DESIGN

REGULATION OF THE MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA NUMBER ... YEAR ... ABOUT CLINIC BUSINESS ACTIVITIES IN SPECIAL ECONOMIC ZONES BY THE GRACE OF GOD ALMIGHTY

MINISTER OF HEALTH OF THE REPUBLIC OF INDONESIA,

Considering: to implement the provisions of Article 3 paragraph (3) of Law Number 39 of 2009 concerning Special Economic Zones as amended by Law Number 11 of 2020 concerning Job Creation, and Article 11 of Government Regulation Number 40 of 2021 concerning the Implementation of Special Economic Zones, it is necessary to stipulate a Minister of Health Regulation concerning Clinical Business Activities in Special Economic Zones;

Considering: 1. Article 17 paragraph (3) of the 1945 Constitution of the Republic of Indonesia;

2. Law Number 39 of 2008 concerning the Ministry of State (State Gazette of the Republic of Indonesia of 2008 Number 166, Supplement to State Gazette of the Republic of Indonesia Number 4916);
3. Law Number 36 of 2009 concerning Health (State Gazette of the Republic of Indonesia of 2009 Number 144, Supplement to State Gazette of the Republic of Indonesia Number 5063);
4. Law Number 39 of 2009 concerning Special Economic Zones (State Gazette of the Republic of Indonesia of 2009 Number 147, Supplement to State Gazette of the Republic of Indonesia Number 5066);

5. Law Number 11 of 2020 concerning Job Creation (State Gazette of the Republic of Indonesia of 2020 Number 245, Supplement to the State Gazette of the Republic of Indonesia Number 6573);
6. Government Regulation in Lieu of Law Number 2 Year 2022 on Job Creation (State Gazette of the Republic of Indonesia Year 2022 Number 238, Supplement to State Gazette of the Republic of Indonesia Number 6841);
7. Government Regulation Number 5 of 2021 concerning the Implementation of Risk-Based Business Licensing (State Gazette of the Republic of Indonesia of 2021 Number 15, Supplement to State Gazette of the Republic of Indonesia Number 6617);
8. Government Regulation Number 40 of 2021 concerning the Implementation of Special Economic Zones (State Gazette of the Republic of Indonesia of 2021 Number 50, Supplement to the State Gazette of the Republic of Indonesia Number 6652);
9. Presidential Regulation Number 18 of 2021 concerning the Ministry of Health (State Gazette of the Republic of Indonesia of 2021 Number 83);
10. Minister of Health Regulation Number 9 of 2014 concerning Clinics (State Gazette of the Republic of Indonesia Year 2014 Number 232;
11. Regulation of the Minister of Health Number 5 of 2022 concerning the Organization and Work Procedures of the Ministry of Health (State Gazette of the Republic of Indonesia Year 2022 Number 156);

DECIDE:

Setting : A REGULATION OF THE MINISTER OF HEALTH CONCERNING CLINICAL BUSINESS ACTIVITIES IN SPECIAL ECONOMIC ZONES.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Ministerial Regulation, what is meant by:

1. Special Economic Zones, hereinafter abbreviated as SEZs, are areas with certain boundaries within the jurisdiction of the Unitary State of the Republic of Indonesia which are designated to organize economic functions and obtain certain facilities.
2. Clinic is a health service facility that organizes health services in the form of basic medical services, basic and specialized medical services, or specialized medical services. comprehensively.
3. The electronic integrated business licensing system (*online single submission*), hereinafter referred to as the OSS system, is an integrated electronic system managed and organized by a government agency that organizes government affairs in the field of investment coordination for the implementation of risk-based business licensing.
4. SEZ Administrator is a work unit in charge of organizing business licensing, other licensing, services, and supervision in SEZ.
5. The Central Government is the President of the Republic of Indonesia who holds the power of government of the Republic of Indonesia assisted by the Vice President and ministers as referred to in the 1945 Constitution of the Republic of Indonesia.
6. Regional Government is the regional head as an element of regional government organizers who lead the implementation of government affairs which are the authority of autonomous regions.
7. Minister is the minister who organizes government affairs in the field of health.
8. Head of Agency means the Head of the Food and Drug Administration.

