DECREE reforming, adding to and repealing various provisions of the General Health Law.

On the margin, a seal with the National Coat of Arms, which reads: United Mexican States.- Presidency of the Republic.

CLAUDIA SHEINBAUM PARDO, President of the United Mexican States, to its inhabitants know ye:

That the Honorable Congress of the Union has seen fit to address to me the following

DECREE

"THE GENERAL CONGRESS OF THE UNITED MEXICAN STATES DECREES:

VARIOUS PROVISIONS OF THE GENERAL HEALTH LAW ARE AMENDED, ADDED AND REPEALED

Sole Article.- The following articles are **amended :** 3, current section XXVIII; 6, section XII; 7, sections VIII Bis, current X, which becomes IX Bis, XIV Bis and current XV; 10, first paragraph and current second paragraph; 13, section B, sections V, VI and current VII; 17 Bis, first and second paragraphs, sections II, VI, X and XI; 18, first paragraph; 19, first paragraph; 32, second paragraph; 41 Bis; 51 Bis 3; 77 bis 5, subsection A), section VI, and subsection B), sections V and VI; 77 bis 8; 77 bis 9, second paragraph; 77 bis 10, section III; 77 bis 17; 77 bis 29, first paragraph, section II, and fourth paragraph; 77 bis 30, fourth and fifth paragraphs; 77 bis 35, third paragraph, section XII; 98; 104, first paragraph; 105; 194, first and second paragraphs, section I; 222, second paragraph; 234; 245, sections I, second paragraph, II and IV; 259, first paragraph; 313, sections III and V; 314, sections XIV Bis, XVII, XXV, XXVII and XXVIII; 316, first, second, fifth, sixth and seventh paragraphs; 316 Bis 1; 319; 321 Bis; 322, fifth paragraph; 323, section II; 327, first paragraph; 332, second paragraph; the name of Chapter III Bis of Title Fourteen; 341, first paragraph, subsection A), section IV, and second paragraph; 341 Bis, first paragraph; 342 Bis 1, first paragraph; 342 Bis 3, first paragraph and section III; 371; 375, section VI; 376; 396, section I; 414 Bis, first paragraph, subsections a) and b), and 431; articles **3 ,** with sections III Bis, XXVIII and XXIX; 6, with section XIII; 7, with sections II Ter, X, XIV Ter, XV and XVI, renumbering the subsequent ones accordingly; 9 Bis; 10, with the second paragraph, the current one becoming the third and last paragraph; 13, section A, with section III Bis, and section B, with section VII, renumbering the subsequent ones accordingly; 17 Bis, second paragraph, with sections XII Bis, XII Ter, XII Quater and XII Quinquies; 35 Bis; Chapter IV Bis to Title Three, comprising articles 60 Bis, 60 Ter, 60 Quater, 60 Quinquies and 60 Sexies; Chapter IV Ter to Title Three, comprising articles 60 Septies, 60 Octies, 60 Nonies, 60 Decies; Chapter VI Bis to Title Three, comprising articles 71 Bis, 71 Ter, 71 Quater, 71 Quinquies, 71 Sexies, 71 Septies and 71 Octies; 77 bis 10, with section IV Bis; 222, third paragraph; 245, section III, the fifty-sixth paragraph, with the subsequent paragraphs being renumbered accordingly, and the last paragraph; 262 Bis; Chapter XII Ter to Title Twelve, comprising articles 282 Ter, 282 Quater and 282 Quinquies; 314, with sections XI Bis, XXIX, XXX, XXXI and XXXII; 340 Bis; 340 Ter; 340 Quater; 341, with a third paragraph; 342 Bis 1, with the sixth and seventh paragraphs; 342 Bis 4; 414 Bis, first paragraph, with a subsection c), and 456 Bis, and articles 7, section II, the third paragraph; 108; 245, section III, forty-fifth paragraph, and 314, section IV, of the General Health Law are **repealed ,** to read as follows:

Article 3.- ...

I. to **III.** ...

III Bis. **Planning the creation, replacement, and expansion of infrastructure for the provision of health services;**

IV. to **XXVII. ...**

XXVII Bis. Comprehensive pain management;

XXVIII. **Digital health, and**

XXIX. Other matters established by this Law and other legal regulations, in accordance with the third paragraph of Article 4 of the Constitution.

Article 6.- ...

