



INFECTION CONTROL PLAN TOOLKIT:

CREATING AND MAINTAINING AN EFFECTIVE ROAD MAP
TO YOUR FACILITY'S INFECTION PREVENTION PROGRAM

Pennsylvania Department of Health

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This toolkit was created by the Pennsylvania Department of Health (Department), Bureau of Epidemiology, HAIP Division for PA healthcare facilities to reference as they develop their infection control plans for submission to the Department. The Department respectfully requests that prior to using this document or its content in any manner for other purposes, such as by other entities, that written permission be given by the Department: RA-DHHAI@pa.gov

PURPOSE

Who Is This Toolkit for?

This toolkit is a resource for infection preventionists (IPs) and other healthcare facility personnel (HCP) involved in infection control plan development. IPs can have a background in nursing, medical technology, microbiology, public health, or other allied health disciplines. Other names for an IP include an infection control nurse, infection control officer, infection control coordinator, and infection control professional. Regardless of their title, IPs should have the full support of leadership – to include the formal delegation of authority for implementation of the infection control (IC) program and plan.

What The Toolkit *Is*:

This toolkit was created by the Bureau of Epidemiology’s HAIP Division IC plan review team (or “IC plan review team”) to guide the reader in the creation or revision of an effective IC plan. The toolkit has been broken down into separate pieces or “building blocks” to help the reader craft an integrated, successful plan.

What It *Is Not*:

This toolkit is not designed to be a boilerplate template. An IC plan should be tailored to a facility, its unique characteristics, and specific risks. It is not intended to be read in full, from front-to-back. In a similar way, the regulations it contains are not transcribed in full – but rather, selectively quoted to aid instruction.

Using the Toolkit:

- IPs with new healthcare facilities should incorporate this information while developing a new IC plan.
- IPs with healthcare facilities that have existing plans, or plans that have been returned by the IC plan review team, should take the table of contents as a starting point, and navigate to section(s) as needed.

SCOPE

A Word about Practice Settings:

Some practice information can be specific to the facility setting – whether this is an acute care hospital, long-term care facility, or ambulatory surgery facility. When the content of this toolkit does not apply to all practice settings, specific facility types will be identified using the following symbols:

[HOSP] Hospitals. In Pennsylvania hospitals are licensed as one of the following:

- HOSP-ACU: Acute care hospital
- HOSP-CAH: Critical access hospital
- HOSP-CHD: Children’s hospital
- HOSP-PSY: Psychiatric hospital
- HOSP-RHB: Rehabilitation hospital
- HOSP-LTAC: Long-term acute care hospital

[LTC] Long-term care facilities. May also be referred to as nursing homes, nursing facilities, long-term care nursing facilities. This document does not pertain to assisted living facilities.

[ASF] Ambulatory surgical facilities. May also be referred to as ambulatory surgical centers (ASCs).

Definitions of facility types are available in [Appendix B](#) on pages 25-26. For licensing or other regulatory classification information, please contact the [Bureau of Long Term Care Programs \(RA-DHLTCregs@pa.gov\)](#), or the Bureau of Non Long Term Care Programs ([RA-DHDEPSECOA@pa.gov](#)), housed under the Quality Assurance Deputate (or QA).¹

THE IC PLAN AS “ROAD MAP”

A useful analogy for the IC plan is that of a road map. Like IC plans, the most popular road maps are now electronic. Simplicity, ease of usage, and the flexibility to respond to changes along the way are valuable attributes that apply to plans and road maps alike.

IC Plan – The Road Map

The IC plan can be thought of as a healthcare facility’s road map – it identifies the way that the “driver” – in this case, the organization and its HCP – can get from point A to point B. Facility goals are the destination in this analogy, and the route is made up of the strategies, activities, and metrics that will get the driver where they want to go.

Policies – The Driving Rules/Manual

A policy is a consistent guide to be followed under a given set of circumstances. As with the “rules of the road,” a good policy will provide a framework for decision-making. A policy can be written with – or without – an associated procedure. The HAIP Division has created the following two resources to assist facilities with policy development or enhancement:

- [Policy & Procedure Outline](#)
- [Infection Control Policy & Procedure Development Resource](#)

Procedures – The Driving Directions

Much like driving directions, which tell you when to turn left or right, a procedure is a sequence of steps for completing a given task. A procedure might outline the way in which a policy is to be implemented, but it does not replace the need for a policy. That being said, procedures should be consistent with the policy.



Risk Assessment – The Environment

Just as a driver ideally wouldn't set out on a big trip without knowing the weather, terrain, or potential "roadblocks" they might hit along the way, a facility shouldn't create a plan without identifying some of the risks and barriers they may encounter. The HAIP Division has created the following resource that can be modified and used to perform a risk assessment:

- [Infection Control Risk Assessment Resource](#)



Rules and Regulations – The Compass

Federal, state, and local regulations serve as the magnetic north on a compass in this comparison, enabling the driver to get – and keep – their bearings. The traveler orients to and aligns with this compass, so that they can navigate the map without veering unexpectedly off course.

The IC Plan Review Team – The Navigational System

The best systems seamlessly integrate many different aspects, so that the driver can maximize the efficiency of their trip and cut down on needless time spent by the side of the road poring over a map. They enable drivers – in this case, facility HCP – to optimize for their chosen destination, redirecting the driver as needed to avoid slowdowns and other barriers.

IC PLANS: AN OVERVIEW

An infection control (IC) plan is a [legal requirement](#) for Pennsylvania healthcare facilities. Information on this law is included on page [11](#) of the toolkit. Beyond the requirement for a plan, developing a program in this way makes good business sense. An IC plan is a living document, so it should provide HCP with a clear, up-to-date view of the facility's IC program. It is a cohesive, standalone resource that will provide a return on your organization's investment by helping to prevent costly healthcare-associated infections (HAIs). Here are a few more key points about IC plans to consider:

- An IC plan is a key component of a robust IC program.
- An IC plan serves as a comprehensive framework for effective program implementation.
- Much like a strategic or business plan, it can be thought of as an organizational “road map.” For this reason, many facilities will choose to include their vision, mission, and values statements in their plans.
- An IC plan is more than just a policy and procedure manual. For example, a plan should include organizational goals (**S**pecific, **M**easurable, **A**chievable, **R**elevant, **T**ime-Bound,), which are updated annually and based off of the highest scored items from the annual risk assessment. In this way, information is synthesized across plan and risk assessment.²
- While written by IC departments, plans can benefit from the contributions of other departments like quality, nursing education, central sterile processing, or facilities.
- The IC plan is updated annually, to reflect changes in practice, priorities, regulations, evidence-based guidelines, national standards, and consensus documents.

