Republic of the Philippines
DEPARTMENT OF HEALTH
Office of the Secretary

BAGONG PILIPINAS

ADMINISTRATIVE ORDER
No. 2025- 0024

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SUBJECT : Guidelines in Availing Compassionate Special Permit for the Restricted Use of Covered Pharmaceutical Products and Medical Devices for Human Use

I. BACKGROUND

Under Republic Act (RA) No. 3720, known as the Food, Drug, and Cosmetic Act, as amended by Executive Order No. 175 s. 1987 and further amended by RA No. 9711 or the Food and Drug Administration (FDA) Act of 2009, the Philippine Government upholds the policy to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed, and designed to protect and promote the right to health of the Filipino people.

In line with this mandate, Administrative Order (AO) No. 4 s. 1992 introduced the Compassionate Special Permit (CSP), allowing access to unregistered drugs and medical devices for terminally or seriously ill patients with acquired immunodeficiency syndrome (AIDS), cancer, or life-threatening conditions, when no superior or alternative therapy exists. FDA Memorandum Circular No. 2015-008 later clarified CSP issuance for medical devices, and AO No. 2020-0028 expanded its scope to include investigational products and those required during public health emergencies (PHEs) under RA No. 11332 (Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act).

Recognizing the significant impact of emerging and re-emerging infectious diseases, the FDA underscores the importance of including vaccines under CSP coverage when no viable alternatives exist, as evidenced during the COVID-19 pandemic. This ensures equitable access to vaccines during PHEs, particularly for vulnerable populations such as healthcare workers. Furthermore, expanding the applicability of CSP to include treatments for rare diseases and conditions that cause permanent medical impairment or disability aligns with the policy's foundational purpose.

Consistent with the 1987 Constitution, and RA No. 3720, as amended by RA No. 9711, this Order establishes the requirements and procedures for availing of CSP for the restricted use of covered pharmaceutical products and medical devices.

II. OBJECTIVES

This Order aims to provide updated guidelines for availing CSP from the FDA to enable access to pharmaceutical products and medical devices for human use covered herein.

III. SCOPE

A. This Order applies to qualified institutions, DOH-licensed hospitals, and specialty societies, as well as licensed physicians who shall be responsible for complying with the technical requirements of the FDA for CSP.

B. This Order covers the guidelines for availing CSP from the FDA, specifically, among others:

1. The applicable patient diseases or medical conditions, and acceptable product registration status, wherein a CSP may be issued by the FDA;
2. The conditions governing the issuance of CSP and restricted use of covered pharmaceutical products and medical devices for compliance among parties involved in the access and utilization; and
3. Specific guidelines for application, requirements, and post-approval commitments.

IV. DEFINITION OF TERMS

All the terms or words and phrases used herein that are already defined under RA No. 3720 as further amended by EO No. 175 and RA No. 9711, other related FDA-implemented laws and their respective Implementing Rules and Regulations (IRRs), for the purpose of implementing this Order, shall have the same meaning as defined therein. The following non-exclusive list of terms and phrases used in this Order shall mean or be understood as follows:

A. Compassionate Special Permit (CSP) refers to a special permit issued by the FDA granting authority to a qualified applicant the privilege to avail a pharmaceutical product or medical device through an FDA-licensed establishment or through a donor for its restricted use. The CSP is not equivalent to a marketing authorization and does not constitute evidence of the product's clinical safety or efficacy, nor should it be used as a substitute for the conduct of a clinical trial. The FDA issues two types of CSPs as follows:

1. **Named Patient Use** refers to a CSP granted for the compassionate use of a subject product on an identified patient.
2. **Institutional Use** refers to a CSP granted to a qualified institution for the compassionate use of a subject product on patients or patient groups under the care of the said institution.

B. CSP Holder refers to a qualified institution or qualified licensed physician that has applied before the FDA and has been granted the CSP. The CSP Holder shall have full responsibility for the restricted use of the product granted CSP and for compliance with the post-approval technical requirements related to the CSP.

C. Department of Health-License to Operate (DOH-LTO) refers to the formal authority issued by the DOH to an individual, agency, partnership or corporation to operate a hospital or other health facility.

D. DOH-licensed health facility refers to a facility, whether stationary or mobile, land-based or otherwise, issued a DOH-LTO in the provision of any of the following services: diagnostics, therapeutic, rehabilitative, and other health care services.