I. a **X.** ...

XI. To design and implement public policies that promote nutritious, sufficient and quality food, which efficiently counteracts malnutrition, overweight, obesity and other eating disorders;

XII. To promote the creation of comprehensive care programs for victims and perpetrators of bullying and school violence, in coordination with educational authorities **and in accordance with other applicable legal provisions, and**

XIII. **Promote universal access to healthcare through the exchange of services between public health institutions, to guarantee effective access to timely and quality care for all people.**

Article 7.- ...

I. **...**

II. **...**

...

Repealed

II Bis. **...**

II Ter. **To plan and integrate the demand for medicines, high-tech medical equipment that has been determined and other health supplies, as well as to monitor and advise during the consolidated contracting procedures and their execution, in which the agencies and entities of the Public Administration intervene**

Federal entities that provide medical care, public health and social assistance services, in accordance with the Law on Acquisitions, Leases and Services of the Sector
Public and other applicable provisions;

III. and **VIII.** **...**

VIII Bis. Promote the incorporation, use and exploitation of information and communication technologies in health services , **such as, among others, telehealth, telemedicine, mobile health, electronic medical or health records and portable devices;**

IX. **...**

IX En. Promote the establishment of the National Basic Information System on the subject of Health **and the National Health Information System as mechanisms for reporting and collecting statistical and nominal information generated by the members of**
National Health System, for the consolidation of the national base referred to in section X of this article;

X. **To integrate and manage a national health information database with information on service provision, infrastructure and medical equipment, enabling the evaluation of the performance of members of the National Health System, the exchange of services and the strategic planning of health policies, criteria and guidelines;**

X Bis. a **XIV. ...**

XIV Bis. Promote and incorporate gender-sensitive approaches into strategies, **the** information campaigns, and other programs within the framework of their powers to contribute to equality between women and men in access to the right to health protection, including neoplasms that affect the sexual and reproductive health of men and women;

XIV Ter. Coordinate the planning for the creation, replacement and expansion of medical units, as well as for high-technology medical equipment, through the implementation of the National Master Plan for Health Infrastructure and High-Technology Medical Equipment;

XV. **Coordinate the preparation of the needs assessment for medicines, high-tech medical equipment and other health supplies required for the provision of health services, based on the information provided by the medical units of the health sector;**

XVI. **To carry out control regarding the preparation, application, possession, use, supply, import, export and distribution of medicines, biological products, vaccines, supplies and medical devices, with the exception of those for veterinary use, and**

XVII. Other powers required for the fulfillment of the objectives of the National Health System, and those determined by applicable **legal** provisions .

Article 9 Bis.- The Federal Health System is made up of the Federal Commission for Protection against Health Risks and the health protection authorities of the federative entities with which a coordination agreement has been signed for the exercise of powers in matters of health regulation, control, surveillance and promotion, as well as the laboratories of the federative entities in their health regulation component.

Article 10.- The Ministry of Health will promote the participation, in the National Health System , of health service providers, from the public, social and private sectors, their workers and **the users of said services,** as well as the authorities or representatives of the indigenous and Afro-Mexican peoples and communities, in accordance with the provisions issued for this purpose.

Based on information on the planning and consolidated procurement procedures for medicines, high-tech medical equipment and other health supplies, the Ministry of Health will define plans, projects and mechanisms that allow for the timely and high-quality optimization of the supply of medicines, high-tech medical equipment and other health supplies in the public institutions of the National Health System, without prejudice to the powers that correspond to the Ministries of Finance and Public Credit and Anti-Corruption and Good Governance.

It will also promote coordination with **suppliers** of **medicines, high-tech medical equipment and other** health supplies, in order to rationalize and ensure their availability.

In consolidated procurement procedures for medicines, medical devices, and other health supplies, in accordance with applicable legal provisions, including international instruments, the Ministry of Health shall promote the participation of individuals or legal entities that demonstrate investment within the national territory in the production chain of medicines, medical devices, and other health supplies, or that have begun the installation of factories, laboratories, or warehouses that form part of said chain, or that conduct scientific research, or when the procurement involves innovative health products. This is without prejudice to the provisions of the public procurement chapters of the trade agreements entered into by the Mexican State.

Article 13.- ...