“An IC plan serves as a framework for effective program implementation.”

- The complexity of an IC plan can increase with the complexity of the healthcare facility structure it reflects. The addition of service lines, campuses, and other factors can and should trigger revisions to the plan.
- The plan should be readily accessible to HCP who are educated on its contents and use. Many facilities make their IC plan available electronically, and include hyperlinks to related content.
- Pennsylvania is unique in its regulatory authority for IC plan review. By enacting the Medical Care Availability and Reduction of Error (MCARE) Act in 2002, the General Assembly requires that healthcare facilities develop and implement an IC plan that includes specific components (corresponding to the components of the law). In addition to ensuring that plans align with the MCARE and other applicable laws (such as federal and state codes), the IC plan review team partners with facilities to ensure that IC plans reflect current best practices.

- An IC plan is supported by an annual risk assessment (which is discussed in greater detail on page 9), as well as policies and procedures that are updated:
 - [HOSP] every 2 years, [LTC] annually [ASF] recommend annually
- An IC plan, risk assessment, and policies and procedures should receive formal approval from a healthcare facility's infection control committee (or ICC). The resulting documents should therefore include certain key fields – such as the name of the specific facility in question (plus any logo or branding); and the creation, effective, review, and revision dates. The document should also be signed and dated by the ICC signatory.
- While regulatory and accreditation requirements can be referenced, the IC plan and policies are to be facility specific versus only containing copied and pasted content from regulations, guidelines or standards. The same is true for manufacturer's instructions for use (or IFUs). While the plan and supporting documents can reference and should require HCP to follow IFUs, their content should not be duplicated.

POLICIES AND PROCEDURES

Many of the same best practices that are true of IC plans, also hold for policies and procedures:

- A policy establishes and communicates in writing the behavior, actions, or processes that all employees are expected to follow and provides for consistency in the standards of practice within an organization. A policy explains the rule that must be followed, and not how to implement the rule.
- A procedure provides step-by-step instructions and identifies who is responsible for completing them.
- A comprehensive, well-managed set of policies and procedures provides clear guidance to HCP when they need it.
- Policies and procedures should be developed in a systematic manner, so that they have a consistent organization and format. This will ensure that a consistent standard of care is provided, which reduces medical errors and increases patient safety. Many facilities will use a facility template for this purpose.
- Regulators will ask about policies, and check to see if an organization is following them. Compliance with policies and procedures should therefore be regularly enforced and periodically reassessed, using feedback from HCP about potential workarounds or reasons for noncompliance.
- HCP should be educated on these policies and procedures, both prior to their introduction and annually, so staff will be knowledgeable.
- The HAIP Division has created the following two resources to assist facilities with policy development or enhancement:
 - [Policy & Procedure Outline](#)
 - [Infection Control Policy & Procedure Development Resource](#)

INFECTION PREVENTION AND CONTROL RISK ASSESSMENTS

Risk assessments play a fundamental role in the work of an IC program. Mitigating risk – to exposure, infection, or unsafe practices – is one of an IP’s central activities. A risk assessment works by enabling a facility to help identify the unique risks they face, and prioritize their management. These risks can vary according to the environment, infrastructure, services provided, and population served. A few things to keep in mind include:

- An infection prevention and control risk assessment is different from a gap analysis or all-hazards self-assessment, or rounds checklists.³ It is also different from an infection control risk assessment (ICRA) for construction.⁴
- Like the IC plan, an infection prevention and control risk assessment is a living document that is tailored to the facility, and updated annually or when there are significant changes, such as a change of building, ownership, addition of a service line, or changes in staffing or turnover.
- Work on the infection prevention and control risk assessment should involve a multidisciplinary committee (in many cases, this is the facility ICC). While the risk assessment and its scoring can be subjective, the inclusion of many voices and perspectives can help to minimize such subjectivity bias. These might include quality, risk management, front-line HCP, pharmacy and laboratory services, and facilities.

“The risk assessment is a living document that is tailored to the facility, and updated annually or when there are significant changes.”

- The IP and their multidisciplinary team should harness data – for example, HAI rates, vaccination reports, sharps injury reports, serious event reports, performance information, audit and rounding information, survey findings, and other information – to identify new or existing risks.
- There are different kinds of risks (for instance, medical device utilization or building age), which can be thought of as falling into different categories or “buckets.” These include environmental risks, community risks, patient / resident risks, HCP risks, and procedure-related risks.⁵
- Risks are then listed, scored, and ranked according to specific criteria like probability, severity (should the risk occur), impact (to the patient or facility), and facility preparedness to address the issues, should they arise. Priority can be given to the highest-scored risks, so that resources can be allocated appropriately and they can be addressed first.

- New facilities performing risk assessments without historic data should still complete a baseline risk assessment to assist in plan development. Consider the following alternative data sources:
 - State and national HAI reports
 - Data from the National Surgical Quality Improvement Program (NSQIP)⁶
 - Service registries
 - Data from specialty-specific accrediting bodies
 - Data from similar healthcare system facilities
- Risk assessment templates are available for use by healthcare facilities. Similar to policy and procedure templates, versions are available that are specific to facility type and services provided. A sample is also available in the “Example Documents” section on page [27](#).
- The HAIP Division has created the following resource that can be modified and used to perform a risk assessment:
 - [Infection Control Risk Assessment Resource](#)

THE MCARE LAW

The Medical Care Availability and Reduction of Error (MCARE) Act (Act 13) was signed into law on March 20, 2002.⁷ Also known as Act 13, it was passed by the Pennsylvania General Assembly to improve patient safety and promote the welfare of Pennsylvania citizens. Pennsylvania's Health Care Associated-Infection Prevention and Control Act (Act 52) of 2007 amended the MCARE Act, adding Chapter 4.⁸ It recognizes that healthcare-associated infections (or HAIs) are a public health issue, and establishes Pennsylvania as a leader in their prevention and reduction. There are a few different sections of the law that can impact an IC plan.