Article 2

The Regulation on the Implementation of SEZ Clinic Business Activities aims to provide a reference for business actors, the head of the Clinic, the government and related stakeholders in organizing the SEZ Clinic.

CHAPTER II
ORGANIZATION

Section One Business Activity Standards

Paragraph 1
General

Article 3

(1) SEZ clinics can be government clinics and private clinics.

(2) The Government Clinic as referred to in paragraph (1) is a Clinic organized by the Central Government, Regional Governments, Government Institutions, TNI and POLRI.

(3) The Government Clinic as referred to in paragraph (1) is in the form of a technical implementation unit of the agency in charge of the health sector, or certain agencies in accordance with the provisions of laws and regulations.

(4) The private clinic as referred to in paragraph (1) is a clinic organized by the community in the form of a legal entity in Indonesia.

Paragraph 2 Business Classification

Article 4

(1) The classification of SEZ private clinic businesses based on capital ownership consists of:

a. Clinic with Foreign Investment; or

b. Clinic with Domestic Investment.

(2) The clinic as referred to in paragraph (1) must meet international service standards.

(3) International service standards as referred to in paragraph (2) are Clinic services accredited by international accreditation agencies or domestic accreditation agencies in accordance with the accreditation standards of international accreditation agencies or accreditation standards set by the Minister no later than 2 (two) years after the Clinic becomes operational.

(4) Clinic with Foreign Investment as referred to in paragraph (1) letter a may be a branch Clinic of a foreign Clinic or foreign health care facility.

(5) Clinics with Domestic Investment as referred to in paragraph (1) letter b may cooperate with foreign Clinics or foreign health care facilities.

Article 5

Classification of SEZ Clinic business based on service delivery, consisting of

a. Outpatient clinic; and

b. Inpatient clinic.

Paragraph 3

Requirements

Article 6

(1) SEZ Clinic business activity requirements consist of:

a. general requirements; and

b. special requirements.

(2) General requirements as referred to in paragraph (1) letter a consist of:

a. legal entity documents;

b. The detailed RKL-RPL document for clinics refers to the SEZ AMDAL;
c. Clinic profile;
d. document *self assessment document* Clinic in accordance with the services provided; and
e. a document of commitment to accreditation.

(3) The special requirements as referred to in paragraph (1) letter b consist of:
a. List of facilities, infrastructure, buildings, equipment and list of medicines and consumables;
b. HR list in accordance with authority, competence and organizational structure;
c. List of types of health services at the Clinic;
d. Documents of practice licenses of all health workers; and
e. Hazardous and toxic waste disposal cooperation agreement document.

(4) The practice license document as referred to in paragraph (3) letter d, can be in the form of a practice license document at the local SEZ clinic, a practice license document in the SEZ area, and/or an assignment letter issued by the SEZ administrator.

(5) To obtain a letter of assignment as referred to in paragraph (4), the Head of the clinic submits the name of a particular specialist doctor or specialist dentist who will provide services at the SEZ Clinic to the SEZ administrator, along with the reasons for the service needs to be provided.

(6) Certain specialist doctors or specialist dentists who will provide services at the SEZ Clinic as referred to in paragraph (5) must have a license to practice in other health care facilities with the appropriate clinical authority needed;

Article 7

(1) In addition to the requirements for SEZ Clinic business activities as referred to in Article 6 paragraph (1), for Clinics

SEZs that provide certain health services must meet the general requirements and special requirements for business licenses to support business activities.

(2) Business licensing to support business activities as referred to in paragraph (1) is a legality given to business actors to support business activities at the SEZ Clinic.

