



BETSY LEHMAN CENTER

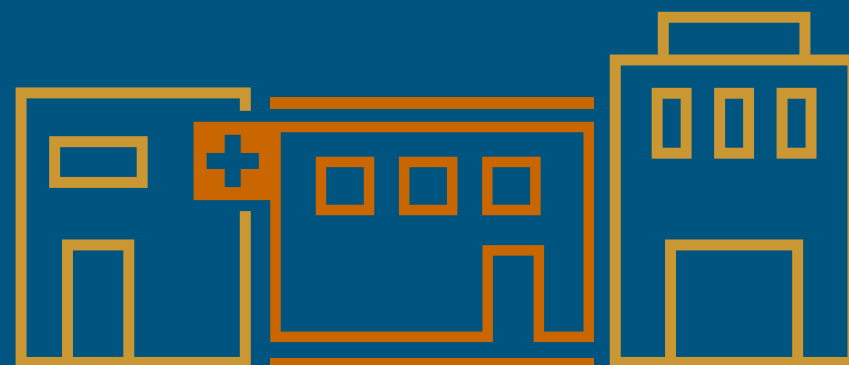
for Patient Safety and Medical Error Reduction



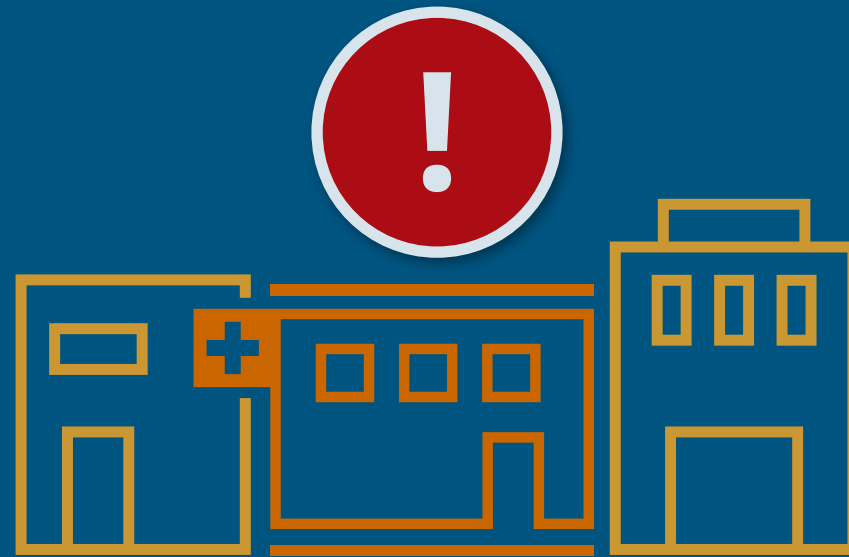
BETSY LEHMAN CENTER

for Patient Safety and Medical Error Reduction

How to Use the Patient Safety Navigator



In our complex healthcare system,



patient harm happens every day, despite best intentions



The Betsy Lehman Center created the Patient Safety Navigator to help Massachusetts healthcare organizations of all sizes respond effectively to patient safety events ...



