

Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City
TWENTIETH CONGRESS
First Regular Session
HOUSE BILL NO. 7722



Introduced by Rep. CIRIACO B. GATO, JR., M.D., FPSO-HNS

Healthcare-associated infections (HAIs) remain a serious but preventable threat to patient safety and healthcare quality in the Philippines. Largely attributable to poor sterilization, decontamination, and waste disposal practices, HAIs contribute to prolonged hospital stays, increased healthcare costs, and preventable morbidity and mortality.

A critical component of effective infection prevention is sterile processing. Sterile processing encompasses the cleaning, decontamination, disinfection, sterilization, packaging, storage, and distribution of medical instruments and equipment used in patient care. These processes directly affect the safety of surgical procedures, diagnostic interventions, and other invasive treatments. When sterile processing is inadequately regulated or inconsistently implemented, the risk of cross-contamination, infection outbreaks, and harm to patients and healthcare workers increases significantly—especially in high-risk areas such as operating rooms, intensive care units, and neonatal wards.

While significant efforts have been made to address HAIs through infection prevention and control policies, hospital licensing and regulation, and the issuance of administrative and technical guidelines, the absence of uniform national standards and a dedicated regulatory framework for sterile processing has resulted in wide variability in practices across healthcare facilities.

This bill, filed in the 19th Congress by Representative Peter B. Miguel, seeks to professionalize and elevate sterile processing as a core component of healthcare quality and patient safety. It mandates the adoption of standardized, science-based practices for the cleaning, decontamination, disinfection, and sterilization of medical devices, consistent with internationally recognized guidelines and best practices, including the Spaulding Classification System. Furthermore, it requires all hospitals and healthcare facilities to secure a Sterile Permit prior to operation, ensuring compliance with minimum safety and quality standards essential to infection prevention.

The refiling of this bill underscores the continuing relevance and necessity of the proposed reforms, particularly in light of evolving medical technologies and heightened awareness of infection control and patient safety.

In view of the foregoing, the immediate passage of this bill is earnestly sought.


CIRIACO B. GATO JR.

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**AN ACT MANDATING TO PROFESSIONALIZE AND ELEVATE THE
STERILE PROCESSING AS A CRITICAL COMPONENT OF HEALTHCARE
QUALITY AND PATIENT SAFETY AND DEVELOP THE INTERNATIONAL
STANDARD, RESOURCES AND BEST PRACTICES IN STERILIZATION
SCIENCES**

**Be it enacted by the Senate and House of Representatives of the Philippines in
Congress assembled:**

SECTION 1. Short Title. – This Act shall be known as the “Sterile Permit Act of the Philippines.”

SECTION 2. Declaration of Policy. – The State shall promote, foster, nurture, and protect the right to health of the people by issuing policies and standards intended for use by healthcare members and for use by health care facilities to help ensure that reusable medical instruments are sterilized and decontaminated for patient use, work spaces have been properly disinfected and single use devices have been disposed of properly.

SECTION 3. Definition of Terms. - As used in this Act, the following terms shall mean:

1. Central Services: service which provides cleaning, storing, and dispensing of supplies and equipment required for all aspects of patient care.
2. Central Sterile Services Department: area in the hospital where medical devices, both sterile and non-sterile, are cleaned, packed, disinfected/sterilized, stored and then issued for patient care.
3. Sterilization: Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods.
4. Cleaning: The removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.
5. Decontamination: Process of cleaning and disinfecting soiled medical devices to render them safe for handling and to the extent necessary for subsequent processing.
6. Disinfection: Process that kills pathogenic and other microorganisms by physical or

chemical means. Disinfection destroys most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the safety margin associated with sterilization processes.

7. Health care products: Medical devices, including in vitro diagnostic medical devices, or medicinal products, including biopharmaceuticals.
8. Health care facility: Specialized facility where professionals deliver services utilizing medical devices. It means hospitals, nursing homes, extended-care facilities, free-standing surgical centers, clinics, and medical and dental offices.
9. Contaminated: Presence of potentially infectious, pathogenic organisms (e.g., found in blood or other potentially infectious material) in or on an object.
10. Decasing/breakout area or space: Unpacking area or space where products are removed from their external shipping containers before being taken into the preparation and packaging area or the sterile storage area.
11. Decontamination room: Room designated for collection, retention, and cleaning of soiled and/or contaminated items.
12. Labeling: Any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product.
13. Loaned items: Medical devices used in health care facilities that are not owned by the facility
14. Medical device: Instrument, apparatus, material, or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
 - diagnosis, prevention, monitoring, treatment, or alleviation of disease;
 - diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or handicap;
 - investigation, replacement, or modification of the anatomy or of a physiological process; or
 - control of conception; and
 - which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.
15. Medical washer: Device that is intended for general medical purposes to clean and dry surgical instruments, anesthesia equipment, hollowware (e.g., basins, medicine cups), and other medical devices.
16. Occupational exposure: Contact, through inhalation, ingestion, skin contact, or absorption, with a potentially hazardous material during the course of employment.
17. Office-based health care facility: Health care facility designed for short-term treatment of ambulatory patients (e.g., freestanding surgical centers, clinics, and medical and dental offices).