A. ...

I. to **III.** ...

III Bis. **The coordination of planning actions for the creation, replacement and expansion of infrastructure for the provision of health services;**

IV. to **X.** ...

B. ...

I. a **IV.** ...

V. **Integrate a database with local statistical information fed by health care service providers, both public and private, with nominal information on the provision of their services, which allows the evaluation of the performance of the members of the National Health System, the exchange of services and the strategic planning of policies, criteria and guidelines in health matters;**

WE. To monitor, within their sphere of competence, compliance with this Law and other applicable provisions;

VII. **To promote the implementation and operation of the exchange of healthcare services in their federal entities, and**

VIII. Other specific powers established in this Law and other applicable **legal** provisions .

C. ...

Article 17 Bis.- The Ministry of Health shall exercise the powers of regulation, control, **surveillance** and health promotion that, in accordance with this Law, the Organic Law of the Federal Public Administration and other applicable regulations, correspond to said agency in the matters referred to in Article 3 of this Law, in its sections I, regarding the control and surveillance of health establishments referred to in Articles 34 and 35 of this Law, XIII, XIV, XXII, XXIII, XXIV, XXV, XXVI, except as regards corpses, and XXVII, except as regards persons, through a decentralized **administrative** body that shall be called the Federal Commission for Protection against Health Risks.

...

I. **...**

II. To propose to **the head of the Ministry** of Health the national policy for protection against health risks, as well as its implementation in matters of: health establishments; health supplies, **including those containing narcotics and psychotropic substances;** disposal of organs, tissues, cells of human beings and their components; **embryos, germ cells;** food and beverages; cosmetic products; cleaning products; tobacco; pesticides, plant nutrients, toxic or hazardous substances; biotechnological products; food supplements, raw materials, additives involved in the manufacture of the above products **or any product for human use and consumption that represents a risk to health,** as well as prevention and control of the harmful effects of environmental factors on the health of the person, occupational health, basic sanitation **and authorized third parties;**

III. and **V** **...**

WE. To exercise sanitary control and surveillance of the products, **substances and products containing them, with respect to those** indicated in section II of this article, of the activities related to the former, of their import and export, as well as of the establishments intended for the processing of said products **and substances** and the health establishments, without prejudice to the powers that the [authority/regulation] may have in matters of processes and practices applicable in establishments dedicated to the slaughter of animals and primary processing of goods of animal origin for human consumption.

Ministry of Agriculture **and** Rural Development in accordance with the Federal Law on Health Animal;

VII. and **IX.** **...**

X. To impose sanctions, apply **and withdraw** security measures within its area of competence;

XI. To exercise the powers conferred by this Law, the Organic Law of the Public Administration Federal and other applicable regulations confer upon the Ministry of Health the authority to address the effects of the environment on health, occupational health, hazardous waste, basic sanitation, **pesticides, plant nutrients ,** and toxic, hazardous substances or radiation;

XII. Participate, in coordination with the competent administrative units of the Ministry of Health, in the implementation of actions for the prevention and control of diseases, as well as epidemiological surveillance, especially when these are related to the health risks derived from the products, activities or establishments under its jurisdiction;

XII Day. **To propose to the head of the Ministry of Health the regulation of protection against health risks in cases of health emergency in order to implement, supervise and guarantee the quality, safety and effectiveness of health supplies;**

XII Ther. **Issue temporary authorizations for the use of health supplies during public health emergencies;**

XII Quater. Coordinate the Federal Health System, in collaboration with the governments of the federative entities, in accordance with the applicable provisions and under the terms of the coordination or collaboration agreements that are entered into;

XII Quinquies. Coordinate and report pharmacovigilance and technovigilance activities in the country, through its National Center for Pharmacovigilance and Technovigilance, based on applicable regulations, and

XIII. ...

Article 18.- The bases and modalities of coordinated exercise of the powers of the Federation and the federative entities in the provision of general health services, **as well as for the exercise of powers of control, surveillance and health promotion,** must be subject to the content of this Law, coordination agreements and conventions that may be signed, as well as the other applicable provisions.

...

...

Article 19.- The Federation and the governments of the federative entities, in accordance with the applicable legal provisions, shall provide the material, human and financial resources that are necessary for the operation of the general health services, **as well as for the exercise of health control, surveillance and promotion powers,** which are included in the coordination agreements and conventions that are entered into for this purpose, in accordance with the previous article.

...

Article 32.- ...