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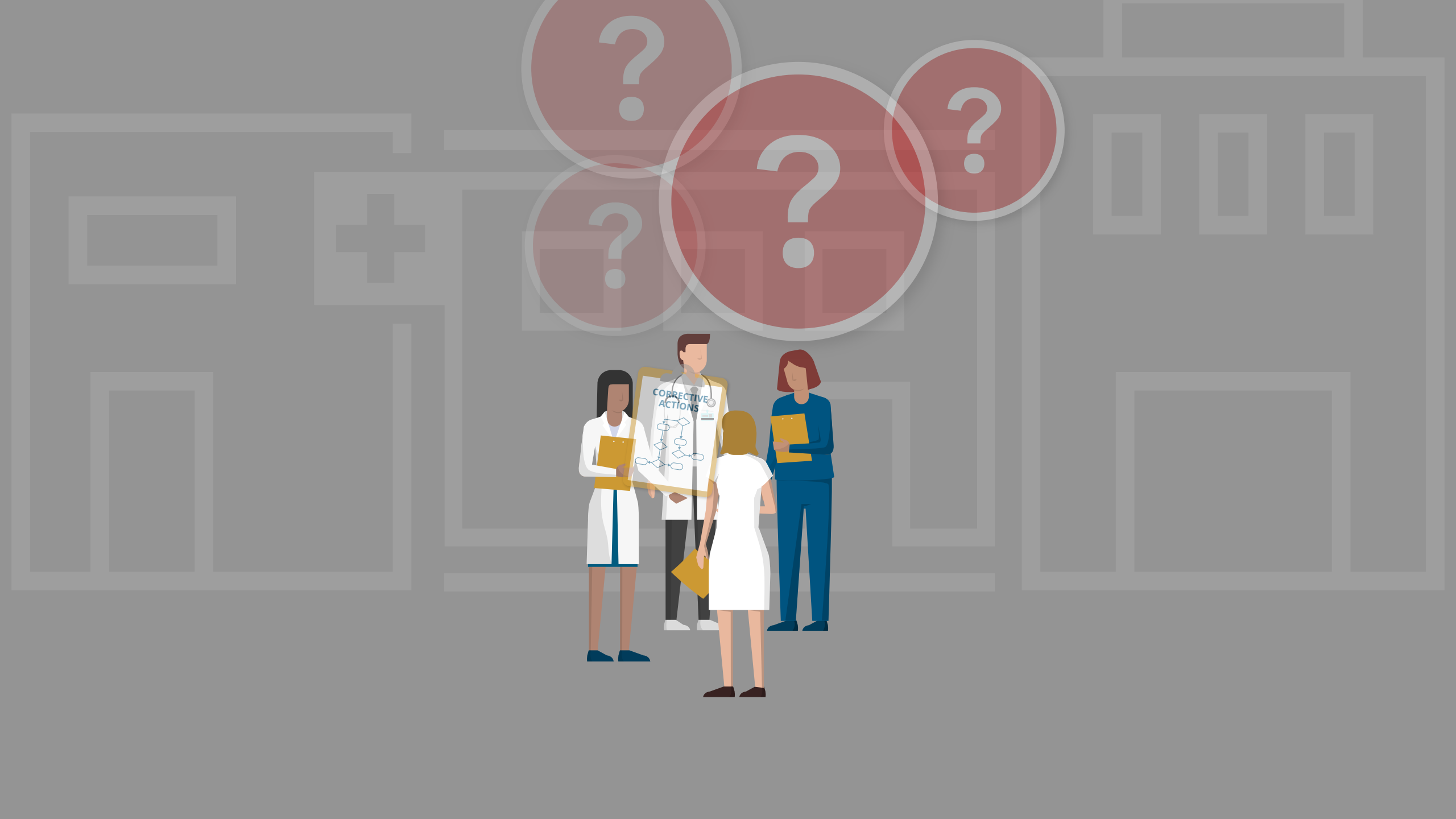
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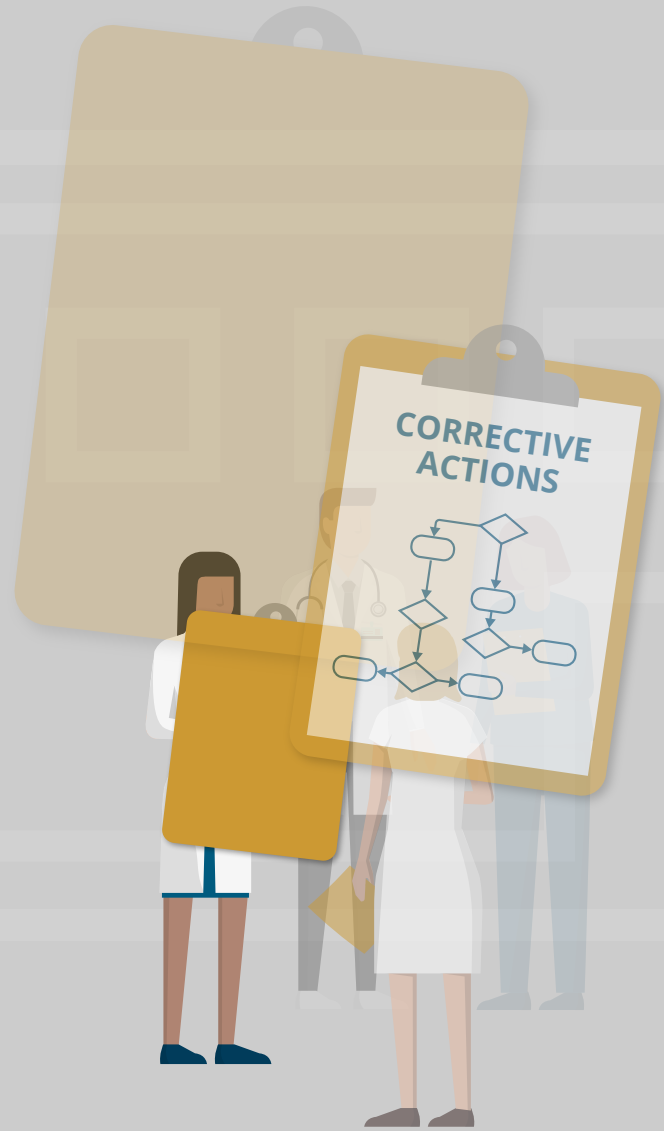
The Betsy Lehman Center created the Patient Safety Navigator to help Massachusetts healthcare organizations of all sizes respond effectively to patient safety events ...



...learn from these events...



...and take action to prevent future harm.



...and take action to prevent future harm.



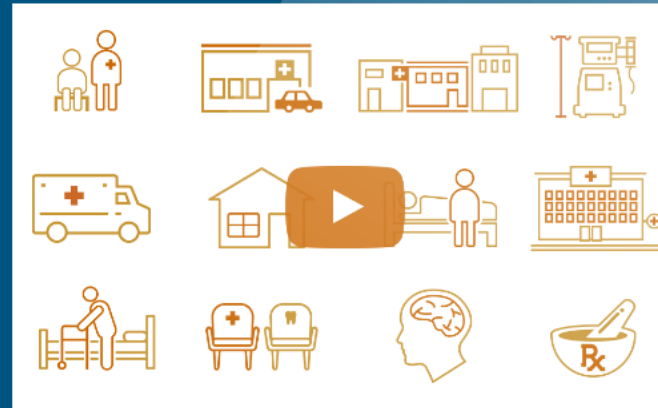
PATIENT SAFETY NAVIGATOR

Plan Analyze Communicate Report About this Tool About Us

Medical errors and other patient safety events take place in health care settings across Massachusetts every day, despite best intentions.

This site will help providers of all types navigate state and federal requirements for reporting adverse events.

[READ MORE →](#)



HOW TO PLAN

Use these resources to man



HOW TO ANALYZE

Probe root causes to



HOW TO COMMUNICATE

Inform patients and families



HOW TO REPORT

Navigate state and federal

The Patient Safety Navigator offers four intuitive modules to assist you.

reporting adverse events.

[READ MORE →](#)



HOW TO PLAN

Use these resources to map strategies for preventing patient harm.

[LEARN MORE](#)



HOW TO ANALYZE

Probe root causes to understand what went wrong and prevent recurrence.

