this section)
- None - default
- Peer group periodic falls rate
- State group periodic falls rate
- Peer group aggregate falls rate
- State group aggregate falls rate

FALLS RATES REPORTS available for unit-level enrolled hospitals only include the following additional configurable options:

**Rate Calculation:**
- Patient-days (used to calculate inpatient falls rate) – default
- Patient encounters (used to calculate outpatient falls rate)
- Adjusted patient-days (combined patient-days and encounters, used to calculate facility falls rate)

**Level:**
- Facility – default
- Unit

**Individual Unit:**
- All falls tracking groups (e.g., general medical/surgical, critical care) – default
- Individual falls tracking group
- Individual units within a falls tracking group

The screenshot below shows the configurable options for facility-level enrolled hospitals.
The screenshot below shows the configurable options for unit-level enrolled hospitals.

**Benchmarking**

Benchmark falls rates will vary based on comparison group and time period selected. The system will include hospitals or units within a hospital in the comparison group falls rate calculation on a monthly basis when non-zero utilization data is entered for the care areas. Comparison group falls rates are calculated for each individual time period when a minimum of five hospitals with complete utilization data for the falls rates is available.

The State Group includes all facilities enrolled in the falls reporting program that have entered non-zero utilization data.
The Peer Group includes all facilities enrolled in the falls reporting program that have entered non-zero utilization data, and that are of similar hospital type (see below).

**Acute Care Hospitals** are separated into four peer groups based on bed size:
- 0 – 100 beds
- 101 – 200 beds
- 201 – 300 beds
- > 300 beds

**Specialty Hospitals** are separated into five peer groups based on specialty:
- Behavioral Health
- Critical Access
- Long-Term Acute Care
- Pediatric
- Rehabilitation

Both State and Peer Group rates can be calculated and displayed as periodic and aggregate rates (see the Falls Rates Reports section below for examples):

- The peer/state **periodic falls rate** information will provide benchmarking falls rates that fluctuate with each time period.
- The peer/state **aggregate falls rates** information provides the average single falls rate for the time period selected and is constant over time.

**Falls Rates Reports**

**Facility-level enrollment**

Hospitals enrolled at the facility-level will have one falls rates report selection: Falls Rates Facility Report. This report selection will provide two facility-level falls rates reports: falls per 1,000 patient days and falls with harm per 1,000 patient days.

The default report (see below) will display the most recent month for which utilization data has been entered. There is no comparison group.
A facility falls rates report comparing falls rates over a specified time period with the peer group periodic falls rate (i.e., the comparison falls rate will fluctuate with each time period) is shown below.
A facility falls rates report comparing falls rates over a specified time period with the peer group aggregate falls rate (i.e., the comparison falls rate will be displayed as a single rate averaged over the selected time period) is shown below.

![Facility Falls Rates vs Peer Group Facility Falls Rates](image)

**Unit-level enrollment**
Hospitals enrolled at the unit-level will have two different falls rates report selections: Falls Rates Report and Falls Rates Report – Inpatient vs. Outpatient Care Areas.

Unit-level enrolled hospitals will have access to all the configurable options listed above. There are three main types of Falls Rates Reports available based on the utilization data:

- **Patient Days** provide falls rates for inpatient care areas
- **Patient Encounters** provide falls rates for outpatient care areas (e.g., ED, radiology, physical therapy)
- **Adjusted Patient Days** provides a facility-level falls rate that combines inpatient and outpatient care areas

The Falls Rates Report – Inpatient vs. Outpatient Care Areas is shown below.
A trend-line facility falls rates report based on adjusted patient days with peer group periodic falls rate comparison data is shown below:

A maximum of 13 facilities are included in the comparison group calculation. Each time period is calculated separately and it’s possible that each time period has a different number of facilities that are included in the comparison group calculation. The comparison group calculation must have at least 5 facilities to work.
Facilities enrolled at the unit-level are also able to calculate falls rates for individual Falls Tracking Groups. See section on Falls Tracking Group Rates Reports.