For the purposes of the preceding paragraph, health service providers may rely **on methodological tools generated with evidence-based medicine, such as** Clinical Practice Guidelines, **Protocols** and electronic means in accordance with the official Mexican standards issued for this purpose by the Ministry of Health.

Article 35 Bis.- Every project for the creation, replacement or expansion of medical units, planned by the public institutions that make up the National Health System, as well as the acquisition of high-technology medical equipment, must have a registration number in the National Master Plan for Health Infrastructure and High-Technology Medical Equipment, through which its need and justification will be certified, and will allow monitoring from its beginning until its commissioning, regardless of the source of financing.

Article 41 Bis.- The establishments for medical care of the public, social or private sector of the National Health System, according to **their functions,** degree of complexity and level of resolution, will have the following committees:

I. A Bioethics Committee for **Health Care, which is responsible** for resolving problems arising from medical care as referred to in Article 33 of this Law, as well as the analysis, discussion and support in decision-making **regarding**
The organization addresses bioethical issues that arise in clinical practice or in teaching within the health sector , **and promotes the development of** institutional ethical guidelines and protocols for medical care and education. It also **promotes** ongoing bioethical education for its members and staff.

The Bioethics Committee for Health Care will be multidisciplinary and interdisciplinary, and must be made up of health professionals and other related professions that have training in bioethics, it is essential to have non-scientific representatives, up to the agreed number of its members, maintaining a balance of gender and age;

II. **An Ethics and Research Committee is** established **for** healthcare facilities that conduct **health research with human participants or use biological data or samples from** humans **or non-human animal models. This committee is responsible for registering,** evaluating, and approving health research protocols **regarding their scientific, methodological, ethical, and regulatory content. It is also responsible for formulating** appropriate recommendations; **supervising the execution of approved research protocols until their completion;** and developing institutional ethical **and technical** guidelines **for** health research.

This Committee will also be responsible, together with the Biosafety Committee, for reviewing the biosafety and environmental impact aspects of the submitted protocols.

The Ethics and Research Committee will be interdisciplinary and multidisciplinary, and must be made up of health professionals and other related professions who demonstrate experience and training in bioethics, research methodology, research ethics, and clinical medical care according to the discipline, specialty or area of research they evaluate, as well as the aspects of biosafety and environmental impact as appropriate, it being essential to have non-scientific representatives, up to the agreed number of its members, maintaining gender and age balance;

III. **A Biosafety Committee, responsible for determining and regulating within the establishment the use of ionizing radiation or genetic engineering techniques, based on applicable legal provisions, as well as ruling on the biosafety and environmental impact of health research protocols in conjunction with the Ethics and Research Committee, or**

IV. **The committees referred to in Article 316 of this Law.**

The Bioethics Committee for Health Care and the Ethics and Research Committee will be subject to **applicable** legislation , the criteria **for their integration and the requirements for their accreditation** established by the National Bioethics Commission.

The National Bioethics Commission will define the classification of Ethics and Research Committees based on the level of risk of the research, the type of health research they evaluate, as well as the level of complexity and resolution power of the institution that requests its accreditation.

Article 51 Bis 3.- Complaints submitted by **users** regarding the medical care received
They must be addressed and resolved in a timely and effective manner by:

I. **Healthcare providers;**

II. **The National Medical Arbitration Commission, or**

III. **The bodies that the health institutions of the federal entities have defined for this purpose, when the solution corresponds to their area of competence.**

CHAPTER IV BIS

From the National Medical Arbitration Commission

Article 60 Bis.- The National Medical Arbitration Commission is the decentralized administrative body of the Ministry of Health, with full technical, operational, administrative and management autonomy, with the power to issue opinions, recommendations, agreements, rulings and arbitration awards, within its area of competence, in accordance with the applicable regulations.

Its purpose is to contribute to resolving conflicts arising between users and health service providers, through alternative dispute resolution mechanisms in health services established in this Law.

Article 60 Ter.- These are alternative mechanisms for resolving disputes in matters of services health, among others, the following:

I. **Immediate action;**

II. **Reconciliation;**

III. **Mediation, and**

IV. **Arbitration.**

Article 60 Quater.- The alternative dispute resolution mechanisms in matters of health services contemplated in this Chapter, are governed in a supplementary manner by the principles established in the General Law of Alternative Dispute Resolution Mechanisms and other applicable regulations.