(3) The general requirements as referred to in paragraph (1) consist of:

a. SEZ Clinic standard certificate document;

b. environmental licensing documents in accordance with the provisions of laws and regulations;

c. a letter of commitment to report/register services at least 1 (one) time a year; and

d. duration of requirement fulfillment for 3 (three) months

(4) The special requirements as referred to in paragraph (1) are documents that must be fulfilled by the SEZ Clinic based on the activities of providing certain health support services in accordance with the provisions of laws and regulations in the field of risk-based business licensing in the Health sector.

Paragraph 4

Buildings, infrastructure and equipment

Article 8

(1) SEZ clinics must have buildings, infrastructure, and equipment in accordance with the type and form of health services they provide.

(2) The building of the SEZ Clinic as referred to in paragraph (1) is adjusted to the needs of the health services provided.

(3) The SEZ Clinic equipment as referred to in paragraph (1) is in the form of examination equipment and health service support equipment.

(4) In addition to having buildings, infrastructure, and equipment as referred to in paragraph (1), the SEZ Clinic must have procedures for:

a. ensure the quality of service;

b. ensuring the safety, health, and occupational safety of Clinic staff (health and non-health personnel); and

c. control and handling of medical waste generated (excluding transportation, treatment and disposal).

Paragraph 5

Organization and Human Resources

Article 9

(1) The organizational structure of the SEZ Clinic consists of at least:

a. head of the Clinic;

b. the person in charge of health services; and

c. responsible for operational services.

(2) In addition to the organizational structure as referred to in paragraph (1), SEZ clinics can add other organizational elements according to the needs and capabilities of the clinic in the context of good clinic governance.

(3) The Head of the SEZ Clinic as referred to in paragraph (1) letter a must be a doctor, dentist, specialist doctor, or specialist dentist.

(4) The Head of the SEZ Clinic as referred to in paragraph (3) must have a License to Practice (SIP) at the SEZ Clinic, and can double as a service provider.

(5) The Head of the Clinic, the person in charge of health services, and the person in charge of operational services at the SEZ Clinic with Domestic Investment and Foreign Investment as referred to in paragraph (1) must be Indonesian citizens.

Article 10

(1) Human resources at the SEZ Clinic include:

a. medical personnel;
b. other health personnel; and
c. support/support personnel.

(2) Other health workers as referred to in paragraph (1) letter b in accordance with the service needs of the SEZ Clinic.

(3) Support/support personnel as referred to in paragraph (1) letter c are clinic management personnel and/or non-health personnel.

(4) The number and qualifications of SEZ Clinic personnel are adjusted to the results of the workload analysis, as well as service needs and capabilities.

Article 11

(1) The SEZ Clinic can utilize health workers of Indonesian citizens who have graduated from abroad, and health workers and non-health workers of foreign nationals according to service needs.

(2) The utilization of foreign health workers and non-health workers at the SEZ Clinic as referred to in paragraph (1) shall receive assistance for the transfer of science, technology, and expertise.

(3) The Head of Clinic in SEZ must make plans and appoint Health Workers to assist in the transfer of science, technology, and expertise as referred to in paragraph (1).

Article 12

(1) Utilization of health workers of Indonesian citizens who have graduated from abroad, and health workers of foreign nationals as referred to in Article 11 paragraph (1) is implemented to provide direct or indirect health services to patients at the SEZ Clinic.

(2) Foreign health workers as referred to in paragraph (1) are only allowed to perform

practice at SEZ Clinics and are prohibited from organizing independent practice.

(3) Foreign health workers as referred to in paragraph (1), must fulfill technical requirements field health and labor requirements.

(4) Technical requirements in the field of health and labor requirements as referred to in paragraph (1) shall be submitted by the business actor or head of the SEZ Clinic as a user of foreign health workers.