SECTION 308: REPORTING AND NOTIFICATION⁹

- **308 (a):** *A health care worker who reasonably believes that a serious event or incident has occurred shall report the serious event or incident... The report shall be made immediately or as soon thereafter as reasonably practicable, but in no event later than 24 hours after the occurrence or discovery...* All HAIs are considered to be serious events, and must be reported.
- **308 (b):** *A medical facility through an appropriate designee shall provide written notification to a patient affected by a serious event... within seven days of occurrence or discovery of a serious event.* Patient notification that an HAI has occurred must be in writing, within 7 days of its occurrence or discovery.

For additional information on reporting, please see Section 404 on page [16](#).

SECTION 403: INFECTION CONTROL PLAN¹⁰

- **403: Infection control plan.** While the law refers to an “infection control plan,” the trend seems to be that more facilities are now referring to their plans as “infection prevention plans” or “infection prevention and control plans.” This is in recognition of the importance of preventing – and not just controlling – infections. Regardless of its title, facilities must have a comprehensive plan for their infection control program to be in compliance with the law.
- **403 (a)(1): A multidisciplinary committee.** This section refers to the healthcare facility's infection control committee (or ICC). The ICC should meet on at least a quarterly basis. Subsection (i)-(x) contains information on the representatives a committee should include. These individuals, as representatives of the ICC, should attend meetings regularly. The committee chair or co-chairs should also be identified. On a related note: Section 310 of the MCARE Law requires healthcare facilities to have a patient safety committee; a quality assessment and performance improvement (QAPI) committee is also a requirement of select state and federal codes.^{11,12,13,14,15} While there can be overlap between these different committees, a distinct ICC must still be identified. The relationship between these committees and the governing body should be clearly outlined in the IC plan. Using an organizational chart can provide lots of information about reporting structure at a glance.
- **403 (a)(2): Effective measures for the detection, control and prevention of health care-associated infections.** This section encompasses a wide range of information. Some

facilities find it helpful to break the plan down into separate sections corresponding to prevention, detection, and control. In reality, there is some overlap – not only between prevention, detection, and control activities; but with these activities and other sections of the MCARE Law. A full discussion of this area is beyond the scope of this toolkit, but measures can include:

- Employee health
 - Components of a strong employee health program should be identified, such as pre-employment screening, HCP vaccination/immunity, communicable disease exposures and subsequent work restrictions, assessment process and/or work restrictions for dietary and HCP with open skin lesions and (bloodborne pathogen) BBP exposure management.^{16,17}
- Screening of patients and residents prior to or upon admission (e.g. for respiratory viruses , other communicable diseases, multi-drug resistant organisms (MDROs), etc.)
- Standard Precautions¹⁸
 - Elements include but are not limited to hand hygiene, personal protective equipment (PPE), respiratory hygiene/cough etiquette, injection and sharps safety, patient placement, etc.^{19,20,21,22} All elements of Standard Precautions as defined by the CDC ^{23, 34} should be addressed in the plan.
- Patient education
 - Education of the patient, their family, or other designees on subjects such as hand hygiene; device, wound, or post-operative care; pre-operative CHG bathing or nasal decolonization; the chain of infection; Transmission-Based Precautions (TBPs); reporting the signs and symptoms of infection; etc.
- TBPs (e.g. Airborne, Droplet, and Contact Precautions)²³
 - This section should incorporate a basic review of the components of airborne, droplet, and contact precautions. It should also review how patients on TBPs will be cared for and managed until they are transferred or discharged as in the case of those facilities without airborne infection isolation rooms (AIIR).
- Cleaning and disinfection of the environment and patient care equipment
 - Environmental cleaning includes things like high-touch surfaces, patient care areas, shared spaces like waiting rooms, operating and procedure rooms, etc.²⁴
 - Patient care equipment includes the many items that are used on a daily basis by HCP, from glucometers and bladder scanners to vital signs and cardiac equipment.²⁵
- Handling, transport, and storage of equipment, linens, supplies, and other items.²⁶
 - Clean vs. Dirty: Include information in the plan about how clean and dirty supplies are kept separate, as well as the process for HCPs to tell whether an item has been reprocessed and is ready for use.
 - Clean vs. Sterile: Information should be included in the plan about how clean and sterile supplies are stored separately, as well as sterile storage requirements. Event-related sterility is a concept that should be addressed, if applicable.

