pennsylvania DEPARTMENT OF HEALTH
PA Department of Health, Bureau of Epidemiology
Healthcare Associated Infection Prevention (HAIP) Division

Infection Control Plan Submission Checklist

INTRODUCTION

The "Infection Control Plan Submission Checklist" is a resource to guide the submission of a facility's infection control plan (IC plan) and supporting documents to the PA Department of Health, Bureau of Epidemiology, Healthcare Associated Infection Prevention (HAIP) Division, IC Plan Review Team. **Any (initial and/or subsequent) IC plan submission that does not fully comply with the "Submission Checklist" elements below will immediately be rejected.**

Submission Checklist: Check off each checkbox before emailing your submission

☐ Submit/email **ONLY the plan, risk assessment, and infection control (IC) policies** noted below, to the attention of the HAIP Division at **RA-DHHAI@pa.gov**, **ensuring that the following submission criteria are met**:

- ☐ All requested documents must be sent as **individual attachments**. The Department **will reject the entire submission** if it includes **zip files**, **scanned documents**, **policy manuals**, **or links to policy / SharePoint sites**.
- ☐ All submitted documents must be in **Word, PDF, or Excel** format.
- ☐ The IC plan and Infection Control Risk Assessment must be **facility-specific.**
- ☐ Submission of **system** versus facility-specific policies will be considered for **hospitals and ASCs if they meet the requirements for acceptance detailed in the** *"Requirements for System Policy Submission"* **on pg. 6**.
  - Note: LTC facilities may only utilize **facility-specific** policies. If corporate policy templates are desired for use, they must be modified to include the **facility-specific** name versus the corporate name and language within the policy only representing processes and services offered at that particular facility versus any facility falling under the corporation.
  - HAIP Division Resources for P&P development or enhancement:
    - Policy & Procedure Outline
    - Infection Control Policy & Procedure Development Resource
- ☐ Submitted documents must **meet the respective content and law/code requirements** detailed within the "**Infection Control Plan Toolkit"**.
- ☐ Submitted documents must utilize and contain references to **current nationally recognized standards** and **evidence-based** IC practices, as detailed in the "PA DOH IC Plan Outline/s" (e.g., hand hygiene vs. handwashing, standard precautions vs. universal precautions, most recent vs. outdated versions, etc.).
- ☐ Submitted documents must be **organized** (i.e., logical content sequence, structured layout: section headers, numbering/lettering, and/or bullet points).
- ☐ Submitted documents must contain, **effective/implementation, creation/origination**, **reviewed/revised,** and **facility-specific infection control committee approval dates**.
- ☐ **Separate policies are recommended** for each IC topic listed below. Policy titles must be reflective of policy content (e.g., HAI Surveillance and Reporting).
- ☐ Additional policies or supportive documents, **outside of the required IC P&Ps for submission listed below,** may be requested at the discretion of the HAIP Division reviewer if needed to clarify IC plan content.

- ☐ **Bloodborne pathogens exposure control plan**
- ☐ **Cleaning/disinfection (environmental svs.) policy**
- ☐ **Cleaning/disinfection of OR/procedure room policy***
- ☐ **Cleaning/disinfection of patient equipment policy**
- ☐ **Clean & sterile storage/event-related policy**
- ☐ **Disinfection (HLD of scopes or probes) policy***
- ☐ **HAI surveillance and reporting policy**
- ☐ **Hand hygiene policy**
- ☐ **Infection control plan**
- ☐ **Infection control risk assessment**
- ☐ **Influenza and COVID-19 vaccination policies**
- ☐ **Linen management policy**
- ☐ **Outbreak response/containment policy**
- ☐ **Reporting of infection control breaches policy**
- ☐ **Respiratory protection plan***
- ☐ **Standard precautions policy**
- ☐ **Sterilization (surgical instruments/devices) policy***
- ☐ **Transmission-based precautions (TBPs) policy**
- ☐ **Utility management/physical plant (HVAC & water)**

* *Policy may not apply to all facility types. If the policy topic services are not offered at your facility, a corresponding policy is not required for submission.*

PA Department of Health, Infection Control Plan Submission Q & A / "office hours"

For questions during the IC plan submission and screening process, please join the recurring, weekly "office hours" hosted by the HAIP Division reviewers, utilizing the web link or phone number listed below.