Article 60 Quinquies.- The members of the National Health System may sign the legal instruments that allow recognition of the competence, procedures and determinations issued by the National Medical Arbitration Commission.

Article 60 Sexies.- The National Medical Arbitration Commission shall have the power to agree with public and private institutions, bodies and organizations, on coordination and agreement actions that allow it to fulfill its functions.

It may also enter into coordination agreements with the governments of the federal entities, the state medical arbitration commissions and with the Health Services agency of the Mexican Social Security Institute for Well-being (IMSS-BIENESTAR), in order to establish the guidelines, criteria and actions under which medical complaints filed against the health services provided by said agency will be addressed.

CHAPTER IV TER

From the investment and strengthening of infrastructure for the provision of health services

Article 60 Septies.- The Ministry of Health and the governments of the federative entities, within the scope of their competencies and in coordination with their respective public institutions of the National Health System, shall carry out the necessary actions so that their medical units have adequate infrastructure, in order to strengthen the provision of medical care services, through the planning, projection and programming of the resources that are assigned to them for the development and equipping of the infrastructure for the provision of health services, regardless of the source of financing, according to the priorities that are determined, and in accordance with the National Master Plan for Health Infrastructure and High Technology Medical Equipment.

Article 60 Octies.- The federal public institutions of the National Health System will carry out the necessary actions to request the Ministry of Health to register their projects for the creation, replacement or expansion of medical units, or for the acquisition of high-technology medical equipment, in the National Master Plan for Health Infrastructure and High-Technology Medical Equipment, in accordance with the guidelines issued by the Ministry of Health, who must resolve regarding said registration within a period of two business days.

Registration in the National Master Plan for Health Infrastructure and High Technology Medical Equipment will have a maximum validity of six years from the date the Ministry of Health grants the corresponding registration number, which may be renewed in accordance with the guidelines issued by the aforementioned Ministry.

Article 60 Nonies.- The National Master Plan for Health Infrastructure and High Technology Medical Equipment will be available for permanent consultation, for the verifications required by the competent authorities regarding the registration folios granted by the Ministry of Health.

Article 60 Decies.- The Ministry of Health, in planning the creation, replacement and expansion of medical units, as well as high-technology medical equipment, will promote the increase of health service coverage in a systematic and orderly manner.

The federal public institutions of the National Health System must identify the infrastructure needs for the provision of health services referred to in the previous paragraph, taking into consideration the investment programs and projects in progress, as well as those that may be executed in the short, medium and long term, so that these projects are integrated into the corresponding planning mechanism.

CHAPTER VI BIS

Digital Health

Article 71 Bis.- Digital health refers to the application of information and communication technologies in health services, such as, among others, telehealth, telemedicine, mobile health, electronic medical or health records and portable devices.

Article 71 Ter.- The purposes of digital health are:

I. **Facilitate the provision of remote medical services, to allow the population to receive care without the need for travel;**

II. **Optimize the use of human and technological resources in healthcare;**

III. **Expand the coverage of health services, especially in communities with limited access to medical infrastructure;**

IV. To provide support and advice to healthcare professionals through interconsultations with specialists;

V. Implement educational programs using digital tools aimed at health personnel and the general population for disease prevention;

WE. Digitizing patient medical information to facilitate access, updating, and secure data exchange between healthcare professionals and facilities, to ensure continuity of care, and

VII. Analyze large volumes of data to identify patterns, optimize diagnoses, personalize treatments, and improve hospital management.

Article 71 Quater.—The Ministry of Health shall be responsible for issuing the provisions for the implementation, supervision, and continuous improvement of digital health services in all public institutions of the National Health System. For the purposes of the foregoing, the following aspects shall be considered:

I. Consulting services to integrate the technological infrastructure, according to the needs, conditions and existing infrastructure;

II. Continuing education for healthcare professionals on the proper use of digital health tools;

III. Development of guidelines and criteria for medical care through digital health systems, including telemedicine, to ensure the safety and quality of care;

IV. Development of security protocols for the confidentiality of information and protection of patients' personal data, and

V. Implementation of monitoring and evaluation mechanisms to measure the impact and effectiveness of digital health services.