Article 13

(1) Technical requirements in the field of health as referred to in Article 12 paragraph (4) for health workers of Indonesian citizens with foreign graduates and foreign citizens consist of:

a. Diploma, proof of graduation, or certificate of completion of education according to competence from the original educational institution;
b. *certificate of good standing* from the authorized institution at the last place of practice or certificate of competence and/or certificate of professional registration from the country of origin or authority of the last place of practice;
c. a certificate of work experience of at least 3 (three) years in accordance with the competence in the professional field;
d. a job offer letter from the Indonesian utilizer; and
e. a statement that will not engage in professional practice outside the SEZ area while working at the SEZ Clinic.

(2) Documents as referred to in paragraph (1) letter a through letter e that use a language other than English or Indonesian must be translated into English by the agency that uses them.

publish document such as or a sworn translator.

Article 14

Labor requirements as referred to in Article 12 paragraph (4) in the form of authorization for the use of foreign health workers in accordance with the provisions of laws and regulations.

Article 15

(1) Indonesian health workers graduated from abroad and foreign nationals who will practice at the SEZ Clinic must take part in an evaluation to obtain a certificate of competence.

(2) Document requirements in the context of carrying out the evaluation as referred to in paragraph (1) consist of:
   a. document requirements technical field health as referred to in Article 12;
   b. valid proof of identity;
   c. curriculum vitae;
   d. physical and mental health certificate in accordance with the provisions of laws and regulations;
   e. a recent 4 x 6 cm color photograph with a red background;
   f. a statement that will comply with the provisions of ethics and laws and regulations; and
   g. a certificate of police record or *criminal record*.

Article 16

(1) Evaluation as referred to in Article 15 paragraph (1) for medical personnel is organized by way of:
   a. portfolio assessment and orientation at the SEZ Clinic where they work, for Indonesian medical personnel who graduated from abroad and foreign nationals who obtained professional certificates, competency certificates, and / or other certificates that

certifying competence from an authorized institution of a foreign country;

b. adjustment of skills at the SEZ Clinic where they work with a period of time according to the results of equalization, for medical personnel of Indonesian citizens graduated from abroad and foreign citizens who obtain professional certificates, competency certificates, and / or other certificates stating competence from authorized institutions of foreign countries other than as referred to in letter a; or

c. portfolio assessment, for overseas-educated Indonesian medical personnel and foreign nationals who have expertise and are recognized at the international level.

(2) Foreign state authorized institutions as referred to in paragraph (1) letter a shall be determined by the Minister.

Article 17

(1) Evaluation as referred to in Article 15 paragraph (1) for health workers other than medical personnel is organized by way of:

a. portfolio assessment for:

1) health personnel other than medical personnel of Indonesian citizens who graduated from abroad and foreign citizens who obtained proof of graduation, professional certificates, competency certificates, and/or other certificates stating competence from authorized institutions of foreign countries; and

2) health personnel other than medical personnel of Indonesian citizens who graduated from abroad and foreign citizens who have expertise and are recognized at the international level.

b. portfolio assessment and interview/oral test, for other health workers other than medical personnel of Indonesian citizens who graduated from abroad and citizens of Indonesia.

foreign countries that obtain proof of graduation, professional certificates, competency certificates, and/or other certificates that certify competence from authorized institutions of foreign countries other than as referred to in letter a number 1).

(2) Foreign state authorized institutions as referred to in paragraph (1) letter a number 1) shall be determined by the Minister.

Article 18

(1) Evaluation for medical personnel as referred to in Article 16 is organized by a special competency evaluation sub-committee under the joint committee on adaptation.

(2) Evaluation for health workers other than medical personnel as referred to in Article 17 is organized by the Minister through the director general who has duties and functions in the field of health workers.

(3) The special competency evaluation sub-committee as referred to in paragraph (1) is determined by the Minister.

(4) Based on the evaluation results as referred to in paragraph (1) and paragraph (2), a competency certificate is issued which is the basis for issuing a registration certificate.

(5) Registration certificate as referred to in paragraph (4) issued by the council in accordance with the provisions of laws and regulations.

(6) Based on the registration certificate as referred to in paragraph (5), the SEZ Administrator issues a license to practice.