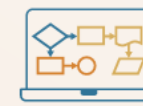
[LEARN MORE](#)



HOW TO COMMUNICATE

Inform patients and families – and support medical staff – after an error or unexpected outcome.

[LEARN MORE](#)



HOW TO REPORT

Navigate state and federal patient safety reporting requirements.

[EXPLORE THE TOOL →](#)

Information for:

Consumers



Policymakers



The Patient Safety Navigator offers four intuitive modules to assist you.

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HOW TO PLAN

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[LEARN MORE](#)



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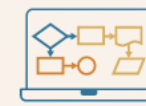
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HOW TO REPORT

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Information for:

Consumers



Policymakers



PLAN provides tools to help your organization develop a comprehensive blueprint for preventing patient harm.

reporting adverse events.

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HOW TO PLAN

Use these resources to map strategies for preventing patient harm.

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HOW TO ANALYZE

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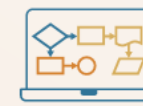
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HOW TO COMMUNICATE

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[LEARN MORE](#)



HOW TO REPORT

Navigate state and federal patient safety reporting requirements.

[EXPLORE THE TOOL →](#)

Information for:

Consumers



Policymakers



And, when something does go wrong, ANALYZE provides step-by-step help in determining what happened and preventing recurrence.

reporting adverse events.

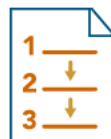
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HOW TO PLAN

Use these resources to map strategies for preventing patient harm.

[LEARN MORE](#)



HOW TO ANALYZE

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[LEARN MORE](#)



HOW TO COMMUNICATE

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[LEARN MORE](#)



HOW TO REPORT

Navigate state and federal patient safety reporting requirements.

[EXPLORE THE TOOL →](#)

Information for:

Consumers



Policymakers



COMMUNICATE informs conversations with patients, families and staff following an error or unexpected outcome.

reporting adverse events.

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HOW TO PLAN

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[LEARN MORE](#)



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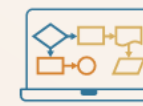
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HOW TO COMMUNICATE

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HOW TO REPORT

Navigate state and federal patient safety reporting requirements.

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Information for:

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Policymakers



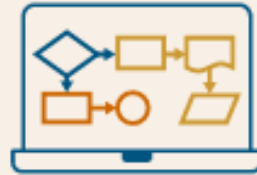
And REPORT makes it easy to identify and report adverse events to state and federal agencies.



HOW TO COMMUNICATE

patients and families –
report medical staff – after
error or unexpected
outcome.

[LEARN MORE](#)



HOW TO REPORT

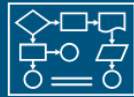
Navigate state and federal
patient safety reporting
requirements.

[EXPLORE THE TOOL →](#)

Let's take a closer look at the REPORT tool.



Home / Provider









Report



Did something occur at your facility that you need to report to a state or federal agency? This four-step tool will help you navigate those requirements; it is not a mechanism for collecting event reports. Read more in [About this Tool](#).

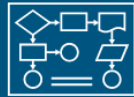
SELECT YOUR PROVIDER TYPE:

 Adult Day Health Programs	 Ambulatory Surgery Center	 Clinic	 Dialysis Center
			

It leads you through the process of reporting a patient safety event to the appropriate agencies, step by step.



Home / Provider










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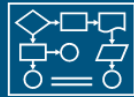
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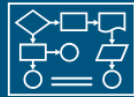
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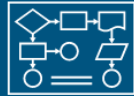
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Home / Provider



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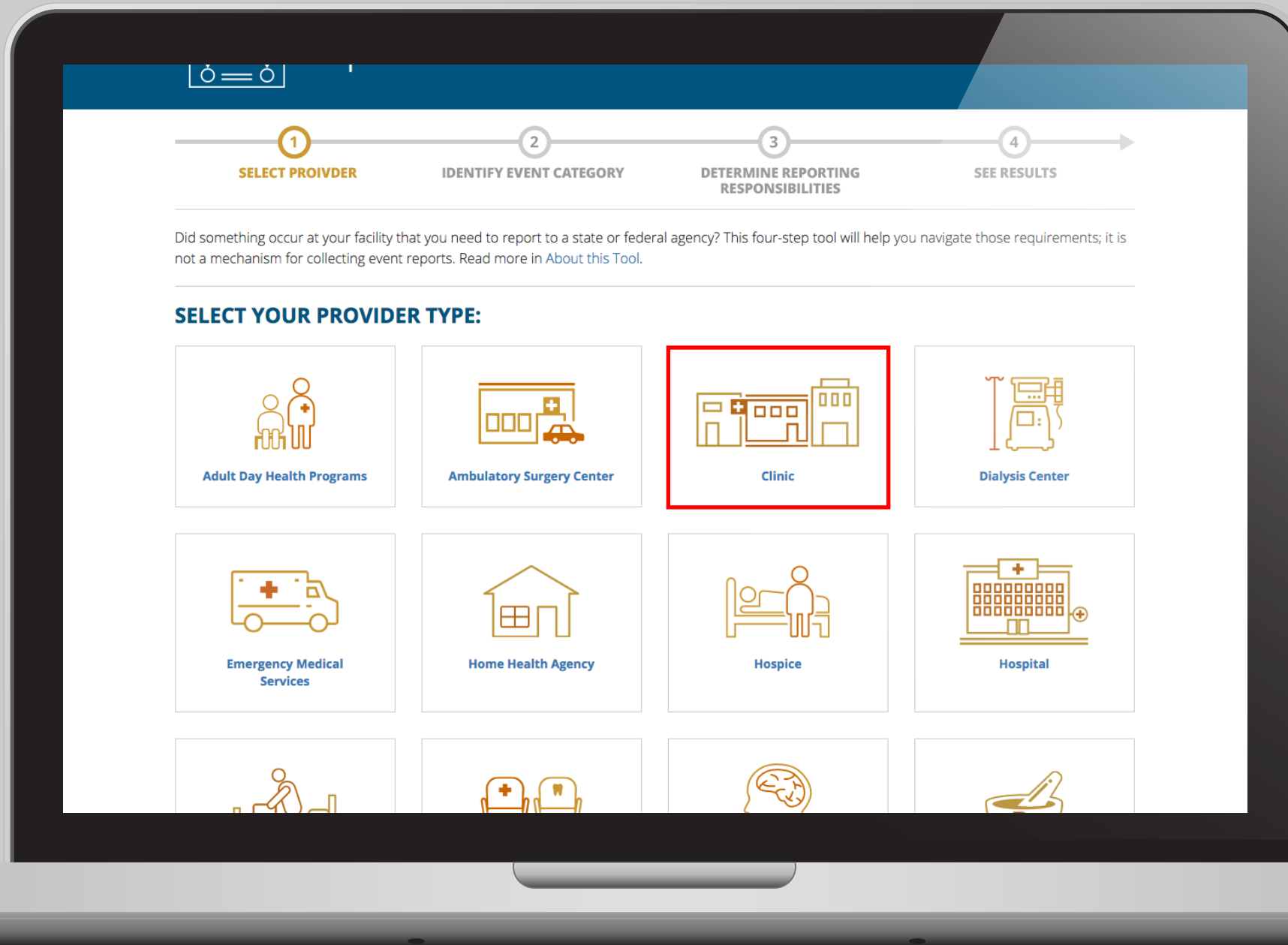