- Proper handling and disposal of municipal, regulated, and hazardous waste should be discussed (e.g. in a policy). Working with life safety, if appropriate, can be helpful.
- Disinfection and sterilization of instruments and devices²⁷
 - The types of sterilization and quality controls used at the facility should be discussed in the plan.
 - Where relevant to the facility, this should include a minimum of high-level disinfection (HLD) of items like anesthesia and respiratory equipment (laryngoscope blades/handles, laryngoscope mask airways (LMAs)) flexible endoscopes, specula, and ultrasound probes.
- HAI and infection control breach reporting²⁸
- Outbreak investigation and management²⁹
- Compliance monitoring and quality improvement
 - Auditing of staff compliance of hand hygiene, PPE use, immunization rates, and other infection control practices. Compliance monitoring measures, including how feedback is provided, should be described in the plan. Auditing frequency should also be outlined, as well as the process for addressing noncompliance. See Section 403 (c) on page [16](#) for more information.
- **403 (a)(3): Culture surveillance processes and policies.** A robust surveillance plan is a cornerstone of an effective IC plan that identifies HAIs, communicable diseases, and outbreaks. Surveillance should take place on a consistent, continual basis and extend to all units, procedures. IPs should complete training in NHSN surveillance upon hire and on an annual basis, and make use of consistent definitions, as identified in the MCARE Law and PA Bulletins, appropriate for the practice setting.³⁰ **[HOSP] Hospitals** must use a qualified electronic surveillance system (QESS), while LTCs and ASFs may use a paper-based method for data collection, management, and analysis. See Section 404 (d)(1)-(5) on page [17](#) for hospital QESS requirements. A mix of surveillance data sources should be used, and can include:
 - Laboratory-based
 - Chart review
 - Pharmacy antibiotic monitoring
 - Surgeon reporting (e.g. attestation letter, line list based on NHSN definitions)
 - Post-discharge phone calls or surveys (note: follow-ups should be done at 30 and 90 days for SSI surveillance, based on the surveillance period)
 - Post-discharge readmissions, office visits, home health visits
 - Reports from other healthcare facilities
- **403 (a)(4): A system to identify and designate patients known to be colonized or infected with MRSA or other MDRO.**
 - Facilities should screen patients prior to or during admit. Screening should encompass things like communicable disease (or recent exposure), and colonization or infection with multi-drug resistant organisms (MDROs) like *Candida auris* (*C. auris*), Carbapenem-resistant Enterobacterales (CRE), extended spectrum beta-lactamases

(ESBLs), methicillin-resistant *Staphylococcus aureus* (MRSA), or vancomycin-resistant enterococci (VRE).

- **[HOSP]** The procedures necessary for requiring cultures and screenings for nursing home residents admitted to a **hospital**
- **[HOSP]** The procedures for identifying other high-risk patients admitted to the **hospital** who necessitate routine cultures and screening (e.g. dialysis patients, patients with a history of incarceration or IV drug use, travel / healthcare outside of the US).
 - Some of these groups will be identified during the annual IC risk assessment.
- **403 (a)(5): The procedures and protocols for staff who may have had potential (unprotected) exposure to a patient or resident known to be colonized or infected with MRSA or MDRO...**
 - There are challenges with implementing this particular component, given the fact that culture and prophylaxis are not recommended for MDROs outside of outbreak settings. Facilities should focus on documentation, reporting, quality improvement (e.g. root cause analyses to prevent future occurrence), and adhering to CDC and OSHA guidelines.³¹
- **403 (a)(6): An outreach process for notifying a receiving health care facility or an ambulatory surgical facility of any patient known to be colonized prior to transfer within or between facilities.**
 - The best practice is to include both a verbal and a written report when transferring a patient between facilities. There should be an interfacility transfer form that includes infection control information. The CDC has developed a good example.³² Many county-municipal health departments and health systems have their own versions.
- **403 (a)(7): A required infection-control intervention protocol which includes:**
 - **(i)** Infection control precautions, based on nationally recognized standards, for general surveillance of infected or colonized patients.
 - The reader will note that this specific subsection pertains to “surveillance of infected or colonized patients.” As such, Section 402 of the law defines “nationally recognized standards” as “Standards developed by the Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and its National Healthcare Safety Network (NHSN).”³³ Related laws also discuss adherence to nationally recognized guidelines and standards. Please see the “Other Relevant Laws” section on page [18](#) for more information.
 - **(ii)** Intervention protocols based on evidence-based standards.³⁴
 - IPs should be familiar with current evidence-based standards from organizations like the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI), American Society for Healthcare Engineering (ASHE), Association for the Health Care Environment (AHE), Association for Professionals in Infection Control and Epidemiology (APIC), Association of periOperative Registered Nurses (AORN), Centers for Disease Control & Prevention (CDC), Facility Guidelines Institute (FGI), Healthcare Sterile Processing Association (HSPA – formerly IAHCMM), Infectious

Diseases Society of America (IDSA), Society for Healthcare Epidemiology of America (SHEA), and others.^{35,36,37,38,39,40,41,42,43,44,45}

- **(iii)** Isolation procedures. The current nomenclature is Transmission-Based Precautions (TBPs)
 - Facilities will have different capabilities depending upon their infrastructure. Regardless of the facility's setup, however, the IP should have the authority to initiate TBPs as they see fit to lessen the risk that an infection will spread. P & Ps should identify persons other than the IP who has the authority to initiate TBPs as well as the authority and process to discontinue TBPs based on CDC recommendations²³. Signage and PPE should be used by HCP for patients in TBPs, and information should be added to the paper chart or electronic medical record so that HCP working with patients are aware of their status.
- **(iv)** Physical plant operations related to infection control.
 - Systems for managing air and water – such as HVAC and plumbing – should receive regular and preventive maintenance by qualified personnel. HCP should monitor these systems on a regular basis, and know the steps to take if control ranges are not maintained. Hospitals and nursing homes are required by CMS to have a water management plan.⁴⁶
- **(v)** Appropriate use of antimicrobial agents.
 - While not all facilities are required to have an antimicrobial/antibiotic stewardship program or committee, key program activities should still be performed, such as adherence to recognized guidelines; HCP education on the elements of antimicrobial/antibiotic stewardship; the development and use of a facility antibiogram; and pharmacist review of antibiotic starts and stops. Guidance from the CDC is available for the inpatient, outpatient, and long-term care settings.^{47,48,49} See the “Other Relevant Laws” section on page 18 for hospital and LTCF antimicrobial/antibiotic stewardship program requirements.
- **(vi)** Mandatory education programs for personnel.
 - The plan should specify what groups are included in mandatory education programs – for example, permanent and contracted HCP, providers, students, or volunteers. It should be done upon hire (prior to working with patients), annually, and whenever information changes. It should be validated through competencies and audits, even if it is done by someone else in the case of contractors. It encompasses areas of the IC program already detailed elsewhere in this toolkit.
 - The infection control plan, policies, procedures, manufacturer IFUs, exposure control plans, Safety Data Sheets (SDS), and other relevant resources should be readily accessible by HCP, who are educated on their use.
- **(vii)** Fiscal and human resource requirements.
 - The plan should contain clear statements about how many IPs the healthcare facility has, whether or not they are full-time employees, and the number of hours per week that they can devote to their IC work. It should also include information about resources – such as access to journals and IC practice standards, memberships to professional organizations like APIC, conference attendance,

educational classes or programs, software, and any other resources – the program has funded.