Paragraph 6 Service

Article 19

(1) KEK Clinic organizes basic medical services and/or specialized medical services in accordance with the competence of medical personnel.

(2) The SEZ Clinic as referred to in paragraph (1) may specialize in services in one particular field based on certain branches/disciplines, organ systems, or advances in health technology.

(3) The types of services of the SEZ Clinic as referred to in paragraph (1) consist of:

a. promotive and preventive services; and

b. curative, rehabilitative, and palliative services.

(4) Promotive and preventive services as referred to in paragraph (2) letter a, include:

a. IEC to patients and families;

b. Medical counseling;

c. Early detection; and

d. Activities promotive and preventive other as needed in the service.

(5) Curative, rehabilitative, and palliative services as referred to in paragraph (2) letter b include:

a. Treatment and medical services including minimally *invasive surgery* services;

b. Oral health services;

c. Reproductive services, including childbirth, assisted reproduction or outside the natural way;

d. Healing of diseases and restoration of health, including stem cell and/or cell services, and aesthetic services;

e. Emergency services;

f. Eye health services include hyperbaric services;

g. Medical rehabilitation services;

h. Medical rehabilitation services for addicts of narcotics, psychotropic substances, and other addictive substances;

i. Nutrition services;

j. Pharmaceutical services; and/or

k. Other health services include geriatric and elderly services, radiology services, laboratories

medical, stem cell laboratories, stem cell and tissue banks, eye banks, and chemotherapy.

(6) The Minister may stipulate other health services, in addition to the health services referred to in paragraph (5) letters a to k, in the context of the development of science and technology in the field of health.

(7) Services as referred to in paragraph (4) and paragraph (5) implemented based on service standards, professional standards, and standard operating procedures in accordance with the provisions of laws and regulations.

(8) SEZ Clinic Services as referred to in paragraph (1) implemented in the form of:

a. Outpatient services; and

b. Inpatient services.

Paragraph 7

Other provisions

Article 20

(1) SEZ clinics can utilize types of drugs including the utilization of drugs through the implementation of clinical trials for health services while still paying attention to safety, efficacy, and quality.

(2) In the utilization of drugs through the implementation of clinical trials as referred to in paragraph (1) must obtain approval by the Minister or Head of the Agency that carries out government affairs in the field of drug and food control in accordance with its authority.

Article 21

(1) Drugs and medical devices used by the SEZ Clinic must have a distribution license in accordance with the provisions of laws and regulations.

(2) In addition to being required to have a distribution license as referred to in paragraph (1), drugs that are brought into the region of

Indonesia must obtain an import certificate from the Head of the Agency.

Article 22

(1) The entry of drugs and medical devices that do not yet have a distribution license as referred to in Article 21 to the SEZ Clinic, is carried out through a special SEZ lane mechanism.

(2) The entry of drugs in the form of narcotics, psychotropic substances, or pharmaceutical precursors must meet the requirements:
   a. analysis of supervision results; and
   b. import approval letter,
   in accordance with the provisions of laws and regulations.

(3) The entry of drugs and medical devices as referred to in paragraph (1) may be carried out by the SEZ Clinic in accordance with the provisions of laws and regulations in the field of SEZ.

(4) Permission to import drugs and medical devices through the SEZ special route mechanism as referred to in paragraph (1) is granted by the Minister and the Head of the Agency in accordance with their respective duties and authorities after fulfilling the criteria and requirements.

(5) The criteria for the SEZ special lane mechanism as referred to in paragraph (4) consist of:
   a. not yet registered drugs with the same active substance or medical devices with the same function;
   b. drugs with the same active substance or medical devices with the same function have been registered but availability is scarce;
   c. has obtained a distribution permit or *emergency use authorization* from the drug authority of the country of origin or the authority of a country that has an *established* evaluation system; and
   d. meet safety, efficacy, and quality standards and requirements.