Frequency: **Every Wednesday from 1 pm – 2 pm**

Join on your computer or mobile app

Click here to join the meeting

Or call in (audio only)

+1 267-332-8737,,375837352#

Phone Conference ID: 375 837 352#

DEFINITIONS

Infection Control Plan:

An infection control plan (IC plan) is a comprehensive document containing high-level details of the facility's specific infection control program, laying out the framework for the detection, prevention, and control of healthcare-associated infections (HAI), and disease transmission among patients, staff, providers, contractors, visitors, volunteers, and students.

- The IC plan should be based on current nationally recognized standards and evidence-based infection control practices and explicitly state the responsibility for oversight and implementation of the program.
- The IC plan acts as a roadmap for facility staff outlining the strategies that must be followed to mitigate or eliminate the risks identified in the facility's infection prevention and control risk assessment, how the staff is educated on the plan, how IC practice compliance is monitored, and how surveillance data is collected and analyzed to monitor the effectiveness of the program and progress towards reaching targeted goals.
- The IC plan is a living document that is reviewed, revised, and approved by the facility-specific infection control committee at least annually and when needs arise. The IC plan must meet requirements detailed in **Section 403** of the Medical Care Availability and Reduction of Error Act (MCARE) of 2002 and other applicable laws.
- Applicable Laws:
- Medical Care Availability and Reduction of Error (MCARE) Act of 2002
- Healthcare Facilities Act of 1979
    - Federal Code
        - Ambulatory Surgical Centers
        - Hospitals
        - Long Term Care Facilities
    - PA Code
        - Ambulatory Surgical Centers
        - Hospitals
        - Long Term Care Facilities

Infection Prevention and Control Risk Assessment:

An infection prevention and control risk assessment (IP&C RA) is a proactive means of preventing infections by systematically assessing and identifying risks for acquiring and/or transmitting infections in a specific facility, prioritizing them, and then developing strategies to mitigate or eliminate the risks that are then detailed in the facility's IC plan.

- The IP&C RA process should consider potential risks related to the following:
    - Community (e.g., geography, rural/urban, weather, natural disasters, etc.)
    - Population served (e.g., age (geriatric/pediatric), characteristics, behaviors, health statistics, high risk, multi-drug resistant organism (MDRO) prevalence, etc.)
    - Facility (e.g., environment, structure, surfaces, age of utilities operating room high-efficiency particulate air (HEPA) filtration, multiservice building with shared systems, etc.)
    - Staff competency (e.g., competency-based training programs for cleaning, high-level disinfection (HLD) & sterilization, etc.)

  - Services offered (e.g., treatments, procedure types (total joints/cardiovascular), invasive device placement/utilization, robotic surgery, extracorporeal membrane oxygenation (ECMO), cardiopulmonary bypass devices, low or high volume procedures, etc.)
  - Staff immunity (e.g., new hire health screening, communicable diseases immunization status, vaccine programs for influenza/COVID-19, etc.)
  - Patient care/infection control practice compliance (e.g., hand hygiene, PPE, not isolating for MDROs, healthcare-associated infection (HAI) prevention bundles, cleaning, HLD & sterilization, injection/medication preparation, etc.)
  - Medical devices (e.g., selection, introduction and training, re-use of single-use items, devices with water reservoirs, handling & storage, cleaning, HLD & sterilization requirements, etc.)
  - Facility type (e.g., ASC, LTC, hospital (academic teaching facility vs. located in a rural community))
  - Patient safety (e.g., healthcare-associated infection trends, etc.)
- An IP&C RA is to be performed annually by the facility's infection preventionist with input from the facility-specific infection control committee.
- HAIP Division Resource for risk assessment development or enhancement:
  - Infection Control Risk Assessment Resource

Infection Control Policies and Procedures:

Infection control policies and procedures (IC P&Ps) should be facility-specific, based on and reference nationally recognized and evidence-based standards, providing staff with clear guidance on the expected infection prevention and control practices to be followed within the facility.