E. **Drug** refers to chemical compound(s) or biological substance(s), other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals, including the following:

1. Any article recognized in official pharmacopoeias and formularies, including official homeopathic pharmacopoeias, or any documentary supplement to any of them, which are recognized and adopted by the FDA;
2. Any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
3. Any article, other than food, intended to affect the structure or any function of the body of human beings or animals; or
4. Any article intended for use as a component of articles, specified in clauses (1), (2), or (3) not including devices or their components, parts or accessories.
5. Herbal and/or traditional drugs, which are articles of plant or animal origin used in folk medicine, that are:
   a. Recognized in the Philippine National Formulary;
   b. Intended for use in the treatment or cure or mitigation of disease symptoms, injury or body defects in humans;
   c. Other than food, intended to affect the structure or any function of the human body;
   d. In finished or ready-to-use dosage form; and
   e. Intended for use as a component of any of the articles specified in clauses a, b, c, and d.

F. **Emerging and re-emerging infectious diseases** refer to diseases that: (1) have not occurred in humans before; (2) have occurred previously but affected only small number of people in isolated areas; (3) have occurred throughout human history but have only recently been recognized as a distant disease due to an infectious agent; (4) are caused by previously undetected or unknown infectious agents; (5) are due to mutant or resistant strains of a causative organism; and (6) once were major health problems in the country, and then declined dramatically, but are again becoming health problems for a significant proportion of the population.

G. **Investigational pharmaceutical product** refers to a pharmaceutical form of an active ingredient being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

H. **Life-threatening medical conditions** refer to any disease or medical condition from which the likelihood of death is probable unless the course of the disease or medical condition is interrupted.

I. **Medical device** refers to any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material, or other similar or related article intended by the manufacturer to be used alone, or in combination, for human beings for one or more of the specific purpose(s) of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the

anatomy or of a physiological process; supporting or sustaining life; preventing infection; control of conception; disinfection of medical devices; and providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body. This device does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but may be assisted in its intended function by such means.

J. **Medical equipment** refers to a medical device requiring calibration, maintenance, repair, user training, and decommissioning, and is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury. It can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. It excludes implantable, disposable, or single-use medical devices.

K. **National drug regulatory authority (NDRA),** also referred to as national regulatory agency, refers to an entity/agency responsible for ensuring that regulated products released for public distribution, such as pharmaceutical products and medical devices, are evaluated properly and meet standards of quality, safety, and efficacy.

L. **Permanent medical impairment/disability** refers to the permanent loss, loss of use, damage, or malfunction of a part of the body, or a part of a bodily system or function caused by a disease or medical condition. The loss or abnormality of a body function may be anatomical, physiological or psychological, e.g., a missing limb or a diagnosed mental disorder.

M. **Pharmaceutical product** refers to drugs, medicines, biologicals, pharmaceutical, and biopharmaceutical products/specialties.

N. **Public health emergency (PHE),** defined in RA No. 11332, refers to an occurrence or imminent threat of an illness or health condition that:

1. Is caused by any of the following:
    a. Bioterrorism;
    b. Appearance of a novel or previously controlled or eradicated infectious agent or biological toxin;
    c. A natural disaster;
    d. A chemical attack or accidental release;
    e. A nuclear attack or accident; or
    f. An attack or accidental release of radioactive materials; and
2. Poses a high probability of any of the following:
    a. A large number of deaths in the affected population;
    b. A large number of serious injuries or long-term disabilities in the affected population;
    c. Widespread exposure to an infectious or toxic agent that poses a significant risk of substantial harm to a large number of people in the affected population;
    d. International exposure to an infectious or toxic agent that poses a significant risk to the health of citizens of other countries; or
    e. Trade and travel restrictions.

O. **Public health emergency of international concern (PHEIC)** refers to an extraordinary event which is determined to constitute a public health risk to other States

through the international spread of disease and to potentially require a coordinated international response. This definition implies a situation that is:

1. Serious, sudden, unusual or unexpected;
2. Carries implications for public health beyond the affected State's national border; and
3. May require immediate international action (World Health Organization – International Health Regulations (2005).

P. Public health threat refers to any situation or factor that may represent a danger to the health of the people.

Q. Qualified institution refers to an institution, such as the DOH, the Bangsamoro Autonomous Region in Muslim Mindanao Ministry of Health, a specialized institution, a DOH-licensed hospital, and a DOH-licensed health facility, that has the medical expertise and technical competence to provide the necessary treatment and interventions for the disease or medical condition/s intended to be addressed by virtue of the professions, trainings, or experiences of the attending physicians belonging to the institution.