Article 71 Quinquies.- Public health service providers, in order to guarantee an effective implementation of digital health, must consider the following aspects:

I. Evaluation of the technological infrastructure available for the proper operation of the services;

II. Ongoing training of healthcare personnel in digital tools and remote care protocols;

III. Coordination between health sector institutions for the integration of telehealth systems and platforms;

IV. Measurement and evaluation of performance indicators for the continuous improvement of telehealth services, and

V. Promoting digital inclusion to reduce the technological gap in the population.

Article 71 Sexies.- Telehealth refers to the use of information technologies to provide person-centered remote health services, which may include, among others, medical guidance, medical care, health education or health research.

Article 71 Septies.- Telehealth services must comply with the following conditions:

I. To be provided by personnel designated and trained for this purpose;

II. Use secure and reliable systems that guarantee confidentiality, protection of personal data, integrity and availability of medical information by authorized personnel, in accordance with applicable legal provisions regarding transparency, access to information and protection of personal data;

III. Incorporate mechanisms for obtaining informed consent in the provision of remote health services, ensuring understanding and voluntariness, and

IV. Ensure proper documentation and recording of medical care provided through digital platforms.

Article 71 Octies.- The Ministry of Health, in coordination with public, social and private sector institutions, will promote the development, research and adoption of emerging technologies in digital health.

Article 77 bis 5.-

A) ...

I. a **V.** ...

WE. To promote the signing of agreements or conventions that contribute to the **effective implementation** of the operation of the Health System for Well-being, **as well as the exchange of goods and services,** in order to expand the coverage of the free provision of health services, medicines and other associated **health** supplies and **the unification of integrated service networks among the different service providers;**

VII. XVII . ...

B) ...

I. a **IV.** ...

V. To allocate, from the resources referred to in Chapter III of this Title, those necessary for the maintenance, development of infrastructure and equipment according to the priorities determined in each federal entity **and, where applicable,** in accordance with the **National Master Plan for Health Infrastructure and**

High-Tech Medical Equipment;

WE. Adopt operational models that improve healthcare, modernize the administration of health services and clinical records, and promote the certification of their staff and healthcare facilities. To this end, agreements may be entered into among themselves and with public institutions of the National Health System in order to optimize the use of their facilities and share the provision of services, in accordance with the guidelines **and other applicable provisions.**

applicable;

VII. and **X .** ...

Article 77 bis 8.- All persons **with or without affiliation to** social security institutions, may access health services provided by **any institution of the public sector according to the condition in question due** to geographical accessibility or medical emergency, **in accordance with** the operation of **the** agreements for the exchange of health services, in which case the institution **to which the person receiving the medical service belongs** must compensate the corresponding expenses **to the institution that provides it.**

The **health** service exchange agreements referred to in the previous paragraph will guarantee the continuity of the provision of medical care services and **the provision of medicines and other health supplies** for people in public institutions that subscribe to the aforementioned agreements **in exchange for the considerations** agreed under a principle of reciprocity.

Article 77 bis 9.-

Health Services of the Mexican Institute of Social Security for Well-being (IMSS-BIENESTAR) **may**
To carry out the necessary actions so that its medical units obtain the corresponding certification from the General Health Council and **so that** they provide comprehensive, mandatory, and high-quality outpatient and inpatient services for the basic specialties of internal medicine, general surgery, obstetrics and gynecology, pediatrics, and geriatrics, according to the level of care, which must operate as an integrated care network system in accordance with the health needs of the beneficiaries. Access to health services for beneficiaries will be expanded progressively based on their needs, in accordance with the regulations of this Title.

...

Article 77 bis 10.-

I. and **II.** **...**

III. They will strengthen the development of infrastructure **for the provision of** health services **and will carry out conservation and maintenance actions,** based on the resources they receive under the terms of this Title, allocating the necessary resources for investment in infrastructure and equipment, in accordance with the **Master Plan**

National Institute of Health Infrastructure and High-Tech Medical Equipment;

IV. They must render accounts and provide the established information regarding the resources they receive, in accordance with this Law and other applicable laws;

IV Bis. **They will prioritize maintenance actions over the creation, replacement, and expansion of medical units, using the resources they receive under this Title, allocating the necessary resources for investment in infrastructure actions for the provision of health services, in accordance with the National Master Plan for Health Infrastructure and**