- **403 (a)(8):** *The procedure for distribution of advisories issued under Section 405 (b)(4) so as to ensure easy access in each health care facility for all administrative staff, medical personnel and health care workers.*
 - The Pennsylvania Patient Safety Authority (or PSA) puts out rolling online journal articles and an annual print/digital Patient Safety Journal that has replaced its advisories.⁵⁰
 - Department of Health advisories are available in the form of health alerts (or HANs) and memos.⁵¹
- **403 (b):** *The department shall review each health care facility's and ambulatory surgical facility's infection control plan to ensure compliance under the Health Care Facilities Act and section 408 (3). If, at any time, the department finds that an infection control plan does not meet the requirements of this chapter or any applicable laws, the health care facility or ambulatory surgical facility shall modify its plan to come into compliance.* The IC plan review team also considers other applicable laws when reviewing plans, including federal and state codes, OSHA standards, the Healthcare Facilities Act, and the Confidentiality of HIV-Related Information Act. See page [18](#) for more.^{52,53,54,55,56,57,58,59,60,61,62,63}
- **403 (c):** *Compliance with the infection control plan shall be enforced by the facility.* Facilities should have a process in place for ensuring HCP compliance. Many facilities draw upon the concept of “just culture” to emphasize the importance of shared accountability. Under this model, the response to an error or near miss has to do with the type of behavior associated with the event (e.g. at-risk and reckless behavior, as opposed to human error).⁶⁴ This should include the management of ongoing HCP and provider noncompliance with the plan and policies, up to and including termination.

SECTION 404: HEALTHCARE FACILITY REPORTING⁶⁵

Pennsylvania is one of 37 states with HAI reporting mandates, in which states have laws requiring the reporting of HAI data to the National Healthcare Safety Network (or NHSN).^{66,33}

- **[LTC] 404 (a):** *...a nursing home shall also electronically report health care-associated infection data to the department and the authority using nationally recognized standards based on CDC definitions...* Although nursing homes report HAIs to the Pennsylvania Patient Safety Reporting System (PA-PSRS), revised McGeer Criteria are used, with further modifications based on CDC criteria.^{67,68} This allows for consistency in reporting.
- **[HOSP] 404 (b):** *...A hospital shall report health care-associated data to the CDC and its National Healthcare Safety Network...*
 - **[HOSP] 404 (b)(1):** *Report all components as defined in the NHSN Manual, Patient Safety Component Protocol... for all patients throughout the facility on a continuous basis.*
 - **[HOSP] [ASF] Hospitals** and **ASFs** that share a CMS certification number (CCN) should use NHSN Patient Safety Component criteria.⁶⁹

- **[ASF]** ASFs that do not share a CCN with a hospital should use NHSN Outpatient Procedure Component criteria.⁷⁰
- **[HOSP]** 404 (d): ***Qualified electronic surveillance system. --A qualified electronic surveillance system shall include the following minimum elements:***
 - Hospitals** must have a qualified electronic surveillance system (QESS) unless their strategic assessment continues to identify barriers to implementation.
 - **[HOSP]** 404 (d)(1): ***Extractions of existing electronic clinical data from health care facility systems on an ongoing, constant and consistent basis.***
 - **[HOSP]** 404 (d)(2): ***Translation of nonstandardized laboratory, pharmacy and/or radiology data into uniform information that can be analyzed on a population-wide basis.***
 - **[HOSP]** 404 (d)(3): ***Clinical support, educational tools and training to ensure that information provided under this subsection will assist the hospital in reducing the incidence of health care-associated infections in a manner that meets or exceeds benchmarks.***
 - **[HOSP]** 404 (d)(4): ***Clinical improvement measurements designed to provide positive and negative feedback to health care facility infection control staff.***
 - **[HOSP]** 404 (d)(5): ***Collection of data that is patient-specific for the entire facility.***

SECTION 405: PATIENT SAFETY AUTHORITY JURISDICTION

HAIs are considered to be serious events. As such, they require reporting and written patient/resident notification. See page [11](#) for more information.

405 (a): *The occurrence of a health care-associated infection in a health care facility shall be deemed a serious event as defined in section 302...*

OTHER RELEVANT LAWS

One thing many facilities might not realize is that plan review entails more than just the MCARE Law – plan reviewers must also consider other applicable laws. See Section 403 (b) on page [16](#) above for more information.



Federal Regulations

Federal regulations include OSHA regulations; Federal Conditions of Participation for Hospitals; Conditions for Coverage for ASCs, Requirements for States and Long-Term Care Facilities. [61,52,53,54](#)



State Regulations

State laws and statutes also include the Confidentiality of HIV-Related Information Act; Health Care Facilities Act (HCFA); and PA Code for reportable diseases, hospitals, ASFs, and nursing homes. It also includes laws governing water use. [63,62,55,56,57,58,59](#)



Other Regulations

Other regulations include county and local public health rules and regulations.

- Facilities must adhere to:
 - **[HOSP]** Nationally recognized infection control guidelines.
 - **[LTC]** Nationally recognized infection control guidelines.
 - **[ASF]** Nationally recognized infection control guidelines.
- Authority should be delegated by the governing body to the ICC and IP:
 - Authority for **oversight** of the IC program should be delegated to the ICC.
 - Authority for **implementation** of the IC program should be delegated to the IP. [60](#)
- IP(s) must be qualified through training in infection prevention and control.
 - The Certification in Infection Control (CIC) is a widely recognized IP credential. [71](#)
 - The CDC and CMS offer a free training series in infection control for LTC. [72](#)
 - APIC offers trainings for the ASF and LTC settings. [73](#)
 - AORN offers an online training course in infection control for ASFs. [74](#)
- The facility must have a program for bloodborne pathogens exposure control. [75](#)
- The facility must have a respiratory protection program with required facility-specific procedures and elements for required respirator use if the facility's hazard assessment indicates a potential risk to HCP. [76,77](#)
- Facilities that must have formal QAPI programs. [13,14,15,](#)
- **[HOSP]** **[LTC]** Both **Hospitals** and **LTCFs** must have formal antimicrobial/antibiotic stewardship programs. [78,79](#)

- HCP and LTC residents must receive education about COVID-19 and be offered COVID-19 vaccination.⁸²
- The facility must have policies for the monitoring and maintenance of water systems.⁸³
 - **[HOSP]** **[LTC]** **Hospitals** and **LTCFs** must have a formal water management program.