R. Qualified licensed physician refers to a physician licensed by the Professional Regulation Commission who possesses the medical expertise and technical competence that matches the disease or medical condition/s intended to be addressed by virtue of training or experience.

S. Rare disease, as defined in RA No. 10747, refers to disorders such as inherited metabolic disorders and other diseases with similar rare occurrence as recognized by the DOH upon recommendation of the National Institutes of Health (NIH) but excluding catastrophic (i.e., life threatening, seriously debilitating, or serious and chronic) forms of more frequently occurring diseases.

T. Vaccine refers to a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins.

U. Willful violation refers to an act or omission committed with gross negligence or with clear, deliberate, or intentional disregard of applicable laws, regulations, or requirements beyond mere error, oversight, or misunderstanding.

V. GENERAL GUIDELINES

A. The CSP shall serve as a regulatory mechanism that grants a qualified applicant the privilege to avail a specific pharmaceutical product or medical device through an FDA-licensed establishment or donor for restricted use. This can either be for Named Patient Use, granted for the compassionate use of a subject product on an identified patient by a licensed physician; or for Institutional Use, granted to a qualified institution for the compassionate use of a subject product on patients or patient groups under the care of the said institution.

A CSP does not constitute marketing authorization and is intended solely to facilitate controlled access to critical therapeutic and preventive medical interventions subject to specific conditions in the absence of available alternatives.

B. The following are the diseases and medical conditions for which a CSP application for a pharmaceutical product or medical device intended for their treatment or management may be submitted to the FDA:

1. For pharmaceutical products (including orphan drugs) and medical devices (including medical equipment and orphan products) used in the treatment of the following:
   a. Human Immunodeficiency Virus (HIV) infection/AIDS
   b. Cancer
   c. Life-threatening medical condition/s
   d. Emerging or re-emerging infectious disease/s declared by the President of the Republic of the Philippines as a PHE
   e. Disease/s or condition/s declared by the World Health Organization (WHO) as a PHEIC
   f. Disease/s which may lead to permanent medical impairment/disability
   g. Rare disease/s (as identified by the Rare Diseases Technical Working Group established in accordance with RA No. 10747 or the Rare Diseases Act of the Philippines)
2. For vaccines used in the immunization of populations who are most vulnerable or at high risk of contracting the following diseases, in cases where there are no recommended and available alternatives for prevention as determined by national and/or international health authorities and experts, other than to prevent the infection:
   a. Emerging or re-emerging infectious disease/s declared by the President of the Republic of the Philippines as a PHE
   b. Infectious disease/s leading to a life-threatening medical condition as determined by the Secretary of Health upon the recommendation of an expert body
   c. Infectious disease/s declared by the WHO as a PHEIC, with reference to the International Health Regulations (IHR) 2005, or its amendments

C. The following are the acceptable registration statuses of pharmaceutical products or medical devices that may be applied for CSP and considered by the FDA:

1. For pharmaceutical products, including vaccines:
   a. A CSP may be issued for a covered pharmaceutical product or vaccine that does not have a valid FDA registration/authorization. However, the product to be applied for CSP shall be currently registered/authorized in the National Drug Regulatory Authority (NDRA) of the country of origin or other NDRAs, with the same approved indication as the intended use of the product by the CSP applicant.

b. A CSP may be issued for an investigational pharmaceutical product for the same indication with any of the following conditions:

   i. The requested investigational pharmaceutical product must be produced by the same manufacturer of the investigational product that has an ongoing clinical trial in the country of origin or in other countries, or has a signed voluntary licensing agreement with the innovator;

   ii. The requested investigational pharmaceutical product is in a global or national registry (i.e., investigational product is registered and recognized by international health institutions or NDRAs);

   iii. There is an ongoing clinical trial of the investigational pharmaceutical product in the Philippines, but the enrollment of the patient in the clinical trial is not possible; or

   iv. The investigational pharmaceutical product has entered the process of marketing authorization application in the country of origin or in the Philippines.

c. Alternatively, a CSP may be issued for a pharmaceutical product with valid marketing authorization in the Philippines in cases where there is an unavailability of stocks or its alternative, as duly confirmed by the relevant marketing authorization holders.

2. For medical devices, including medical equipment:

   a. A CSP may be issued for a covered medical device or medical equipment that does not have a valid FDA registration/authorization. However, the product to be applied for CSP shall be currently registered/authorized in the NDRA of the country of origin or other NDRAs.

   b. No CSP shall be issued for previously used medical devices from other countries or for refurbished medical equipment.