**Missing Data**

When a facility is missing utilization data for a given time period, the charts will not have a trend-line or bar chart for that time period and the table will be marked with a capital letter "M" to indicate “Missing Data” as illustrated in the examples below.

![Facility Falls Rates](image1.png)

**Falls Risk and Strategy Process Measure**

The Falls Risk Strategy Process Measure report may only be run in tabular format. By default, this report displays information as entered in PA-PSRS reports for all falls (i.e., Incidents and Serious Events) for the most recent month of complete data.

This 2 X 3 table displays the total number of falls reported, the number of patients assessed for falls risk and either identified or not identified at risk to fall, and the number of patients in each category that were reported to have a fall precaution/protocol in place. If event reports do not indicate whether or not a falls risk assessment was completed, this is noted below the chart.

"Unexpected – Follow up Suggested" is displayed to indicate falls reports that may reveal a mismatch between falls risk assessment and implementation of falls prevention strategies. (e.g., falls reported in patients assessed and identified at risk to fall, without falls prevention strategies in place).
This report may be modified to display only Incidents, or only Serious Events. It may also be modified to display information from falls reported for specific Falls Tracking Groups (e.g., only Pediatric units), or for individual care areas (e.g., “5 West”). Click on “Select New Criteria” for additional configurable options.

When the “Click for more details” link is selected, a detailed list of the patients who are represented in each box of the 2 x 3 table are displayed as shown below.

Click on one of the (+) signs and the list of event report information (i.e., event ID, event classification, event date, fall type, patient status, and harm score) will appear as shown below. To close this list of patients, click on the (-) sign for the open category.
Falls Dashboard

By default, the Falls Dashboard displays information from the most recent month of complete data. For best viewing of the dashboard, set the "zoom" to 100% in the drop-down box; otherwise, the chart in the dashboard will overlap the tables and quartile report.

A screenshot of the complete Falls Dashboard is shown below. Each component of the dashboard will be described in further detail.
Information displayed across the top of the Falls Dashboard includes the total number of falls reported as Serious Events and Incidents, the facility enrollment date for the Falls Reporting Program, and the enrollment level.

Graphs and table displayed include:

- **Periodic Falls Rates** (see section on Falls Rates Reports)
- **Facility Level Patient Days Falls Rates Quartiles**
  - Three quality improvement tables:
    - Falls Risk Assessment
    - Falls Details
    - Falls Prevention Strategies in Place

The **Facility Level Patient Days Falls Rates Quartiles** table (shown below) provides the ranking of an individual hospital compared to the state ranking of hospitals’ falls rates. The quartiles are based on facility-level patient days falls rates. This report will not change when a falls tracking group or care area (unit) data is selected for the falls dashboard report.

**Facility Level Patient Days Fall Rates Quartiles**

For falls rate 3.167 falls per 1,000 patient days

<table>
<thead>
<tr>
<th>Quartile</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1 (25%)</td>
<td>2.638 falls or fewer per 1,000 patient days</td>
</tr>
<tr>
<td>Q2 (50%)</td>
<td>4.014 falls or fewer per 1,000 patient days</td>
</tr>
<tr>
<td>Q3 (75%)</td>
<td>5.987 falls or fewer per 1,000 patient days</td>
</tr>
<tr>
<td>Q4 (100%)</td>
<td>19.066 falls or fewer per 1,000 patient days</td>
</tr>
</tbody>
</table>
The **Falls Risk Assessment** table (shown below) identifies information about completed risk assessments, identification of patients at risk for falls, prevention strategies in place, and prior history of falls. The column responses reflect answers provided in the PA-PSRS falls event detail questionnaire form, which contains three responses: Yes, No, and Unknown. The 'No Response' column indicates the number of patient event reports that have no response (i.e., the data field is blank).