ADDITIONAL CONSIDERATIONS

The IC Plan Review Team - Partners in Collaboration:

The Bureau of Epidemiology's HAIP Division IC plan review team is made up of infection preventionists who are Certified in Infection Control.⁷² The IC plan review team brings together professionals with experience in nursing, public health, and medical technology to provide subject matter expertise to healthcare facilities working on their infection prevention and control plans. A facility-centered approach ensures that solutions are tailored to meet each facility's unique needs.

PA DOH Resources:

The HAIP Division has a [website](#) that includes many additional resources that can be helpful when establishing an IC program plan.⁸⁴

Staying Current:

As part of their program implementation, IPs stay up-to-date with changing guidelines, recommendations, and requirements. This includes following changes to federal, state, and local regulations; and engaging in professional development.

This toolkit was created by the Pennsylvania Department of Health (Department), Bureau of Epidemiology HAIP Division for PA healthcare facilities to reference as they develop their infection control plans for submission to the Department. The Department respectfully requests that prior to using this document or its content in any manner for other purposes, such as by other entities, that written permission be given by the Department: RA-DHHAI@pa.gov

APPENDIX A: RESOURCES

1. PA Department of Health (DOH). [Bureau of Quality Assurance](#).
2. CDC. [Developing Program Goals and Measurable Objectives](#).
3. CDC. [Emergency Preparedness and Response](#).
4. ASHE. [Infection Control Risk Assessment 2.0 Toolkit for Construction & Renovation](#).
5. Joint Commission. [The Joint Commission Guide to Risk Assessment](#).
6. American College of Surgeons. [National Surgical Quality Improvement Program](#).
7. [PA Medical Care Availability and Reduction of Error \(MCARE\) Act](#).
8. [Health Care Associated-Infection Prevention and Control Act](#).
9. PA MCARE Law. [Section 308, Reporting and Notification](#).
10. PA MCARE Law. [Section 403, Infection Control Plan](#).
11. PA MCARE Law. [Section 310, Patient Safety Committee](#).
12. Pennsylvania Code. Title 28, Health and Safety. Subpart F, Ambulatory Surgical Facilities. Chapter 557, Quality Assurance and Improvement. [§ 557.4. Quality Assurance and Improvement Committee](#).
13. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter B, Medicare Program. Part 416, Ambulatory Surgical Services. Subpart C, Specific Conditions for Coverage. [§ 416.43 Conditions for coverage - Quality assessment and performance improvement](#).
14. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. Part 483, Requirements for States and Long Term Care Facilities. Subpart B, Requirements for States and Long Term Care Facilities. [§ 483.75 Quality assurance and performance improvement](#).
15. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. Part 482, Conditions of Participation for Hospitals. Subpart C, Basic Hospital Functions. [§ 482.21 Condition of participation: Quality assessment and performance improvement program](#).
16. Centers for Disease Control and Prevention (CDC). [Infection Control in Healthcare Personnel](#).
17. CDC. [Recommended Vaccines for Healthcare Workers](#).
18. CDC. [Standard Precautions for All Patient Care](#).
19. CDC. [Hand Hygiene in Healthcare Settings](#).
20. PA DOH. [Make Your Intention Prevention Clean Hands Stop the Spread](#).
21. CDC. [Respiratory Hygiene/Cough Etiquette](#).
22. CDC. [Sharps Safety for Healthcare Settings](#).
23. CDC. [Isolation Precautions](#).
24. CDC. [Environmental Infection Control Guidelines](#).

25. CDC. [Infection Prevention During Blood Glucose Monitoring and Insulin Administration.](#)
26. APIC. [Strategies to Mitigate Cross Contamination of Non-Critical Medical Devices – An APIC Issue Brief.](#)
27. CDC. [Disinfection and Sterilization.](#)
28. CDC. [HAI Outbreak Investigations Toolkit.](#)
29. CDC. [Outbreak Investigations in Healthcare Settings.](#)
30. Commonwealth of Pennsylvania. [Pennsylvania Code & Bulletin.](#)
31. CDC. [Multidrug-Resistant Organisms \(MDRO\) Management.](#)
32. CDC. [Inter-Facility Infection Control Transfer Form for States Establishing HAI Prevention Collaboratives.](#)
33. CDC. [National Healthcare Safety Network \(NHSN\).](#)
34. CDC. [Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings.](#)
35. [American National Standards Institute.](#)
36. [Association for the Advancement of Medical Instrumentation.](#)
37. [American Society for Healthcare Engineering.](#)
38. [Association for the Healthcare Environment.](#)
39. [Association for Professionals in Infection Control and Epidemiology.](#)
40. [Association of periOperative Registered Nurses.](#)
41. [Centers for Disease Control & Prevention.](#)
42. [Facility Guidelines Institute](#)
43. [Healthcare Sterile Processing Association](#)
44. [Infectious Diseases Society of America.](#)
45. [Society for Healthcare Epidemiology of America.](#)
46. CMS. June 2, 2017. S&C 17-30-Hospitals/CAHs/NHs. [Requirement to Reduce *Legionella* Risk in Healthcare Facility Water Systems to Prevent Cases and Outbreaks of Legionnaires' Disease \(LD\).](#)
47. CDC. [Core Elements of Hospital Antibiotic Stewardship Programs.](#)
48. CDC. [Core Elements of Outpatient Antibiotic Stewardship.](#)
49. CDC. [Core Elements of Antibiotic Stewardship for Nursing Homes.](#)
50. Pennsylvania Patient Safety Authority. [Patient Safety Journal.](#)
51. Pennsylvania DOH. [PA Health Alert Network \(PA-HAN\).](#)
52. Code of Federal Regulations. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. [Part 482, Conditions of Participation for Hospitals.](#)
53. Code of Federal Regulations. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter B, Medicare Program. Part 416, Ambulatory Surgical Services. [Subchapter C, Specific Conditions for Coverage.](#)
54. Code of Federal Regulations. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. [Part 483, Requirements for States and Long Term Care Facilities.](#)