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Begin by selecting your provider type. Because different providers face different reporting requirements, the Navigator offers customized guidance.

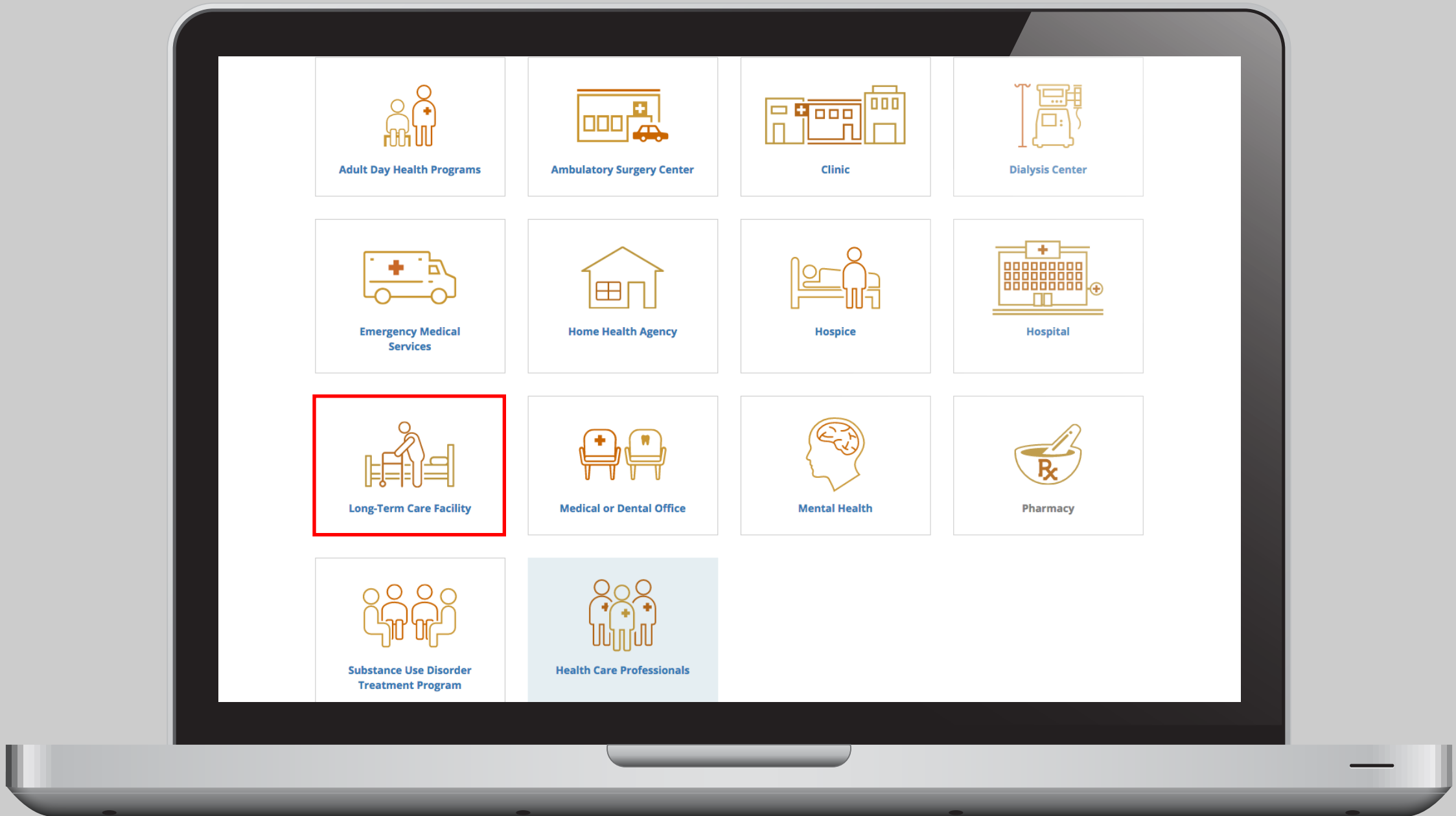


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SELECT YOUR PROVIDER TYPE:

- Adult Day Health Programs
- Ambulatory Surgery Center
- Clinic
- Dialysis Center
- Emergency Medical Services
- Home Health Agency
- Hospice
- Hospital
- Person sitting at a desk
- Two dental chairs
- Brain with a gear
- Mortar and pestle

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YOUR PROVIDER TYPE:



Day Health Programs



Ambulatory Surgery Center



Clinic



Let's take the example of an ambulatory surgery center where a patient was given the wrong dose of a medication during a procedure.
Click the icon...