<table>
<thead>
<tr>
<th>Falls Risk Assessment</th>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
<th>No Response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Falls Risk Assessment Completed</td>
<td>16</td>
<td>0</td>
<td>5</td>
<td>9</td>
<td>30</td>
</tr>
<tr>
<td>Patient Identified at Risk of Fall</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>17</td>
<td>30</td>
</tr>
<tr>
<td>Falls Precaution(s) in Place</td>
<td>16</td>
<td>5</td>
<td>0</td>
<td>9</td>
<td>30</td>
</tr>
<tr>
<td>Prior History of Falls in the past 12 months</td>
<td>6</td>
<td>5</td>
<td>2</td>
<td>17</td>
<td>30</td>
</tr>
</tbody>
</table>

The **Falls Details** table (shown below) identifies the top three falls event types stratified by patient characteristics of patients who fell for the time period selected. The total number of patients in this chart reflects the top three fall event types, as reported in PA-PSRS. If the total number of patients does not add up to the total number of falls identified at the top of the falls dashboard, it means that there were four or more fall event types.

<table>
<thead>
<tr>
<th>Falls Details</th>
<th>Patient depressed</th>
<th>Altered mental status</th>
<th>Requires assistance from chair</th>
<th>Visual or hearing impairment</th>
<th>Dizziness or vertigo</th>
<th>Altered elimination</th>
<th>Drug induced falls</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Found on floor</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>15</td>
</tr>
<tr>
<td>Other/Unknown (specify)</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Ambulating</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

*The number of falls details represents 'Yes' responses for each patient characteristic. No, Unknown and blank responses were excluded.

**Patient total includes all patient falls for that event type. Patients could have had multiple falls details indicated.

The table of **Falls Prevention Strategies in Place** (shown below) identifies the top three falls event types stratified by prevention strategies that were in place for patients who fell for the time period selected. The total number of patients represents only those patients with a prevention strategy in place.

<table>
<thead>
<tr>
<th>Falls Prevention Strategies in Place</th>
<th>Risk Identifiers</th>
<th>Patient and Family Education</th>
<th>Monthly (or more frequent) Covert or Toilet Rounds</th>
<th>Nurse Call System</th>
<th>Appropriate Footwear and Clothing</th>
<th>Alarms (Pain, Bed)</th>
<th>Equipment Used: High/low beds; bed falls up, Falls Risk</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Found on floor</td>
<td>8</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>4</td>
<td>1</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Other/Unknown (specify)</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Ambulating</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*Individual patients could have had multiple prevention strategies in place.

**Patient total represents all patients for each falls event type that had a prevention strategy in place. Patients without a prevention strategy indicated were excluded.
Falls Tracking Groups Rates Reports

Facilities enrolled at the unit-level are able to calculate falls rates for the following individual Falls Tracking Groups:

**Inpatient Falls Tracking Groups**
- Critical Care
- General Medical-Surgical
- Inpatient Rehabilitation
- Intermediate Care
- Pediatrics
- Specialty Units

**Outpatient Falls Tracking Groups**
- Emergency Departments
- Outpatient Clinics
- Radiology Services
- Rehabilitation Services

A trend-line falls tracking group falls rates report with state group periodic falls rates comparison data is shown below:

*A maximum of 67 facilities are included in the comparison group calculation. Each time period is calculated separately and it’s possible that each time period has a different number of facilities that are included in the comparison group calculation. The comparison group calculation must have at least 5 facilities to work.*
Falls Utilization Data Report

Falls Utilization Data Summary

This report provides facilities with a summary of the utilization data entered by month. The only criteria required for this report is the facility name. The “Additional Criteria” link on the report selection screen is disabled.

For facility-level enrolled hospitals, the only column displaying data will be the facility total patient days column.

For unit-level enrolled hospitals, data is displayed in both the patient days and patient encounters columns.

If all data has been entered, a green checkmark appears in the complete column. If data is missing, a red X is displayed (see below).
Click on a green checkmark or a red X in the complete column to see a detailed report of all entries for the month (shown below).