D. The following are the general conditions on the issuance of CSP:

1. The product issued with CSP shall be valid only for the use of the allowed quantity intended for the treatment and/or prevention of the conditions specified in the CSP. Any use beyond the specified conditions is not authorized by the FDA. Furthermore, the product shall not be sold, transferred, or otherwise donated without explicit approval from the FDA.

2. The CSP Holder shall have the full responsibility for the covered product, shall be solely accountable for any death, damage or injury to the patient arising from the use of the pharmaceutical product or medical device product, and shall make FDA free and harmless from any and all third-party claims arising from the issuance of the CSP and use of the covered pharmaceutical or medical device product.

   This, however, does not exempt other healthcare professionals, healthcare institutions, or marketing authorization holders, where applicable, from fulfilling their respective pharmacovigilance obligations, including the reporting of any suspected adverse drug reactions (ADRs) or adverse events following immunization (AEFI), in accordance with prevailing FDA policies and issuances.

3. The CSP Holder shall be responsible for obtaining full informed consent from each patient (or their legal guardian) prior to the administration of the covered product,

through a duly signed consent form. The form should indicate that the patient understands and acknowledges the potential uncertainties associated with the product's unregistered status, and includes the following information:

a. A description of the covered product and its intended purpose
b. The potential risks and side effects
c. The available alternatives
d. A clear statement that the use of the covered product is voluntary
e. Signature lines for the patient (or guardian) and a witness

4. For imported products:
   a. Importation shall be done through an FDA-licensed importer or, if donated, through a donor who has a signed deed of donation or equivalent instrument with the donee. The FDA-licensed importer or donor shall notify the FDA of the importation. The volume or quantity to be imported shall not exceed the allowed maximum number as stated in the CSP.
   b. Any pharmaceutical product, including vaccines or medical devices, imported by the CSP Holder in excess of the approved quantity stated in the issued CSP shall be deemed unauthorized and illegally diverted into the country, hence considered outright a violative product subject to appropriate regulatory action by the FDA. Thus, appropriate regulatory actions shall be pursued against the use of the product and the institution or facility or physician, including the importer, and the appropriate penalty allowed by law shall be imposed accordingly.

5. For unused products covered by a valid CSP, the CSP Holder shall notify the FDA of the number and justification for the unused quantity through the post-approval commitment form (*Annex A* for pharmaceutical products or *Annex B* for medical devices). In addition, the CSP Holder shall identify its plans for the unused quantity, which may be any of the following:
   a. The unused quantity shall be applied for a new application by the same CSP Holder for use by the same physician or institution for a different patient or disease/medical condition;
   b. The unused quantity shall be transferred to a different applicant who shall submit a new CSP application; or
   c. The unused quantity is no longer intended for use, and a formal notification for the voluntary cancellation of the CSP shall be filed.

6. For medical equipment used under CSP and intended for reuse with a different patient, disease, or medical condition, the CSP Holder shall notify the FDA and provide the corresponding justification through the post-approval commitment form (*Annex B*). The reuse may be permitted through a new CSP applied by either the same CSP Holder or a different CSP applicant.

7. The clinical report/s after the use of the product, reconciliation report, and other product details shall be submitted by the CSP Holder as part of the post-approval commitments (see VI.C below). Immediate reporting of serious ADRs for pharmaceutical products, AEFIs for vaccines, and adverse events involving medical devices shall be spontaneous and mandatory consistent with the National Policy and

Program on Pharmacovigilance following the latest guidelines as per AO No. 2011-0009 and its succeeding amendments and/or issuances.

8. It shall be the FDA's prerogative to determine the allowable quantity or the number of times a product shall be approved for CSP to regulate the use of CSP.

9. The FDA shall regularly monitor the products imported or manufactured under CSP and prioritize/facilitate processing should companies decide to apply for marketing authorization in accordance with the current rules on registration.

10. All information, data, and personal or sensitive personal information (SPI), including but not limited to medical abstracts, diagnoses, treatment plans, and adverse event data collected, used, stored, shared, or otherwise processed under this Order shall be handled in accordance with, and noncompliance shall be subject to the sanctions as provided under, Republic Act No. 10173, or the *Data Privacy Act of 2012*, its IRR, and related issuances, including but not limited to National Privacy Commission (NPC) Circular No. 2020-03, AO No. 2020-0030 entitled *Data Privacy Guidelines on the Processing of Health Information* dated 09 July 2020, and their amendments.