18. **Personal protective equipment (PPE):** Specialized clothing or equipment worn for protection against hazardous materials, blood-borne pathogens, or other potentially infectious materials.
19. **Prions:** Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including scrapie in sheep and goats, bovine spongiform encephalopathy (BSE) in cattle, and Creutzfeldt-Jakob disease (CJD) in humans. They are unlike any other infectious pathogens, including viruses, because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prion diseases are disorders of protein configuration involving template-assisted replication and resulting in abnormal protein accumulation in the brain, which causes neuronal dysfunction, degeneration, and death. Prions are extremely resistant to inactivation by heat and disinfecting agents.
20. **Process failure:** Condition in which one or more monitored parameters of cleaning, sterilization, or packaging is outside the defined specification for that parameter.
21. **Pyrogen:** Fever-producing substance. Debris from killed microorganisms can be pyrogenic. Limiting the bioburden before sterilization minimizes this debris.
22. **Qualified:** As the term is used with respect to personnel, prepared by training and experience to perform a specified task.
23. **Restricted area:** Area where access and traffic are limited to authorized personnel and where special attire is required.
24. **Reusable medical device:** Device intended for repeated use on different patients, with appropriate decontamination and other processing between uses. Examples include surgical instruments, endoscopes, basins, and electromedical equipment.
25. **Spaulding Classification:** The selection of a disinfectant must be based, in part, upon the intended use of the device and the degree of disinfection required for that device. The Spaulding Classification System divides patient care items into three categories, each based on the degree of risk of infection when the items are used in patient care. the Center for Disease Control and Prevention (CDC) and the Association for the Advancement of Medical Instrumentation (AAMI) use the Spaulding Classification System in their guidelines and standards. The three Spaulding categories are:
 - a. **Critical items** - Instruments or objects introduced directly into the bloodstream or into other sterile areas of the body; examples include surgical instruments, cardiac catheters and implants, these items must be sterilized before use (disinfection is inadequate).
 - b. **Semi-critical items** - Although these items come in contact with intact mucous membranes, they do not ordinarily penetrate body surfaces. Examples include non-invasive flexible fiberoptic endoscopes, endotracheal tubes and anesthesia breathing circuits. Semi- critical items should be subjected to a high- level disinfection process that can be expected to destroy all microbial organisms, but not necessarily microbial spores.
 - c. **Non-critical items** - These items usually come into direct contact with the patient's unbroken skin. Examples include crutches and countertops. These items require thorough cleaning, and in some cases, low- level disinfection to intermediate-level disinfection.

26. **Sterile:** Free from viable microorganisms.
27. **Sterile processing department/area:** Area within a health care facility that processes and controls medical supplies, devices, and equipment, sterile and not sterile, for some or all patient care areas of the facility.
28. **Sterile storage room:** Room designed to store clean and sterile items and protect them from contamination.
29. **Sterilization cycle:** Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.
30. **Transmission-based precautions:** Precautions designed for patients documented or suspected to be infected with highly transmissible or epidemiologically important pathogens for which additional precautions beyond standard precautions are used to interrupt transmission in health care facilities. There are three types of transmission- based precautions: airborne precautions, droplet precautions, and contact precautions.
31. **Work practice controls:** Safe work practices that reduce the risk of exposure to blood-borne pathogens and other potentially hazardous materials.

Section 3. Sterile Permits. — No hospital, government or private, health care facility, office-based health care facility or any establishment providing medical or diagnostic services shall be allowed to operate unless plans have been approved and a sterile permit is issued by the licensing agency as defined in this Act.

Section 4. Licensing Agency. – For purposes of setting standards in sterile processing, the Health Facilities and Services Regulatory Bureau and the Regulation Licensing and Enforcement Division within the regional offices, in addition to its present duties shall act as the licensing agency. The Secretary of Health shall reorganize this Bureau to include a staff of hospital infection prevention and control practitioners, hospital administrators, sanitary engineers, at least two (2) prominent citizens from the private sector who have distinguished themselves in their profession or fields of central services and sterile management and such personnel as may be necessary to carry out the purposes of this Act without necessarily increasing the present personnel strength of this Bureau.