- The IC P&Ps provide additional details and support elements outlined in the IC plan. Staff should be educated on IC P&Ps, monitored for adherence, and held accountable for noncompliance.
- Each policy should be structured with an appropriate title, created/last revised/effective dates, and should be reviewed and approved by the facility-specific infection control committee on an annual or biannual basis depending on the facility type and associated requirements.
- HAIP Division Resources for P&P development or enhancement:
  - Policy & Procedure Outline
  - Infection Control Policy & Procedure Development Resource

Infection Preventionist:

An infection preventionist (IP) is a designated and qualified individual/professional who is responsible for the day-to-day operations and implementation of the facility's infection control program.

- Federal code requires that facility IPs are trained in infection prevention and control: **Hospital**, **ASC**, **LTC**.
- Professional standards for IPs include professional accountability to maintain knowledge/skills by staying abreast of updated infection prevention and control evidence-based practices and nationally recognized standards, and through ongoing continuing education.

Infection Control Committee:

An infection control committee (ICC) is facility-specific and designated to provide oversight of a facility's infection control program. The ICC should report through the facility's quality assurance committee structure to the governing body or an avenue defined within the facility's bylaws.

- The ICC should be multidisciplinary and meet at least quarterly.
- Required ICC membership is detailed in **Section 403** of the Medical Care Availability and Reduction of Error Act (MCARE) of 2002.

Key responsibilities of the ICC would include IC plan and policy review and approval, input into the annual IP&C RA and prioritizing and setting annual goals, discussion of healthcare-associated infection rates and strategies to mitigate the risk of occurrence, and review and approval of facility disinfectants and equipment cleaning/disinfection practices.

Infection Control Plan Submission Through Approval Process Steps (for facility awareness)**:**

HAIP Division resources for IC Plan submission, screening, review and approval workflows:

- Infection Control Plan Approval Process Graphic with Resource Links

The plan review process begins when the plan review team becomes aware of a need to review a facility's IC plan. This might be due to one of the following: opening of a new facility, change of facility ownership, new inclusion of joint replacement services, or licensure surveyor referral. The IC plan review process includes several phases which are displayed and detailed below.

- **Plan submission needed:** The HAIP Division identifies a need for a facility to submit its IC plan for review and approval.

- **IP or interim point of contact (POC) identified:** The facility administrator receives an IC plan submission requirement email and submits the name and contact information for the designated, trained IP or interim POC to the HAIP Division.

- **Toolkit and checklist sent:** The facility's IP or interim POC is emailed a copy of the "Infection Control Plan Toolkit" and specific facility type "Infection Control Plan Outline". These references can be used to either guide the development of an IC plan or enhance an existing IC plan while ensuring alignment with MCARE, state, and federal code requirements, before submitting the IC plan and supporting documents to the HAIP Division. A copy of the "Infection Control Plan Submission Checklist" is also provided, detailing the required submission criteria and submittal process.

- **Plan submitted:** The facility submits the IC plan, IP&C RA, and requested policies to the HAIP Division via email.

- **Plan assessed with rubric**: The HAIP Division receives the IC plan document submission and within 14 days of receipt, utilizes a standardized form titled, "DOH Infection Control Plan Submission Assessment Rubric" to evaluate the submission for the inclusion of requested documents that meet the submission criteria detailed in the "Submission Checklist".

- **Plan accepted for review or returned:**
  - The HAIP Division notifies the facility contact via email of either the acceptance or unacceptance of their IC plan document submission.

- Acceptable submissions: The HAIP Division moves acceptable submissions into the queue for plan reviewer assignment. IC plan submissions that have been placed into the queue are prioritized for reviewer assignment based on the date of acceptance notification.
- Unacceptable submissions: The facility will receive a copy of the "DOH Infection Control Plan Submission Assessment Rubric" which identifies the rationale for submission unacceptability.
  - The facility must revise any document that failed to meet the submission criteria, referencing the "DOH Infection Control Plan Submission Assessment Rubric" for rationale and the "Infection Control Plan Toolkit" and "Infection Control Plan Outline" for guidance.
  - Once all the necessary revisions are made, the facility must resubmit all documents requested in the "Infection Control Submission Checklist" to the HAIP Division. The submission process is repeated until the document submission is acceptable for review.

- **Notification of review start:** Once the IC plan submission is assigned to a HAIP Division reviewer, a notification email is sent to the facility IP and administrator.