    SPI collected from application and until post-approval phases of the CSP process shall be for the sole purpose of evaluating the need for CSP issuance or subsequent issuance, and for the fulfillment of post-approval commitments, including monitoring of product safety and outcomes.

    The entities accountable and responsible for the lawful processing of SPI are identified as follows:

    a. FDA – As the issuing authority of the CSP, the FDA acts as a Personal Information Controller (PIC) and shall be responsible for the lawful collection, storage, and use of SPI submitted through its electronic applications platform. SPI shall be stored using secure digital systems and encrypted formats. Oversight shall be provided by the FDA Committee for Data Privacy Compliance (per FDA Personnel Order No. 2023-0614, as amended). Where applicable, processing by third parties shall be governed by Data Sharing Agreements (DSAs).

    b. CSP Applicant/CSP Holder – Acts as a PIC for the collection and initial processing of SPI. Responsibilities shall include obtaining informed consent from the patient or legal guardian; collecting relevant clinical information (e.g., history, diagnosis, treatment plan, risk-benefit assessment, ADRs, AEFIs); and disclosing this information to the FDA in support of the CSP application or post-approval commitments.

    c. DOH, health facilities, and healthcare providers – As the national health authority, the DOH and its attached agencies, as well as licensed public and private health facilities and healthcare providers, are PICs pursuant to AO No. 2020-0030. These entities shall process health information consistent with their mandates and ensure lawful data sharing with FDA or other government agencies through patient consent or statutory authority, under a DSA. These entities shall also be responsible for implementing appropriate security safeguards to protect the confidentiality, integrity, and availability of SPI.

    d. Personal Information Processors (PIPs) – Entities or individuals engaged by any of the above PICs to perform data processing on their behalf, including

consultants, contractors, or outsourced personnel, shall be considered PIPs and subject to the Data Privacy Act, its IRR, and relevant contractual safeguards. Engagement shall be covered by Non-Disclosure Agreements (NDAs) and operate strictly within the limits of their engagement and applicable DSAs.

11. The FDA shall have the sole, exclusive, and discretionary authority to approve, deny, suspend, or revoke any CSP in accordance with the provisions of this Order and other applicable laws.

E. The following are the general requirements for applying for CSP:

1. CSP applicants shall submit applications and post-approval commitments through the FDA online platform in the Philippine FDA Website according to the latest guidelines on FDA applications as applicable.
2. The application shall include the estimated volume or number of units needed and the licensed pharmaceutical product or medical device establishment through which the covered pharmaceutical product or medical device may be procured or received as a donation.
3. The identities and addresses of the medical officers or specialists qualified and authorized to prescribe, administer, or use the product, and the name in case of Named Patient Use, shall be provided, subject to further validation anytime by the FDA.

VI. SPECIFIC GUIDELINES

A. CSP application:

1. All applications for CSP shall be through the FDA eServices Portal (https://eservices.fda.gov.ph/)
2. Documentary requirements for **Named Patient Use**:
   a. Accomplished e-Application Form though the applications platform as prescribed by FDA regulations
   b. Proof of payment of the required fees
   c. Curriculum vitae of the qualified physician applying for CSP
   d. Medical abstract of the patient, which contains patient history, diagnosis, and treatment plan
   e. For imported products with prior NDRA approval, proof or certification of registration of the product from the NDRA of the country of origin or another country
   f. For products to be acquired from an existing CSP Holder, an agreement between the CSP Holder and the applicant on the transfer of the unused quantity, containing details including the CSP Number and quantity to be transferred
   g. For investigational pharmaceutical products, in addition to the above:
      i. The rationale with supporting documents establishing the conditions stated above under V.C.1.b

ii. Investigational Medicinal Product Dossier (IMPD)

h. Additional requirements:

i. For pharmaceutical products, including vaccines: A valid medical prescription

ii. For vaccines: A risk-benefit assessment report conducted and signed by the applicant on the risks and benefits surrounding the use of the vaccine on the target recipient, following the format in *Annex C*

iii. For medical devices:

(1) Official technical description of the medical device from the manufacturer (not sourced or extracted from publicly available content)

(2) Justification letter from the attending physician regarding the urgency of the use of the medical device

(3) If the product is locally manufactured, a copy of the License to Operate as a Medical Device Manufacturer