(6) The requirements for the SEZ special lane mechanism as referred to in paragraph (4) consist of:

a. a statement letter from the head of the SEZ Clinic that based on the review of the medical committee of the SEZ Clinic, there are no drugs or medical devices available for disease management or their availability is scarce;

b. certificate or proof that the medicine and medical device has a distribution permit or *emergency use authorization* from the country of origin;

c. certificate of safety, quality and efficacy of drugs and medical devices (*Certificate of Analysis/CoA*);

d. drugs and medical devices are obtained from authorized manufacturers or distributors in the country of origin as evidenced by:

1) an invoice from the exporter and a certificate of *good manufacturing practices* from the manufacturer, for drugs; or

2) ISO 9001, ISO 13485 certificates, or distributor cooperation agreements with manufacturers, for medical devices.

e. A stamped statement from the head of the SEZ Clinic stating that the drugs and medical devices included are only used in the SEZ Clinic that submitted the application.

f. Specifically for medical devices that contain or emit ionizing radiation and / or radioactive substances for medical, attach technical recommendation/permit from the authorized institution in the country.

(7) In addition to meeting the requirements as referred to in paragraph (6), drugs in the form of vaccines must also meet the following requirements:

a. a vaccine batch/lot graduation certificate from the authority in the country where the vaccine was graduated for each entry; and

b. *summary batch/lot protocol* for 3 (three) consecutive batches published

by the manufacturer.

(8) In the event that the requirements as referred to in paragraph

(7) letter a cannot be fulfilled, approval of the SEZ special pathway mechanism can still be given as long as it fulfills the batch graduation provisions in accordance with the provisions of laws and regulations.

Article 23

The use of drugs and medical devices by SEZ Clinics through the importation of drugs and medical devices as referred to in Article 22 can only be done for SEZ Clinics that submit applications.

Article 24

(1) The entry of medical devices that use ionizing radiation sources and/or radioactive substances into SEZs must obtain a technical recommendation from the Head of the Agency in charge of carrying out supervision through regulations, licensing, and inspections of all nuclear power utilization activities.

(2) Technical recommendation as referred to in paragraph (1) must have been given at the latest 7 (seven) days since the request for recommendation is submitted by the SEZ Clinic to the Head of the Agency in charge of carrying out supervision through regulations, licensing, and inspection of all nuclear power utilization activities.

(3) To obtain a recommendation as referred to in paragraph (1), the SEZ Clinic must submit an application by attaching:

a. permission to use or utilize ionizing radiation sources from the authorized institution of the country of origin;
b. technical certificate of ionizing radiation source equipment; and
c. quality certificate or certificate of eligibility from the manufacturer of the country of origin.

(4) In the case of the entry of medical devices as

referred to in paragraph (1) by using radioactive substances that are category 1, in addition to fulfilling the requirements as referred to in paragraph (2), must also be equipped with a letter of approval or export authorization from the regulatory agency in the producer country.

(5) Utilization of ionizing radiation sources, production of radioisotopes, and/or research and development related to nuclear in the medical field in KEK must have a nuclear utilization permit based on the provisions of laws and regulations regarding business activity standards in the implementation of licensing. business licensing implementation based on risk-based business licensing in the nuclear sector.

(6) The nuclear utilization permit as referred to in paragraph (4) is carried out in accordance with the licensing mechanism for business licensing in KEK.

(7) To have a nuclear utilization permit as referred to in paragraph (4), the SEZ Clinic is given facilities and licensing facilities in the form of a *Service Level Agreement* (SLA) in SEZ while still prioritizing radiation safety and security of radioactive substances.

(8) Supervision for the utilization of ionizing radiation sources, carried out in accordance with the provisions of laws and regulations regarding nuclear inspection.

Article 25

In the context of developing health services, the SEZ Clinic can carry out research and development in the health sector including the implementation of clinical trials whose implementation is in accordance with statutory provisions.

Third Part

Risk-Based Business Licensing Conformity Assessment

Article 26

(1) Risk-Based Business Licensing through the SEZ Clinic OSS System in the form of:
   a. NIB and standard certificate owned by the business actor; and
   b. Fulfillment of standards as stipulated in this Ministerial Regulation.