55. Pennsylvania Code. Title 28, Health and Safety. [Chapter 27, Communicable and Noncommunicable Diseases](#).
56. Pennsylvania Code. Title 28, Health and Safety. Part IV, Health Facilities. [Subpart B. General and Special Hospitals](#).
57. Pennsylvania Code. Title 28, Health and Safety. Part IV, Health Facilities. [Subpart C. Long-Term Care Facilities](#).
58. Pennsylvania Code. Title 28, Health and Safety. Part IV, Health Facilities. [Subpart F. Ambulatory Surgical Facilities](#).
59. United States Environmental Protection Agency. [Water Quality Standards Regulations: Pennsylvania](#).
60. Pennsylvania Code. Title 28, Health and Safety. Part IV, Health Facilities. Subpart F, Ambulatory Surgical Facilities. Chapter 567, Environmental Services. § 567.2, Committee responsibilities. [\(2\). The designation of one full-time or one part-time employe \[sic\] responsible for developing and monitoring the infection control program...](#)
61. [Occupational Safety and Health Administration \(OSHA\)](#).
62. [Health Care Facilities Act of Jul. 19, 1979, P.L. 130, No. 48, Cl. 35](#).
63. [Confidentiality of HIV-Related Information Act – Legislative Intent, Consent to HIV-Related Tests and Counseling Act of Jul. 7, 2011. P.L. 274, No. 59, Cl. 35](#).
64. AHRQ. [Culture of Safety](#).
65. PA MCARE Law. [Section 404. Health care facility reporting](#).
66. CDC. [Health Department HAI/AR Programs](#).
67. Pennsylvania Patient Safety Reporting System (PA-PSRS). Training Manual and Users' Guide. Using the Pennsylvania Patient Safety Reporting System (PA-PSRS). [Nursing Home Event Reporting](#). *User must be logged in to access.*
68. PA Patient Safety Authority (PSA). [Program Memorandum No. 2016-03: Update to PA-PSRS HAI Criteria for Nursing Homes](#). *User must be logged in to access.*
69. CDC. National Healthcare Safety Network (NHSN). [Patient Safety Component](#).
70. CDC. National Healthcare Safety Network (NHSN). [Outpatient Procedure Component](#).
71. APIC. [CIC Certification](#).
72. CDC. [Infection Prevention Training](#).
73. APIC. [Online Learning](#).
74. AORN. [ASC Infection Prevention Online Course](#).
75. OSHA. Bloodborne Pathogens Standard. Title 29, Labor. Subtitle B, Regulations Relating to Labor. Chapter XVII, Occupational Safety and Health Administration, Department of Labor. Part 1910, Occupational Safety and Health Standards. Subpart Z, Toxic and Hazardous Substances. [§ 1910.1030 Bloodborne pathogens](#).
76. Code of Federal Regulations. Title 29, Labor. Subtitle B, Regulations Relating to Labor. Chapter XVII, Occupational Safety and Health Administration, Department of Labor. Part 1910, Occupational Safety and Health Standards. Subpart I, Personal Protection Equipment. [§ 1910.134 \(c\) Respiratory Protection Program](#).
77. OSHA. Respiratory Protection Standard. Title 29, Labor. Subtitle B, Regulations Relating to Labor. Chapter XVII, Occupational Safety and Health Administration, Department of Labor. Part 1910, Occupational Safety and Health Standards. Subpart I, Personal Protective Equipment. [§ 1910.134 Respiratory protection](#).

78. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. Part 482, Conditions of Participation for Hospitals. Subpart C, Basic Hospital Functions. [§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.](#)
79. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. Part 483, Requirements for States and Long Term Care Facilities. Subpart B, Requirements for Long Term Care Facilities. § 483.80, Infection Control. [\(a\)\(3\) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.](#)
80. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter B, Medicare Program. Part 416, Ambulatory Surgical Services. Subpart C, Specific Conditions for Coverage. § 416.51, Conditions for coverage – Infection Control. [\(c\) Standard: COVID-19 vaccination of staff.](#) **Retired content no longer required.**
81. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. Part 482, Conditions of Participation for Hospitals. § 482.42, Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs. [\(g\) Covid-19 vaccination of hospital staff.](#) **Retired content no longer required.**
82. Code of Federal Regulations. Title 42, Public Health. Chapter IV, Centers for Medicare & Medicaid Services, Department of Health and Human Services. Subchapter G, Standards and Certification. Part 483, Requirements for States and Long Term Care Facilities. Subpart B, Requirements for Long Term Care Facilities. § 483.80, Infection Control. [\(d\)\(3\) COVID-19 immunizations.](#)
83. Pennsylvania Code. Title 28, Health and Safety. Part IV, Health Facilities. Subpart F, Ambulatory Surgical Facilities. Chapter 567, Environmental Services. § 567.53, Sterilization Control. [\(1\) A method of control to assure sterilization of supplies and water](#)
84. PA DOH. [Healthcare Associated Infection Prevention/Antimicrobial Stewardship \(HAIP/AS\) Program.](#)
85. PA MCARE Law. [Section 302, Definitions.](#)
86. PA MCARE Law. [Section 402, Definitions.](#)
87. Pennsylvania Code. Title 28, Health and Safety. [Chapter 551, General Information.](#)
88. PA MCARE Law. [Section 103, Definitions.](#)
89. Pennsylvania Code. Title 28, Health and Safety. Chapter 101, General Information. [§ 101.4, Definitions.](#)
90. PA MCARE Law. [Section 101, Short Title.](#)
91. Pennsylvania Code. Title 28, Health and Safety. Chapter 201, Applicability, Definitions, Ownership and General Operation of Long-Term Care Nursing Facilities. [§ 201.3, Definitions.](#)