(4) If the product is to be supplied by a company, a copy of the License to Operate as Medical Device Importer/Distributor of the company

(5) A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device on the patient

3. Documentary requirements for **Institutional Use**:

a. Accomplished e-Application Form though the applications platform as prescribed by FDA regulations

b. Proof of payment of the required fees

c. Rationale for volume/quantity requested

d. Distribution agreement between the importer and the source (product owner or manufacturer)

e. Target indication

f. For DOH-licensed hospitals and health facilities, a License to Operate issued by the DOH through its Health Facilities and Services Regulatory Bureau (HFSRB)

g. For imported products with prior NDRA approval:

i. Proof or certification of registration of the product from the NDRA of the country of origin or another country

ii. If imported through an FDA-licensed importer, the distribution agreement between the importer and the source (product owner or manufacturer)

iii. If donated, the deed of donation and the deed of acceptance

h. For products to be acquired from an existing CSP Holder, an agreement between the CSP Holder and the applicant on the transfer of the unused quantity, containing details including the CSP Number and quantity to be transferred

i. For investigational pharmaceutical products:

i. The rationale with supporting documents establishing the conditions stated above under V.C.1.b

ii. IMPD

j. Additional requirements:

i. For vaccines:

(1) The immunization scheme issued by the DOH as recommended by the National Immunization Technical Advisory Group (NITAG)

(2) A risk-benefit assessment report conducted and signed by the applicant and duly recommended by the NITAG on the risks and benefits surrounding the use of the vaccine on the target recipients/groups, following the format in *Annex C*

ii. For medical devices:

(1) Official technical description of the medical device from the manufacturer (not sourced or extracted from publicly available content)

(2) Justification letter from the attending physician regarding the urgency of the use of the medical device

(3) If the product is locally manufactured, a copy of the License to Operate as a Medical Device Manufacturer

(4) If the product is to be supplied by a company, a copy of the License to Operate as Medical Device Importer/Distributor of the company

(5) A commitment letter from the applicant that a medical report shall be submitted after the operation or use of the medical device on the patient

B. Actions on the application

1. Review and evaluation

a. The FDA shall review and evaluate applications based on the following:

i. Assessment of the submitted application documents for compliance with the requirements; and

ii. Assessment of the qualification of the applying licensed physician or institution, who shall be responsible for complying with the technical requirements of the FDA.

b. The FDA shall consider the benefits and risks as they apply to the Philippine context based on the available data provided by the CSP applicant and may consider seeking opinions from clinical experts as necessary.

c. Actual validation may be pursued during the process of evaluation or thereafter, even after approval of the application, as deemed necessary by the FDA.

2. Regulatory decision

a. Approval

i. A CSP shall only be issued by the FDA upon a determination of full compliance with the requirements.

ii. The CSP shall be issued to the applicant who shall be considered as the CSP Holder and shall be responsible for compliance with the post-approval

requirements related to the CSP (see Section C. Post-approval commitments).

b. Disapproval

i. Any of the following or similar instances shall be grounds for the disapproval of an application for CSP:

(1) The documentary evidence supplied by the applicant shows that:

(a) The product applied for compassionate use is not appropriate or justified for use in the treatment or prevention of the disease or medical condition intended to be addressed; and/or

(b) The applicant does not meet the requirements or appropriate standards for the restricted use of the product applied.

(2) The applicant or its importer made misrepresentations, false entries, other forms of fraud, or withheld any relevant information or data contrary to the provisions of this Order, applicable FDA-implemented laws, rules and regulations or appropriate standards;

(3) Other analogous grounds or causes, such as but not limited to:

(a) In case of subsequent applications:

(i) Non-existence of the patients;

(ii) The covered pharmaceutical or medical device products are resold, redistributed, or otherwise administered not in accordance with their intended use;

(iii) The applicant or its importer refuses access to pertinent records upon request, denies entry to FDA inspection officers if an inspection is pursued, or obstructs the inspection process through acts of intimidation, threats, violence, or by causing fear or using force; and/or

(iv) The applicant or its importer has violated any of the terms and conditions of the CSP, including abuse of the use of CSP.

(b) Findings of violation of any other laws that affect the regulatory compliance of the applicant.

ii. Every disapproval of an application rendered by the FDA shall be fully explained in writing, stating the grounds upon which such disapproval is based.

iii. The disapproval shall be final and executory.