(2) To obtain NIB as referred to in paragraph (1) letter a, business actors register business licenses through the OSS System.

(3) After obtaining a business identification number as referred to in paragraph (2), business actors shall carry out the preparation stage:
   a. land acquisition;
   b. building construction;
   c. procurement of equipment or facilities;
   d. human resource procurement;
   e. fulfillment of business standards; and/or
   f. other activities prior to operations including pre-feasibility or feasibility studies and operational financing during the construction period.

(4) Implementation of the preparation stage as referred to in letter b for a maximum of 1 (one) year;
   a. business actors submit business license applications to the SEZ Administrator through the OSS System;
   b. application for business licensing as referred to in letter d is accompanied by required documents in accordance with the business activity standards as stipulated in this Ministerial Regulation which are uploaded through the OSS System;
   c. The SEZ Administrator verifies the required documents as referred to in letter e at the latest 5 (five) working days since the application is submitted.

accepted, with the involvement of the Ministry of Health;

d. The SEZ Administrator conducts field verification for a maximum of 20 (twenty) working days since the administrative requirement documents as referred to in letter f are declared complete and correct, by involving the Ministry of Health; and

e. granting of business licensing or submission to fulfill the completeness of the fulfillment of business licensing requirements through the OSS System.

(5) The granting of business licenses as referred to in paragraph (1) is carried out after business actors fulfill the requirements based on the results of verification.

(6) Submission to fulfill the completeness of the fulfillment of business licensing requirements as referred to in paragraph (1) is carried out if the business actor has not fulfilled the requirements based on the results of verification.

(7) Provisions regarding business licensing procedures as referred to in paragraph (1) through paragraph (6) applies mutatis mutandis to business licensing procedures to support the business activities of the SEZ Clinic.

Article 27

(1) The validity period of the SEZ Clinic Business Standard Certificate is valid for 5 (five) years and can be extended again as long as it meets the requirements.

(2) The validity period of business licenses to support SEZ Clinic business activities is valid as long as the service is still being provided and registration is carried out annually.

(3) The extension of the SEZ Clinic business license as referred to in paragraph (1) is carried out no later than 6 (six) months before the SEZ Clinic business license expires.

(4) Requirements for the extension of business licenses for SEZ Clinic as referred to in paragraph (2) consist of:

a. valid business license documents of the Clinic;
b. proof of accreditation document;
c. *self-assessment* of the Clinic which includes types of services, human resources, health facilities, equipment and supporting facilities;
d. documents/evidence of function test and/or trial for new medical devices; and
e. calibration documents for medical devices that are subject to mandatory calibration.

Article 28

(1) Clinic SEZ should do changes business licenses in the event of any changes:
a. legal entity;
b. Clinic name;
c. capital ownership; and/or
d. Clinic address.

(2) Requirements for changes to business licensing as referred to in paragraph (1) consist of:
a. Valid clinical business license document;
b. A statement letter on the change of legal entity, Clinic name, capital ownership, Clinic type, and/or Clinic address, signed by the Clinic owner;
c. change document of business identification number; and/or
d. *self-assessment* of the Clinic which includes types of services, human resources, health facilities, equipment and supporting facilities.

Third Section
Clinic Naming

Article 29

(1) The naming of the SEZ Clinic must take into account religious, socio-cultural and ethical values and norms.

(2) Naming the Clinic as referred to in paragraph (1) can be customized according to its ownership and specificity.

(3) The naming of a special Clinic as referred to in paragraph (2) must include its specificity.

(4) The name of the Clinic in the SEZ can add the words international, *international*, *world class, world class,* global, and/or other names that have the same meaning.