- **Plan approved or rejected:** Once the IC plan review is complete, the HAIP Division reviewer will notify the facility IP and administrator of the IC plan review outcome by sending a letter of approval or rejection via email.
  - Approved IC plan: Once the review is complete and the plan is approved, the facility must implement the approved IC plan.
    - The facility must educate all staff, providers, contractors, students, and volunteers on the IC plan, monitor adherence to the plan, and hold all staff accountable for complying with the IC plan and supporting IC P&Ps.
    - The facility should place a copy of the final approved IC plan in a location where staff can easily access and reference it.
    - The facility should attach a copy of the IC plan approval letter to the final approved IC plan and save both originals in a retrievable location for historical or regulatory survey access purposes.
  - Rejected IC plan: The facility will be provided documentation (i.e., IC plan review form, commented IC plan, commented policies) advising of what needs to be corrected to close the gaps for approval.
    - The facility will revise and resubmit the IC plan and any requested supportive documents, incorporating reviewer recommendations to ensure the documents meet MCARE, state, and federal code requirements.
    - The HAIP Division reviewer will complete a review of only the revised content of the resubmitted documents.
    - Once the resubmitted document evaluation is complete, the HAIP Division reviewer will notify the facility IP and administrator of the outcome via email.
    - The IC plan resubmission and review process is repeated until the IC plan is approved.
    - Note: A rejection letter is only sent with the initial IC plan rejection notification. If subsequent submissions are rejected, only email notification is provided.

Requirements for System Policy Submission

(***Note:*** *a "system" applies to a healthcare network of facilities and does not refer to a management or non-facility corporation*)

- The IC P&Ps provided as part of the IC plan submission serve as evidence of plan implementation, and thus, must provide facility-specific details. However, if a hospital is part of a healthcare system or shares a CMS Certification Number (CCN) with another facility, system-level infection control policies may be adopted by the facility's governing body for use at the facility, if all of the following conditions are met:
  - Note: Ambulatory surgery centers (ASC) must share a CCN with a parent hospital and possess a Division of Acute and Ambulatory Care (DAAC) exception to fall under the hospital's governing structure to consider implementing system policies at the ASC.
  - It is clear that the system IC P&Ps apply to the submitting facility. For example, the system policy includes one of the following:
    - A checkbox is checked next to submitting facility name in an applicability section
    - The policy scope includes the submitting facility name
  - The system IC P&Ps are relevant to the population and services offered by the submitting facility. For example:
    - A facility submits a system-level policy for the reprocessing of reusable equipment and/or instruments which includes high-level disinfection (HLD), but the submitting facility does not perform HLD. In this case, the system-level policy should be adapted to exclude or denote not applicable in reference to HLD, to reflect the actual processes utilized at the facility.
    - A facility submits a system-level sterilization policy that provides details of multiple types of sterilization equipment used throughout the system. An acceptable policy should only discuss or note the specific type of sterilizer (steam, dry heat, ethylene oxide gas (ETO), hydrogen peroxide gas plasma) and quality indicators used at the specific facility.
  - The system IC P&Ps must show that they were approved by the facility-specific infection control committee (ICC) versus a system ICC and show facility-specific effective dates. Documentation should include one of the following:
    - Facility-specific ICC approval and effective dates contained within each system IC P&Ps (e.g., a field/grid within the policy or policy addendum stating the date approved by the facility's ICC and facility effective date, a signature of the facility's ICC chair with approval & facility effective dates).
    - Submission of a policy cover sheet that contains the facility-specific ICC approval, effective, and review dates for each of the system policies in use at the facility.
  - The system IC P&Ps show evidence that they were approved and adopted by the facility's governing body (i.e., the highest facility oversight committee as defined in the facility by-laws). Documentation should include one of the following:
    - A statement within the IC plan such as, "The [name of governing body] has approved and adopted the [name of the system] policies for implementation at [name of facility]."
    - A field at the end of each system policy including the governing body approval/adoption date.
  - The approval and adoption of system IC P&Ps must be reflected in dated, facility-specific committee meeting minutes (i.e., ICC, governing board) which can serve as proof of policy and/or plan approval and adoption documentation for onsite licensing surveys.

In some cases, a facility may utilize a mix of system and facility-specific IC P&Ps. For example, if an ASC has received a DAAC exception permitting off-site sterilization; then the ASC would be required to submit their specific IC P&Ps regarding this process (e.g., preparing dirty items for transport, transport specifications, name, and qualifications of processing location, monitoring for compliance).