Home / Provider / Ambulatory Surgery Center



Ambulatory Surgery Center



Below, you'll find adverse and other patient safety events grouped into categories. Click on the most relevant category to see agency-by-agency descriptions of events that must be reported.

Note that safety-related reporting requirements imposed by the Centers for Medicare & Medicaid Services (CMS), MassHealth, or accrediting organizations are not included in the information provided here. Click [here](#) to learn more about what is and is not included in the Navigator.

ADVERSE EVENT CATEGORIES

EVENT TYPE	DESCRIPTION
Abuse or Neglect	Suspected patient abuse, neglect, mistreatment or misappropriation of property
Blood	Collection, administration, storage, handling, etc. of blood products
Criminal	Suspected/potential criminal activity (e.g. sexual assault, impersonation)
Device, Drug or Biologic	Defects, contamination, etc. of drug, biologic, device or similar product; errors in medication administration
Environmental	Gas mishaps, burns, electric shocks, restraints, metallic objects in MRI areas

?
 What to do if your event is reportable under more than one category

...and the next page shows categories of reportable patient safety events.



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Facility Emergency	Fires, labor actions, evacuations, etc.
Fall	Injuries associated with falls
Infection	Healthcare-associated and other infections
Obstetrical / Reproductive	Labor/delivery, artificial insemination, maternal deaths
Patient Protection	Failure to supervise, care for, or safely discharge a patient (e.g. elopement, suicide)
Pressure Ulcer	Certain serious pressure ulcers

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What to do if your event is reportable under more than one category

Glossary

...and the next page shows categories of reportable patient safety events.

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Pressure Ulcer	Certain serious pressure ulcers
Surgical or Invasive Procedure	Wrong patient, wrong site, wrong procedure, foreign object retention, etc.
Test Results	Failure to follow up with test results
Other	Choose this category if your event does not appear to fit elsewhere.

Glossary

OTHER SAFETY REPORTING

EVENT TYPE	DESCRIPTION
Automated Data Collection	Quality indicators for care reimbursement and research
CMS and MassHealth	Broad overview and links to resources related to conditions of coverage and participation in these programs
Communicable Disease or Unusual Illness	Communicable disease, unusual illness, or other health condition of public concern
Disciplinary Action Taken Against a Physician	Professional review action, clinical privilege suspension, or other disciplinary action taken by a facility against a physician
Drug Diversion	Loss or theft of controlled substances
Influenza Vaccination Rate	Vaccination against influenza by health care personnel at your facility
Physician Misconduct	Fraudulent practice of medicine, prescription violations, gross negligence, sexual misconduct or other misconduct by a licensed physician

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What to do if your event is reportable under more than one category

Glossary

OTHER SAFETY REPORTING

EVENT TYPE	DESCRIPTION
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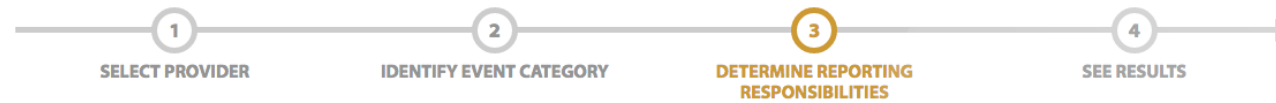
For this example of a medication error, you would select “Device, Drug or Biologic.”



Home / Provider / Ambulatory Surgery Center / Device, Drug or Biologic



Ambulatory Surgery Center Device, Drug or Biologic



Below are detailed descriptions of reportable adverse events, grouped by state or federal agency. Answer the question that appears beneath EACH description. When you're finished, click View Reporting Instructions to move to the next page.

Please note that this section does not yet include reporting requirements for serious adverse drug events (SADEs) under M.G.L. c. 111, § 51H. DPH is expected to promulgate regulations to further specify reporting requirements related to SADEs. Updates will be posted here after they are available.

[PRINT](#)

Serious Reportable Event

Department of Public Health

[Glossary](#)

A patient death or serious injury associated with one of the following must be reported as an SRE:

- The use of contaminated drugs, devices, or biologics provided by the health care setting, or
- The use or function of a device in patient care, in which the device is used or functions other than as intended, or
- Intravascular air embolism that occurs while being cared for in a health care setting, or
- A medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)

The next step helps you determine if and what you need to report based on descriptions of patient safety events from the Department of Public Health and other agencies.

PRINT

Serious Reportable Event

Department of Public Health

Glossary

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MORE INFO

Does your event fit this description?

YES

NO

UNSURE

The Serious Incident section will become available only if "No" or "Unsure" is selected. Otherwise, by selecting 'yes' you will be given directions for reporting an SRE that may also be a serious incident.

Serious Incident

DPH requires you to report any incident that seriously affected the health and safety of a patient or that caused serious physical injury to the patient.

MORE INFO

Does your event fit this description?

YES

NO

UNSURE

The tool provides additional information drawn from relevant laws and regulations to help you make decisions.