(5) In the event that the SEZ Clinic is a Clinic with Foreign Investment that is a branch of a foreign Clinic or foreign health care facility as referred to in Article 4 paragraph (4), or a Domestic Investment Clinic that cooperates with a foreign Clinic or foreign health care facility as referred to in Article 4 paragraph (5), the name of the Clinic may use the name of the foreign Clinic or foreign Health Care Facility.

(6) Naming the Clinic as referred to in paragraph (1) It is forbidden to use the name of a living person.

Fourth Section
Clinic Obligations

Article 30

(1) The SEZ Clinic, in addition to providing health services as referred to in Article 19, is obliged to carry out:

a. Clinic obligations;
b. registration;
c. accreditation; and
d. fulfillment of quality indicators,

in accordance with the provisions of laws and regulations.

(2) Exempted from the provisions as referred to in paragraph (1) letter c, in the event that the SEZ Clinic has the same *brand* as the Clinic of the country of origin, the implementation of

accreditation and accreditation/reaccreditation renewal are carried out in accordance with the accreditation organization of the home country Clinic.

CHAPTER III
RECORDING AND REPORTING

Article 31

(1) SEZ Clinics are required to record and report through an information system developed by the Clinic and an *online* information system developed by the Ministry of Health to present Clinic information nationally.

(2) In addition to recording and reporting as referred to in paragraph (1), specifically related to the entry or realization of imports and the realization and realization of the use of drugs entered through the SEZ special route mechanism, the SEZ Clinic is required to report to the Head of the Agency through an *online* information system developed by the Food and Drug Administration in accordance with the provisions of laws and regulations.

(3) The information system as referred to in paragraph (1) is integrated with the health data interoperability and integration service platform managed by the Ministry of Health in accordance with the provisions of laws and regulations.

CHAPTER IV
SERVICE FINANCING

Article 32

(1) The financing of health services at the SEZ Clinic comes from patient financing, commercial insurance, and/or the national health insurance program.

(2) Financing sourced from the national health insurance program as referred to in paragraph (1)

done via scheme coordination scheme (*coordination of benefits*).

CHAPTER V
COACHING AND SUPERVISION

Article 33

(1) The Minister, Head of Agency, National Council, Regional Council, and SEZ Administrator supervise the implementation of SEZ Clinic business licensing in accordance with their respective duties, functions, and authorities.

(2) Supervision as referred to in paragraph (1) is directed at improving the quality of health services and patient safety.

(3) The Ministry of Health, provincial Regional Governments, and district/city Regional Governments in conducting supervision may assign supervisory personnel carried out in accordance with the Minister of Health Regulation regarding supervision in the health sector.

(4) Supervision is directed towards improving the quality of health services and patient safety and towards the fulfillment of standards in accordance with the provisions of this Ministerial Regulation and Clinic obligations stipulated in Government Regulations governing Risk-Based Business Licensing.

(5) Supervision of SEZ clinic business licenses is carried out in the form of routine and incidental supervision.

(6) Routine supervision is carried out through:
   a. report on the results of the Clinic's activities;
   b. field inspections conducted in the context of administrative and/or physical checks on the fulfillment of standards and guidance.

(7) Field inspections as referred to in paragraph (6) letter b shall be conducted at most once every 1 (one) year.

(1) Incidental supervision can be done through inspections

field in the form of physical visits.

(2) Incidental supervision is carried out based on complaints from the public and/or the owner of the SEZ Clinic.

CHAPTER V
CLOSING PROVISIONS

Article 34

This Ministerial Regulation shall come into force on the date of promulgation.

In order that every person may know it, this Ministerial Regulation shall be promulgated by placing it in the State Gazette of the Republic of Indonesia.

Established in Jakarta on
the date of

MINISTER OF HEALTH OF THE
REPUBLIC OF INDONESIA,

BUDI G. SADIKIN

Promulgated in Jakarta on
the date of

MINISTER OF LAW AND HUMAN RIGHTS OF THE
REPUBLIC OF INDONESIA,

YASONNA H. LAOLY

STATE NEWS OF THE REPUBLIC OF INDONESIA YEAR 2022 NUMBER