APPENDIX B: ACRONYMS AND DEFINITIONS

- **Abortion facility:** A facility or medical facility as defined in 18 Pa.C.S. § 3203 (relating to definitions), which is subject to Chapter 3. Patient Safety of the PA MCARE Law, pursuant to Section 315(b) or (c) and which is not subject to licensure under the act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act.^{62,85}
- **Ambulatory surgical facility (ASF):** Also known as an ambulatory surgery center (ASC). A facility or portion thereof not located upon the premises of a hospital which provides specialty or multispecialty outpatient surgical treatment. This does not include individual or group practice offices of private physicians or dentists, unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis. For the purposes of this provision, outpatient surgical treatment means treatment to patients who do not require hospitalization, but who require constant medical supervision following the surgical procedure performed.⁸⁷
- **Health care personnel (HCP):** Also known as a health care worker (HCW). An employee, independent contractor, licensee or other individual authorized to provide services in a medical facility.⁸⁵
- **Hospital:** Also known as an acute care facility. An entity licensed as a hospital under the act of June 13, 1967 (P.L. 31, No. 21), known as the Public Welfare Code, or the act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act. Can include acute care hospitals, ESRD hospitals, psychiatric hospitals, rehab hospitals, critical access hospitals, long-term acute care facilities, and childrens hospitals.^{88,89}
- **Interim point of contact (POC):** As defined for the purposes of plan review, an interim point of contact is provided if a facility is working towards identifying a designated IP. The expectation is that, once a facility IP has been designated, they become the primary point of contact, even if not yet fully trained.
- **Pennsylvania Medical Care Availability and Reduction of Error (MCARE) Act:** The MCARE Law was passed by the Pennsylvania General Assembly on March 20, 2002. The Act was passed to reform the law on medical professional liability, establish the Patient Safety Authority and Patient Safety Trust Fund, and improving Pennsylvania patient safety and reporting.⁷ The Act should be cited / referred to as the Medical Care Availability and Reduction of Error (MCARE) Act (e.g. as opposed to Acts 13 or 52).⁹⁰
- **Nursing home:** Also known as a long-term care facility. An entity licensed as a nursing home under the act of July 19, 1979 (P.L. 130, No. 48), known as the Health Care Facilities Act.^{62,85} A licensed long-term care nursing facility as defined in Chapter 8 of the act (35 P. S. §§ 448.801—448.821).⁹¹
- **Reportable communicable disease:** Any disease for which reports are required pursuant to the provisions of the Disease Prevention and Control Law of 1955 (35 P. S. §§ 521.1—521.21). Reference should also be made to Chapter 27, Subchapters B, E and F (relating to selected procedures for preventing disease transmission; and miscellaneous provisions).⁸⁹
- **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.⁸⁵

- **Skilled or intermediate nursing care:** Professionally supervised nursing care and related medical and other health services provided for a period exceeding 24 hours to an individual not in need of hospitalization, but whose needs are above the level of room and board and can only be met in a long-term care nursing facility on an inpatient basis because of age, illness, disease, injury, convalescence or physical or mental infirmity. The term includes the provision of inpatient services that are needed on a daily basis by the resident, ordered by and provided under the direction of a physician, and which require the skills of professional personnel, such as, registered nurses, licensed practical nurses, physical therapists, occupational therapists, speech pathologists or audiologists.⁹⁰

APPENDIX C: INFECTION CONTROL TRAINING OPTIONS AND EXAMPLE DOCUMENTS

Example documents in this section should be adapted for use with facility-specific content.

Infection Control Training Options (for designated facility infection preventionists)

1. AORN. [ASC Infection Prevention Online Course](#)
2. APIC. [Online Learning](#)
3. CDC. [Infection Prevention Training](#)
4. CBIC. Certification Board of Infection Control and Epidemiology. [CIC Certification](#)
5. SHEA. [Primer on Healthcare Epidemiology, Infection Control & Antimicrobial Stewardship](#)

Sample HAIP Division IC Plan Outlines:

6. **Hospitals:** [Infection Control Plan Outline for Acute Care Hospitals](#)
7. **ASFs:** [Infection Control Plan Outline for Ambulatory Surgical Facilities](#)
8. **LTCFs:** [Infection Control Plan Outline for Long-Term Care Facilities](#)

Sample Risk Assessments And Related Resources:

1. HAIP Division. [Infection Control Risk Assessment Resource](#)
2. CDC. Nursing Home Infection Preventionist Training Course. Module 1. [IPC risk assessment](#).
3. Oregon Patient Safety Commission (OPSC). [IPP Risk Assessment Surveillance Data Collection Tool \(ASCs\)](#).
4. OPSC. [IPP Risk Assessment Hazard Scoring Tool](#).
5. PA DOH. [County Health Profiles](#).
6. PA DOH. [Pennsylvania Environmental Health Indicators Map](#).
7. University of North Carolina (UNC) Statewide Program for Infection Control (SPICE). [LTC Infection Prevention Risk Assessment](#).

Sample Policies:

1. HAIP Division. [Policy & Procedure Outline](#)
2. HAIP Division. [Infection Control Policy & Procedure Development Resource](#)
3. CDC. [Application of Transmission-Based Precautions](#), resourced from the Nursing Home Infection Preventionist Training Course. Module 6B.
4. CDC. [Environmental Cleaning and Disinfection Template](#), resourced from the Nursing Home Infection Preventionist Training Course. Module 11B.
5. CDC. [Hand Hygiene](#), resourced from the Nursing Home Infection Preventionist Training Course. Module 7.
6. CDC. [HICPAC Sample Policy Template: Reprocessing Flexible Endoscopes](#).
7. OPSC. [Oregon Ambulatory Surgery Center Infection Prevention and Control Toolkit \(includes multiple policy examples\)](#).