MORE INFO

DPH offers the following additional guidance:

- **Contaminated drugs, devices or biologics.** These events are reportable regardless of the source of contamination and/or product. *[Includes the threat of disease that changes the patient's risk status for life-requiring medical monitoring not needed before the event.]* Examples include administration of contaminated vaccine or medication, serious infections from contaminated drugs or devices in an invasive procedure, and occurrences related to use of improperly cleaned or maintained devices.
- **Use or function of a device.** Devices include, but are not limited to, catheters, drains and other specialized tubes, infusion pumps, ventilators, and procedural and monitoring equipment.
- **Intravascular air embolism.** Examples include (but are not limited to) high-risk procedures involving the head and neck, vaginal delivery and caesarean section, spinal instrumentation procedures, and liver transplantation; and low-risk procedures related to lines placed for infusion of fluids in vascular space. Does *not* include neurosurgical procedures that are known to present a high risk of intravascular air embolism.
- **Medication error.** This includes, but is not limited to, death or serious injury associated with:
 - over- or under-dosing,
 - administration of a medication to which a patient has a known allergy or serious contraindication,
 - drug-drug interactions for which there is known potential for death or serious injury, or
 - improper use of single-dose/single-use and multi-dose medication vials and containers leading to death or serious injury as a result of dose adjustment problems

You are required to report an SRE that occurred at another hospital or ambulatory surgery center if you provided services that resulted from the event. You do not have to report the SRE if you have reason to believe the other facility has already reported it to DPH.

Reference: M.G.L. c. 111, § 51H, 105 CMR §§ 130.332, 140.308; [DPH, 2012 SRE Reporting Guidance](#); [Circular Letter #12-9-570](#)

Does your event fit this description?

YES

NO

UNSURE

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MORE INFO

Does your event fit this description?

YES

NO

UNSURE

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✓ Selection recorded

Serious Incident

DPH requires you to report any incident that seriously affected the health and safety of a patient or that caused serious physical injury to the patient.

MORE INFO

Does your event fit this description?

Answer each question, clicking the response that applies to your situation.

Does your event fit this description?

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✓ Selection recorded

Serious Incident

DPH requires you to report any incident that seriously affected the health and safety of a patient or that caused serious physical injury to the patient.

[MORE INFO](#)

Does your event fit this description?

✓ Selection recorded

Major Incident

Quality and Patient Safety Division, Board of Registration in Medicine

QPSD requires you to report any major or permanent impairment of bodily functions or death of a patient not ordinarily expected as a result of the patient's condition on presentation. This is a Type 4 major incident.

Note that it is expected that all events reported to the Department of Public Health as SREs will also be reported to QPSD as major incidents. In addition, QPSD encourages facilities to identify, analyze and report "near miss" incidents.

[MORE INFO](#)

Does your event fit this description?

Answer each question, clicking the response that applies to your situation.

MORE INFO

Does your event fit this description?

YES

NO

UNSURE

✓ Selection recorded

Major Incident

Quality and Patient Safety Division, Board of Registration in Medicine

QPSD requires you to report any major or permanent impairment of bodily functions or death of a patient not ordinarily expected as a result of the patient's condition on presentation. This is a Type 4 major incident.

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MORE INFO

Does your event fit this description?

YES

NO

UNSURE

✓ Selection recorded

Death or Serious Injury Related to a Device

Food & Drug Administration

If a medical device caused or contributed to a patient death or serious injury, inform the FDA.

MORE INFO

Does your event fit this description?

Answer each question, clicking the response that applies to your situation.

MORE INFO

Does your event fit this description?

YES

NO

UNSURE

✓ Selection recorded

Death or Serious Injury Related to a Device

Food & Drug Administration

If a medical device caused or contributed to a patient death or serious injury, inform the FDA.

MORE INFO

Does your event fit this description?

YES

NO

UNSURE

✓ Selection recorded

[VIEW REPORTING INSTRUCTIONS](#)

The Patient Safety Navigator is provided by the [Betsy Lehman Center](#) for informational purposes. You cannot submit adverse event reports or other data through the Navigator. Your use of the Navigator will not be monitored, and no data will be collected beyond what is explicitly noted in the [Website Privacy Statement](#). Although the Betsy Lehman Center intends to maintain the Navigator's contents, we cannot guarantee that the information will be accurate, complete, or up-to-date at all times. You should be aware that regulations and reporting systems are subject to change without our knowledge or could be interpreted differently by the agencies that oversee them. By using the Navigator, you agree that you are solely responsible for determining any reporting obligations applicable to you or your organization. For further terms and conditions, see the [Terms of Use](#).

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[Privacy Statement](#) | [Feedback](#)

Answer each question, clicking the response that applies to your situation.

MORE INFO

Does your event fit this description?

YES

NO

UNSURE

✓ Selection recorded

Death or Serious Injury Related to a Device

Food & Drug Administration

If a medical device caused or contributed to a patient death or serious injury, inform the FDA.

MORE INFO

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YES

NO

UNSURE

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[VIEW REPORTING INSTRUCTIONS](#)

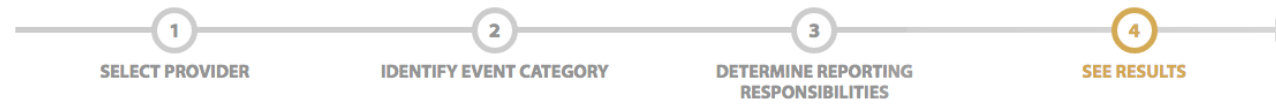
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Then click to see a results page with reporting instructions for that event.



Ambulatory Surgery Center Device, Drug or Biologic



PRINT

Department of Public Health

Serious Reportable Event

You indicated that your event **does not** meet the Department of Public Health's description of a serious reportable event.