C. Post-approval commitments:

1. Documentary requirements to be submitted as post-approval commitments by the CSP Holder:

a. CSP Post-Approval Commitment Report

The CSP Holder shall provide the FDA updates relative to the CSP granted through submission of a CSP Post-Approval Commitment Report (*Annex A* for pharmaceutical products or *Annex B* for medical devices) signed by the attending physician/s. Submissions shall be done quarterly for Institutional Use, and at the end of the treatment for Named Patient Use or the immunization

monitoring, or upon the request for an additional number of units, whichever comes first, following the restricted use of the product issued with CSP.

b. Manufacturing and reconciliation data

The CSP Holder shall provide the FDA with the manufacturing data of the product covered by the issued CSP, including the Certificate of Analysis, Batch/Lot Number, date of manufacture, and expiry date, upon receipt of the stocks/product. Additionally, a reconciliation report detailing the total volume imported shall be provided at the end of the CSP's validity.

Submission of these records must be provided in a .xlxs or .xlsm file format (Microsoft Excel) following the template provided in *Annex D.*

2. For imported products, the licensed pharmaceutical product or medical device importer shall be responsible for the notification of FDA of the total volume/quantity of the pharmaceutical product, vaccine, or medical device imported, through the submission of report or following the latest guidelines on import notification, along with the following importation documents:
   a. Invoice
   b. Bill of lading
   c. Packing list
3. For the unused quantities reported through the submitted CSP Post-Approval Commitment Report, the following shall be conducted as appropriate:
   a. For unused quantities intended to be used by the same physician or institution for a different patient or patient group for the same or different disease/medical condition, a new application for CSP by the same CSP Holder shall be submitted;
   b. For unused quantities intended to be transferred for use by a different physician or institution, a new application for CSP by a different applicant shall be submitted; and
   c. For unused quantities under a CSP intended for voluntary cancellation, formal notification shall be filed by the CSP Holder, and the CSP shall be surrendered to the FDA.

   In addition, if the product is in the Philippines (such as if the product has already been imported into the country), the unused quantity shall be destroyed by the CSP Holder through a Department of Environment and Natural Resources (DENR)-accredited waste treater in accordance with the related implementing guidelines of FDA, with notice to the FDA for witnessing. Alternatively, unused medical equipment may be returned to the country of origin.

   Voluntary cancellation by the CSP Holder of its existing CSP shall be allowed provided that the voluntary cancellation is not intended to defraud the government or escape regulatory accountability. Provided further, that any act of voluntary cancellation shall not remove the FDA of jurisdiction or preclude it in pursuing acts of ensuring the safety of the public or regulatory, enforcement, or other actions as a result of violation or non-conformance of the

authorization holder with FDA-implemented laws, standards, rules and regulations.

No clearance or affirmation of the voluntary cancellation of the existing CSP shall be made unless any FDA-related obligation of the CSP Holder has been settled or unless restrained by the SOH or the Court.

4. For medical equipment used under CSP and intended for reuse as reported through the submitted *Annex B* CSP Post-Approval Commitment Report, the following may be conducted, as appropriate, subject to approval of the FDA:
   a. If intended to be used by the same physician or institution for a different patient or patient group for the same or different disease/medical condition, a new application for CSP by the same CSP Holder shall be submitted; or
   b. If intended to be transferred for use by a different physician or institution, a new application for CSP by a different applicant shall be submitted.
5. Failure on the part of the CSP Holder and importer to conduct the required post-approval commitment activities and submit the required reports shall be grounds for the disapproval of subsequent applications for CSP through or using its establishment and/or future applications for import clearances of the pharmaceutical products, vaccine, or medical device covered under a valid CSP.

D. Fees and Charges

The fees to be paid for a CSP application shall be as follows:

Application Fee:	PhP 500.00
Legal Research Fee:	PhP 10.00
Total:	**PhP 510.00**

E. Processing Time of Applications

CSP applications shall be processed within seven (7) working days from receipt thereof, as outlined in the current FDA Citizen's Charter. The above timeline may be extended consistent with Section 9b of RA No. 11032.

VII. ROLES AND RESPONSIBILITIES

A. The FDA shall exercise its regulatory powers in the implementation and enforcement of this Order. Specifically, it shall:

1. Issue the specific application procedure and forms consistent with this Order;
2. Incorporate digitalization initiatives, such as reengineering and streamlining of processes, to ensure the efficiency of the process; and
3. Monitor and evaluate the implementation of this Order, and submit reports annually, or as often as directed, to the Secretary of Health including, but not limited to, the number of CSPs issued per disease category, the results of safety monitoring

submitted as post-approval commitments, and the status of the products' registration.