Section 5. Powers and duties of the licensing agency. - the Licensing/Accreditation of Health Facilities and Services under the Health Facilities and Services Regulatory Bureau, shall have the following powers and duties:

- a. To conduct an ocular survey of all existing health care facilities and hospitals in the Philippines, government or private, with a view to determine their fitness to operate considering their respective Central Sterile Services Department.
- b. To prescribe guidelines for processing of medical devices according to the Spaulding classification for the intended level of use.
- c. To provide for the standardization of decontamination, disinfection and sterilization processes in line with validated required standards as prescribed by the Department of Health and best practices
- d. To ensure that healthcare facilities are providing medical devices that are safe to use on patients

- e. To approve plans for healthcare facilities and hospitals, government or private, and to issue sterile permits to hospitals in accordance with the provisions of this Act.
- d. To keep a permanent register of licensed health care facilities or those issued licenses to operate indicating the name of the facility, address or location, type of facility, name of the director or administrator, ownership, number of authorized beds and bassinets and such other pertinent data as may be necessary.
- e. To grant licenses for the operation and maintenance of hospitals or revoke the same in accordance with the provisions of this Act.
- f. To make periodic inspection of all hospitals to check compliance with rules and regulations legally promulgated or with the provisions of this Act and to make recommendations to directors or administrators of hospitals for the correction of defects found during such inspections.
- g. To publish yearly a list of all approved hospitals indicating the name, location, type, authorized beds, and name of the director or administrator.
- h. To make a yearly report of infection rates due to HAIs within the licensed hospitals and the steps taken by such hospitals to control such.
- h. To submit yearly reports to the Secretary of Health, the Speaker of the House of Representatives, the President of the Senate and the chairmen and members of the Committees on Health of both Houses of Congress, such reports to include a list of approved health care facilities indicating the name of the facility, location, bed capacity and name of the director or administrator and make recommendations on hospital needs or requirements for hospital central sterile services.

Section 6. Filing of Application for Sterile Permit. — Application for a sterile permit shall be submitted to the Office of the Director, Bureau of Medical Services, in a form prescribed by the latter and accompanied by a decontamination plan proposed to be implemented. The application shall state the name of the healthcare facility, ownership, location and type of facility.

Section 7. Minimum Standards for Issuance of Sterile Permit. — In order that a sterile permit can be issued, the hospital plan shall provide a specified plan for cleaning, disinfection and sterilization for its medical devices and workspaces. There must also be a decontamination room/area, disinfection room/area, a medical washer, a decasing/breakout area or space, a sterile processing department/area and sterile storage room/area. There must also be a showing of proper labeling in the required areas as well as procedures for dealing with loaned items.

There must also be specified plans containing personnel qualifications, PPE requirements, work practice controls, transmission-based precautions, and dealing with process failures, occupational exposures, prion and pyrogen outbreaks.

Section 8. Inspection. — A sterile permit shall be issued by the licensing agency only after a representative of the licensing agency has conducted an ocular inspection and certified that the applicant has satisfactorily complied with requisites prescribed in this Act. The sterile permit shall be renewed every year upon payment of the prescribed fees.

Section 9. Revocation of License.— The licensing agency may suspend or revoke a license already issued for any of the following grounds: (a) repeated violation by the licensee of any provision of this Act or of any other existing law; (b) repeated violation of rules and regulations prescribed in the implementation of this Act; or (c) repeated failure to make necessary corrections or adjustments required by the licensing agency in the improvement of facilities and services.

Section 10. Hearing.— Any person, association, corporation, or any other private entity who has

been refused a sterile permit or whose permit has been suspended or revoked shall be entitled to an administrative hearing to be conducted by the Secretary of Health and his two undersecretaries to determine the justifiability of such denial, suspension or revocation of the permit: Provided, That such party may resort to the courts, as in other cases provided by law.

Section 11. Separate Permits Required.— Separate permits shall be required for health care facilities or branches thereof maintained in separate premises, even though they are operated under the same management: *Provided*, However, That separate permits shall not be required for separate buildings in the same compound: *Provided, further*, That permits of buildings within the same compound shall also be secured from the licensing agency to determine compliance with standards and requirements herein authorized.

Section 12. License not transferable. — The permit shall not be transferable. The licensing agency shall be notified of any change in ownership, change of name of the health care facility, and transfer of location and in the latter case, an application for a new permit should be submitted.

Section 13. Rules and Regulations. — The Health Facilities and Services Regulatory Bureau acting as a licensing agency and subject to the approval of the Secretary of Health, shall promulgate rules and regulations to implement the provisions of this Act.

Section 14. Fees. — Each applicant for a sterile permit shall pay the amount of *five hundred pesos* as permit fee. A registration fee of *five hundred pesos* and an annual license fee of *one thousand pesos* shall likewise be collected for each hospital and for each approved license: *Provided*, that a government hospital shall be exempt from the payment of such fees. The amount herein collected shall be officially receipted by the licensing agency and shall constitute as a revolving fund for the use of the licensing agency.

Section 15. Penalties. — Any person, partnership, association, or corporation who establishes, operates, conducts, manages or maintains a hospital or health care facility within the meaning of this Act without first obtaining a permit as provided for in this Act or violates any provision hereof shall be guilty of a misdemeanor, and upon conviction thereof shall be liable to a fine of not more than five hundred pesos for the first offense and not more than one thousand pesos for each subsequent offense, and each day that the hospital shall operate after the first conviction shall be considered a subsequent offense.

Section 16. Effectivity. — This Act shall take effect fifteen (15) days after each publication in the Official Gazette or in a newspaper of general circulation.

Approved,