Serious Incident

You indicated that your event **does** meet the Department of Public Health's description of a serious incident.

Report to the Department of Public Health.

[VIEW FLOWCHART](#)

[DOWNLOAD FLOWCHART](#)

[VIEW TEXT VERSION](#)



Some patient deaths must also be reported to the state medical examiner. Click for more information.

Quality and Patient Safety Division, Board of Registration in Medicine

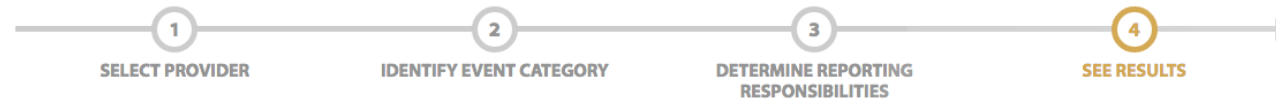
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Home / Provider / Ambulatory Surgery Center / Device, Drug or Biologic / Results



Ambulatory Surgery Center Device, Drug or Biologic



PRINT

Department of Public Health

Serious Reportable Event

You indicated that your event **does not** meet the Department of Public Health's description of a serious reportable event.

Serious Incident

You indicated that your event **does** meet the Department of Public Health's description of a serious incident.

Report to the Department of Public Health.

[VIEW FLOWCHART](#)

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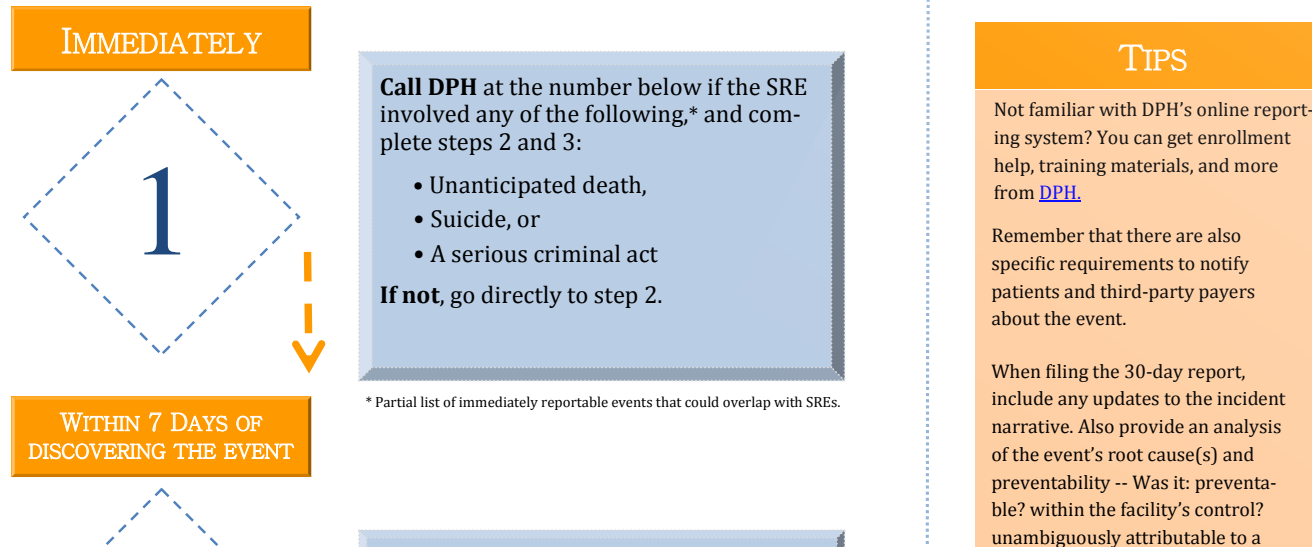
Some patient deaths must also be reported to the state medical examiner. Click for more information.

Quality and Patient Safety Division, Board of Registration in Medicine

View or download the instructions as a flowchart...

How to report SREs to the Department of Public Health

Follow the steps below to report an SRE that occurred at **your** facility. If it occurred at **another** hospital or ambulatory surgery center, you must report the event by fax instead of electronically (use this [form](#)) within 7 days; you do not need to provide a 30-day follow-up report.

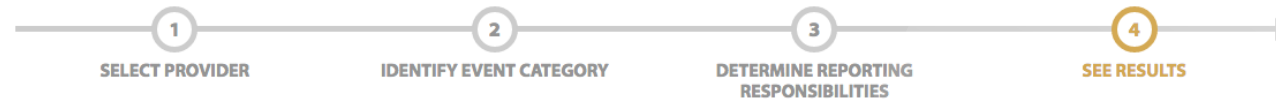




Home / Provider / Ambulatory Surgery Center / Device, Drug or Biologic / Results



Ambulatory Surgery Center Device, Drug or Biologic



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...or in text form.



How to report SREs to the Department of Public Health

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Note: If the SRE occurred at another hospital or ambulatory surgery center, use this form to report by fax within 7 days, instead of electronically. You would not need to provide a 30-day follow-up report.

1. Immediately

If the SRE involved any of the following*, call DPH and complete steps 2 and 3:

- Unanticipated death,
- Suicide, or
- A serious criminal act

(See contact information below).

If not, skip this step and go to step 2

2. Within 7 days [of discovering the event]

Submit an initial report using the [Virtual Gateway - Healthcare Facility Reporting System \(HCFRS\)](#)

3. Within 30 days [of making the initial electronic report]

Submit a follow-up report through HCFRS that reflects the findings of your investigation of the event.

*This is a partial list of immediately reportable events. For the full list, see 105 CMR § 130.331(A) or § 140.307.

Tips:

...or in text form.