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Facility/Care Area</th>
<th>Inpatient/Outpatient</th>
<th>Care Area Type</th>
<th>Falls Tracking Group</th>
<th>Patient Days Total</th>
<th>Patient Encounters Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>May</td>
<td>Facility</td>
<td>Inpatient</td>
<td>Cardiac ICU</td>
<td>Critical Care</td>
<td>1234</td>
<td>45678</td>
</tr>
<tr>
<td>2012</td>
<td>May</td>
<td>Care Area</td>
<td>Inpatient</td>
<td>Med</td>
<td>General Medical Ward</td>
<td>82</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>May</td>
<td>Care Area</td>
<td>Inpatient</td>
<td>MICU</td>
<td>Critical Care</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>May</td>
<td>Care Area</td>
<td>Inpatient</td>
<td>ONCOLOGY</td>
<td>Specialty Units</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>May</td>
<td>Care Area</td>
<td>Inpatient</td>
<td>Newborn Nursery</td>
<td>Pediatric Care</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

This report can be used to identify care areas with missing data or with zeros entered.

Click on the icon to export this report in Microsoft Excel, Word, or PDF format. Refer to Chapter 6: Data Analysis for further instructions on exporting data and reports.
Pressure Injury Reporting
Definition, data entry, and report functions

Background

On April 8, 2017, the Pennsylvania Patient Safety Authority (Authority) and Pennsylvania Department of Health (Department) published Final Guidance for Acute Health Care Facility Determinations of Reporting Requirements for Pressure Injuries under the Medical Care Availability and Reduction of Error (MCARE) Act in the Pennsylvania Bulletin [47 Pa.B. 2163]. The guidance was developed to provide consistent and clear standards for the MCARE Act’s reporting requirements for pressure injuries so that the Authority, the Department, and healthcare facility staff have a shared understanding of the requirements. The subjects of these requirements were identified from inconsistencies evidenced in the data collected by the Authority and the Department.

Implementation

The agencies have modified the Authority’s Pennsylvania Patient Safety Reporting System (PA-PSRS) to support implementation of the guidance and have developed an online education program to inform patient safety officers and other stakeholders of the changes. The new standards became effective January 1, 2018.

Concept of Harm

Patient-safety event reporting in Pennsylvania was designed to be nonpunitive and does not include the concept of preventability. The concepts of human error and preventability are not included in the 2014 Final Guidance for Acute Healthcare Facility Determinations of Reporting Requirements under MCARE Act. It is unnecessary for an error to have occurred, or for harm to be preventable, for an event to be considered reportable.

Statutory Definitions of Reportable Events

The statutory definitions of reportable events are as follows:

Serious Event: An event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services to the patient.

Incident: An event, occurrence, or situation involving the clinical care of a patient in a medical facility, which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional healthcare services to the patient.
Pressure Injury Definition

The definition for pressure injuries that was used to develop the guidance is adopted from the National Pressure Ulcer Advisory Panel (NPUAP). The panel released an update on April 13, 2016, and announced changes in terminology from pressure ulcer to pressure injury and updated the stages of pressure injury.

A pressure injury is defined as localized damage to the skin and/or underlying soft tissue, usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, comorbidities, and condition of the soft tissue.

Final Guidance for Reporting Pressure Injuries under the Medical Care Availability and Reduction of Error Act

The Authority and Department achieved consensus on the following principles and decision tree for reporting pressure injury events. Some of these standards have been revised in response to feedback the Authority and the Department received during public comment.

Principles for reporting pressure injury events

1) Report all unanticipated pressure injuries, both those that are hospital-acquired and those that are present on admission and progress (worsen) during the hospitalization, as either Incidents or Serious Events.

   a. Not reportable:

      1) Deep tissue injuries present on admission.

      2) All pressure injuries present on admission that remain stable (i.e., unchanged) or improve during hospitalization.

   b. Incidents:

      1) All hospital-acquired pressure injuries that do not require additional healthcare services.

      2) All pressure injuries present on admission that progress during the hospitalization but do not require additional healthcare services.

   c. Serious Events:

      1) All hospital-acquired pressure injuries that require additional healthcare services.