B. In promulgating this Order, the CSP Holder and the Importer or Manufacturer of the product under a CSP shall comply with its provisions, including its implementation procedures and documentary requirements. The applicant shall:

1. Undertake responsibility for the submission of complete and correct application documents and ensure unrestricted access to the contact information declared in the submission;

2. Assume accountability for scrutinizing the pharmaceutical product or medical device being applied for, and thoroughly understanding and strictly adhering to the requirements and procedures prior to submitting the application; and

3. Ensure consistent adherence to FDA rules and regulations throughout the validity of the authorization and the timely submission of post-approval commitments.

VIII. SUSPENSION OR REVOCATION OF THE ISSUED PERMIT

A. Violations of this Order shall deem the pharmaceutical product or medical device either unregistered, adulterated and/or misbranded and shall warrant the application of the sanctions and penalties under the applicable provisions of RA No. 3720, as amended by Executive Order No. 175 and RA No. 9711 and its IRR.

B. Grounds for Suspension or Revocation:

1. Except in cases of willful violation of FDA-implemented laws, rules, and regulations, or when public health or safety requires otherwise, no CSP may be suspended or revoked without notice and hearing.

   In any of the instances in the preceding paragraph not requiring prior notice and hearing, an automatic suspension or revocation shall be ordered by the FDA. The CSP Holder shall, within forty-eight (48) hours from receipt of the order suspending or revoking the CSP without notice and hearing, show cause as to why the said order should not remain in force.

   The FDA shall proceed with the disposition of the situation from receipt of the explanation of the CSP Holder.

2. In other instances, any issued CSP shall be suspended or revoked, after notice and hearing, based on any of the following grounds:

   a. The application requirements submitted show that the CSP Holder does not meet the required technical requirements or appropriate standards;

   b. At the time of application, the CSP Holder made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the FDA-implemented laws, their IRR, or appropriate standards;

   c. The CSP Holder has violated any of the terms and conditions of the authorization granted through CSP; and

d. Other analogous grounds or causes, such as but not limited to:

   i. Non-existence of the patients;

   ii. The covered pharmaceutical or medical device products are resold, redistributed, or otherwise administered not in accordance with their intended use;

   iii. The CSP Holder or the Importer refuses access to pertinent records upon request, denies entry to FDA inspection officers if an inspection is pursued, or obstructs the inspection process through acts of intimidation, threats, violence, or by causing fear or using force; and/or

   iv. Findings of violation of any other laws that affect the regulatory compliance of the CSP Holder or the Importer, including abuse of the use of CSP.

The proceedings in the above cases shall follow the Uniform Rules of Procedures under Book III of the IRR of RA No. 9711, and the appropriate penalty imposed as provided by the same law and its IRR.

3. Any suspended or revoked CSP shall have the effect of non-possession of a CSP by the establishment/institution/physician. Thus, the manufacture or importation of the covered pharmaceutical product or medical device is deemed prohibited.

C. Nothing in this section shall restrict the FDA, the DOH or other concerned agencies in imposing other sanctions for administrative violations of any other relevant laws or their implementing rules and regulations or pursuing other legal actions as may be allowed by law.

IX. REPEALING CLAUSE

This Order effectively repeals the following issuances:

A. AO No. 4 s. 1992: Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/Preparation

B. AO No. 2005-0008: Policy and Requirements for Availing of Special Permit for Restricted Use of Unregistered Drug and Test Kits for Human Immune Deficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS)

C. AO No. 2020-0028: Amendment to Administrative Order No. 4 s. 1992 entitled "Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/Preparation

D. FDA Memorandum Circular No. 2015-008: Policy and Requirements for Availing of Compassionate Special Permit for Registrable Medical Devices

This Order also repeals subsection V.7 of AO No. 2018-0002 entitled "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements" to exclude donated medical devices applied for CSP from the Certificate of Medical Device Listing requirement.

Other issuances or parts thereof pertaining to the issuance of CSP by the FDA which are found to be inconsistent with the provisions of this Order are repealed accordingly.

X. SEPARABILITY CLAUSE

If any provision in this Order, or application of such provision to any circumstances is held invalid, the remainder of the provisions in this Order shall not be affected.

XI. EFFECTIVITY

This Order shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines Law Center-Office of the National Administrative Register.

TEODORO J. HERBOSA, MD
Secretary of Health