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Note: If the SRE occurred at another hospital or ambulatory surgery center, use this [form](#) to report by fax within 7 days, instead of electronically. You would not need to provide a 30-day follow-up report.

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Tips:

Not familiar with DPH's online reporting system? You can get enrollment help, training materials, and more from DPH.

Remember that there are also specific requirements to notify patients and third-party payers about the event.

When filling your 30-day report be sure to include in your preventability determination narrative: identification and analysis of root causes; any updates to the incident narrative; and description of any corrective measures taken.

Resources:

[Related DPH forms and instructions](#)

The tool provides links to the correct forms and websites of government agencies that collect patient safety event information.



Welcome to the Virtual Gateway

Login

Username

Password (Case sensitive)

Login

[Forgot Password](#)

Virtual Gateway Customer Service

Monday through Friday
8:30 am to 5:00 pm
800-421-0938 (Voice)
617-847-6578 (TTY for the
deaf and hard of hearing)

Important Messages

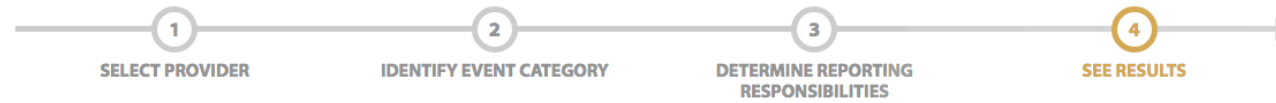
When logging in, you may be required to change your password and update your user profile.
For assistance with logging in, please visit www.mass.gov/vg/loginassistance.

Maintenance Notices

The tool provides links to the correct forms and websites of government agencies that collect patient safety event information.



Ambulatory Surgery Center Device, Drug or Biologic



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Throughout the process, helpful tips are just a click away.

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navigate state and federal requirements for reporting adverse events.

[READ MORE →](#)



HOW TO PLAN

Use these resources to map strategies for preventing patient harm.

[LEARN MORE](#)



HOW TO ANALYZE

Probe root causes to understand what went wrong and prevent recurrence.

[LEARN MORE](#)



HOW TO COMMUNICATE

Inform patients and families – and support medical staff – after an error or unexpected outcome.

[LEARN MORE](#)



HOW TO REPORT

Navigate state and federal patient safety reporting requirements.

[EXPLORE THE TOOL →](#)

Information for:

Consumers

Policymakers

The Patient Safety Navigator shows you how to report and, more importantly, helps you learn from harmful events so you can improve the quality of care for your patients.



PATIENT SAFETY NAVIGATOR

Plan Analyze Communicate Report About this Tool About Us

Medical errors and other patient safety events take place in health care settings across Massachusetts every day, despite best intentions.

This site will help providers of all types navigate state and federal requirements for reporting adverse events.

[READ MORE →](#)



HOW TO PLAN

Use these resources to map



HOW TO ANALYZE

Probe root causes to



HOW TO COMMUNICATE

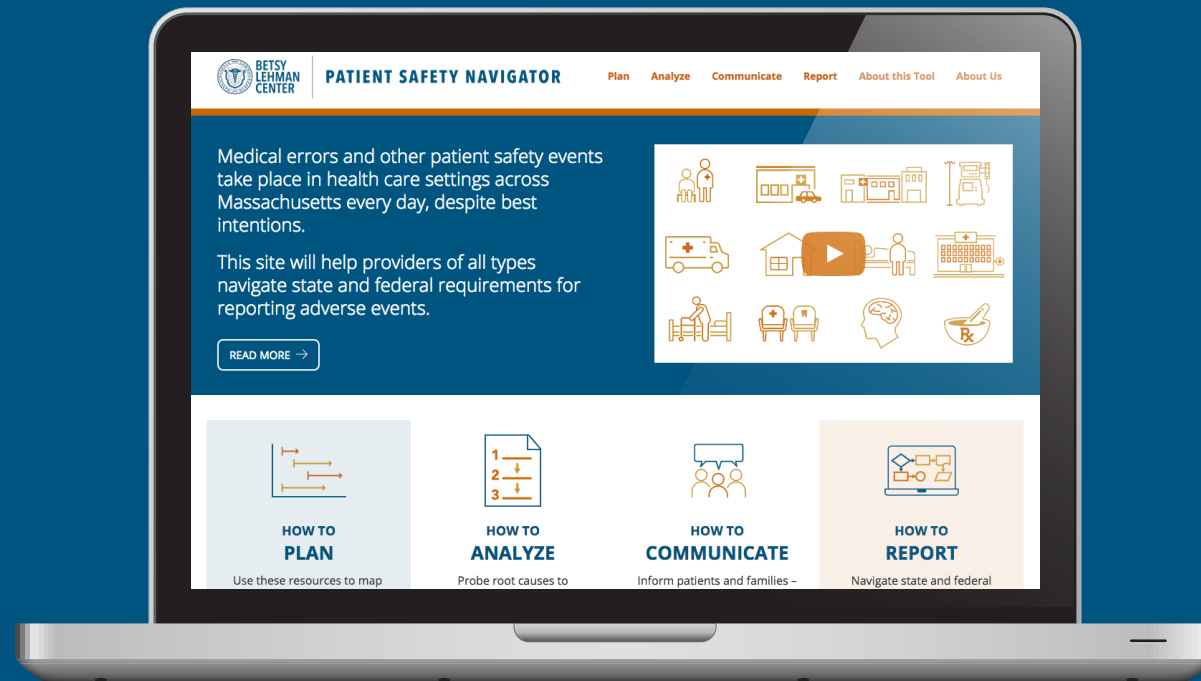
Inform patients and families -



HOW TO REPORT

Navigate state and federal

To learn more, visit navigator.BetsyLehmanCenterMA.gov.



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