      2) All pressure injuries present on admission that progress or worsen during the hospitalization and require additional healthcare services.

2. Report the deepest stage pressure injury when multiple pressure injuries are present.
Acute healthcare facilities should submit a single report that represents the deepest stage pressure injury for each patient with multiple pressure injuries, rather than submitting a report for each pressure injury.

3. Report changes (i.e., worsening) in pressure injuries.

Whether a pressure injury was present on admission or was hospital-acquired, if the injury progresses or worsens during hospitalization, acute healthcare facilities should report a Serious Event or Incident based on the deepest stage of any pressure injuries that progress.

4. Report medical device–related pressure injuries as either Incidents or Serious Events.

Medical device–related pressure injuries may result from devices used for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. These injuries should be staged using the staging system described by NPUAP and reported as either Incidents or Serious Events.

5. Report mucosal ulcers as Incidents or Serious Events.

Mucosal-membrane pressure injuries are found on mucous membranes (e.g., oral cavity, nares). These injuries cannot be staged in the same manner as other pressure injuries but should be reported as either Incidents or Serious Events.

Adding Pressure Injury Reports

As of January 1, 2018, PA-PSRS no longer accepts pressure ulcer events as new event reports, and existing reports (i.e., reports entered before January 1, 2018) cannot be amended to a pressure ulcer event. Instead, pressure injury events will be accepted, and existing event reports, with the exception of pressure ulcer event reports, can be amended to a pressure injury event report.

When "Pressure injury" is selected, a link to the pressure injury decision tree is displayed below the Subcategory – Level 2 drop-down box to help the reporter determine whether the event is consistent with an Incident or Serious Event.
When the “Pressure Injury Decision Tree” link is selected, the document opens a new window (see decision tree figure on page 127).

After selecting “Pressure injury,” the user will need to select the Subcategory – Level 3 value that corresponds to the stage of the pressure injury.

A link to the pressure-injury stage definitions is displayed below the Subcategory – Level 3 drop-down box. When the “Stage Definitions” link is selected, the document opens in a new window (see definitions table following the decision tree).
Pressure Injury Decision Tree

Was the pressure injury present on admission?  
YES → Was the pressure injury a deep-tissue injury?  
→ YES → This is not a reportable event.

NO → Did the pressure injury remain stable (i.e., unchanged) or improve during admission?  
→ YES → This is not a reportable event.

NO → Did the pressure injury present on admission progress during hospitalization, but did not require additional healthcare services?  
→ YES → This is reportable as an Incident.

NO → Did the pressure injury present on admission progress during hospitalization and require additional healthcare services?  
→ YES → This is reportable as a Serious Event.

NO → Did the hospital-acquired pressure injury require additional healthcare services?  
→ YES → This is reportable as a Serious Event.

NO → This is reportable as an Incident.
Pressure Injury Stages

Definitions - Pressure Injury Stages

Pressure Injury:
A pressure injury is localized damage to the skin and underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear may also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

- Stage 1:
  Pressure Injury: Non-blanchable erythema of intact skin
  Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. Color changes do not include purple or maroon discoloration; these may indicate deep tissue pressure injury.

- Stage 2:
  Pressure Injury: Partial-thickness skin loss with exposed dermis
  A reddened area on the skin that, when pressed, is "non-blanchable" (does not turn white). This indicates that a pressure ulcer is starting to develop.

- Stage 3:
  Pressure Injury: Full-thickness skin loss
  Full-thickness loss of skin, in which adipose (fat) is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/ or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

- Stage 4 Pressure Injury:
  Full-thickness skin and tissue loss
  Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss this is an Unstageable Pressure Injury.

- Unstageable Pressure Injury:
  Obscured full-thickness skin and tissue loss
  Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable eschar (i.e. dry, adherent, intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.

- Deep Tissue Pressure Injury:
  Persistent non-blanchable deep red, maroon or purple discoloration
  Intact or non-intact skin with localized area of persistent non-blanchable deep red, maroon, purple discoloration or epidermal separation revealing a dark wound bed or blood filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense and/or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury, or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle or other underlying structures are visible, this indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not use DTPI to describe vascular, traumatic, neurogenic, or dermatologic conditions.

- Medical Device Related Pressure Injury:
  Medical device related pressure injuries result from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant pressure injury generally conforms to the pattern or shape of the device. The injury should be staged using the staging system.

- Mucosal Membrane Pressure Injury:
  Mucosal membrane pressure injury is found on mucous membranes with a history of a medical device in use at the location of the injury. Due to the anatomy of the tissue these ulcers cannot be staged.

Resource: The National Pressure Ulcer Advisory Panel (NPUAP)
http://www.npuap.org/resources/educational-and-clinical-resources/npuap-pressure-injury-stages/
If the report submission type is "Incident," and the user selects stage 3 or 4 or Unstageable, a notification window will appear with the message, "The definition of this stage may be inconsistent with the event you are attempting to report." The user must select one of the following three options: (1) change the report submission type, (2) change the pressure injury stage (Subcategory – Level 3), or (3) continue without changes. Buttons corresponding to each option appear at the bottom of the window. The user will be unable to continue entering or amending the event report until one of the three options in this window is selected.

If the user selects the “Submission Type” button, the user will be returned to the first page to select a new report submission type. If the user selects “Event Type” the Subcategory – Level 3 (pressure injury stage) will be cleared and will allow the user to select a new pressure injury stage.

If the report submission type is "Serious Event," and the user selects “Stage 1,” the same process will be followed as described above.
Acute Care Event Detail Questions

Eight event-detail questions are available when a new Skin Integrity Subcategory – Level 2 "Pressure Injury" event is reported. Five questions are required and must be answered as shown below.

For question A, the valid responses are listed in a drop-down box for selection.

For question G, if the response to "Was the event related to the use of a medical device?" is "Yes," the user is prompted to select which device(s) contributed to the pressure injury.

Event-detail questions for other Skin Integrity events will no longer be available.
Amending Pressure Injury Reports

When a pressure injury event is amended, the web pages will follow the same procedure as when a pressure injury event is added.

When a pressure ulcer event (i.e., submitted before January 1, 2018) is amended, the user will be allowed to change the Subcategory – Level 3, but will not be allowed to change the event to a completely different event type. If the pressure ulcer event is an error, the facility can request that the event report be deleted before adding a new event report with the correct event type. In the screen print below, notice that the Level 1 and Level 2 drop-down boxes are grayed out, indicating that they are disabled and cannot be used to select a different value.

![Screen Print Showing Pressure Ulcer Subcategory](image1)

When a non-pressure-ulcer event is amended, the subcategory cannot be changed to a pressure ulcer. In the screen shot below, notice that the Pressure Ulcer Subcategory – Level 2 is grayed out, indicating that it cannot be selected.

![Screen Print Showing Pressure Ulcer Subcategory](image2)

When a Skin Integrity event other than a pressure ulcer event or a pressure injury event is amended, no event-detail questions will be displayed for the user to view or amend.
Viewing Pressure Injury Reports

When viewing a pressure injury event, the event details will be displayed as shown in the example.

When viewing a pressure ulcer event report, the current pressure ulcer questions will be displayed, regardless of how old the event is.

When a Skin Integrity event other than a pressure ulcer event or a pressure injury event is viewed, no event-detail questions will be displayed.
Searching for Submitted Pressure Injury Reports

The search function is found on the Analytical Data Tools menu. The "Add/Change Event Type Criteria" web page, which allows the user to search specific event types, and the search results will update to accommodate the event type changes as described in the Event Taxonomy section.

The Advanced Data export will update with the new Skin Integrity Pressure Injury event details.

Analytical Reports for Submitted Pressure Injury Reports

The Distribution of Subcategories report will display pressure ulcer and pressure injury events separately. Below is a screen print of how the different skin integrity types will appear in the report legend.