High-Tech Medical Equipment, and

V. **...**

Article 77 bis 17.- The Health Services of the Mexican Social Security Institute for Well-being (IMSS-BIENESTAR), charged to the resources referred to in Article 77 bis 12 of this Law, will annually channel to the Fund referred to in Chapter VI of this Title, the equivalent of 11% of the sum of the resources indicated in Articles 77 bis 12 and 77 bis 13 of this Law. The Health Services of the Mexican Social Security Institute for Well-being (IMSS-BIENESTAR) **will assign these resources to the concepts indicated in sections I, II and III** of Article 77 bis 29, **with the prior approval of the Technical Committee of the Health Fund for Well-being.**

When the Fund accumulates resources exceeding twice the amount approved in the Federal Expenditure Budget for fiscal year 2020 as contributions to the Health Fund for Well-being Trust, the remaining balance may be used to strengthen health initiatives through the return of the corresponding resources to the Federal Treasury or through the Health Fund for Well-being. The resources accumulated in the Fund will continue to **be used to fulfill the provisions of sections I, II, and III** of Article 77 bis 29 of this Law.

Article 77 bis 29.-

I. **...**

II. Addressing infrastructure **and equipment needs, including urgent maintenance and conservation actions,** preferably in the federal entities with the greatest social marginalization, and

III. **...**

...

...

For the purposes of this Title, **high cost** shall be considered to be that which derives from those treatments and associated medications, defined by the General Health Council, that satisfy health needs through the combination of preventive, diagnostic, therapeutic, palliative and rehabilitative interventions, with explicit clinical and epidemiological criteria, selected based on their safety, efficacy, payment, effectiveness, adherence to professional ethical standards and social acceptability, by virtue of their degree of complexity or specialty and the level or frequency with which they occur.

...

...

Article 77 bis 30.-

...

...

In order to rationalize investment in infrastructure **for the provision of** health services and guarantee the availability of resources for the sustainable operation of services, the Ministry of Health **will integrate the National Master Plan for Health Infrastructure and High-Technology Equipment, which considers both construction and high-technology medical equipment in accordance with the provisions of the**

Article 35 Bis of this Law, to which the public institutions of the National Health System will be subject in order to guarantee timely access to health services, **regardless of the source of financing.**

Health establishments that **are** not consistent with the **National Master Plan for Health Infrastructure and High Specialty Equipment** will not be considered eligible for participation in the resources of the fund established under the terms of this Chapter.

Article 77 bis 35.-

...

...

I. a **XI.** **...**

XII. Participate in the consolidated procurement procedures of the Ministry of Health **plan and** that have as their objective the acquisition and distribution of medicines, **high-technology medical equipment that said Secretariat has determined** and other health supplies in which the agencies and entities of the Administration intervene Federal Public entities that provide health services, **in accordance with the Law of Acquisitions, Leases and Services of the Public Sector and other applicable provisions;**

XIII. and **XVII. ...**

Article 98.- The persons holding the directorships of hospitals and health institutions **are responsible,** in accordance with applicable **legal** provisions , **for establishing, according to their degree of complexity and level of resolution, the following committees:**

I. An **Ethics and** Research Committee , **which complies with the provisions of Article 41 Bis of this Law, and**

II. A Biosafety Committee **referred to in Article 41 Bis, section III, of this Law.**

The General Health Council will issue supplementary provisions on areas or modalities of research where it considers it necessary.

Higher education institutions and public research centers, as well as health institutions that have primary health care and public health services, that carry out health research, may integrate and accredit an Ethics and Research Committee before the National Bioethics Commission, in accordance with article 41 Bis of this Law and other applicable legal provisions.

Article 104.- The Ministry of Health and the governments of the federative entities, within the scope of their respective powers, **and in accordance with the applicable legal provisions,** will collect, produce and process the information necessary for the planning, programming, budgeting and control process of the National Health System, as well as on the state and evolution of public health.

...

I. to **III. ...**

Article 105.- The Ministry of Health shall integrate the information referred to in Article **104 of this Law,** to prepare national health statistics that contribute to the consolidation of a National Health Information System , **for the generation of health intelligence products and that serve as input to improve medical care, the management of health services and decision-making in public health, as well as for the guidance and creation of public health policies.**

Article 108.- Repealed

Article 194.- For the purposes of this Title, sanitary control is understood to be the set of actions of guidance, education, sampling, verification **and,** where appropriate, application of security measures and sanctions, carried out by the Ministry of Health with the participation of **producers ,** marketers and consumers, **based** on what is established by the official Mexican standards and other applicable provisions.

...

I. Processing, importing and exporting food, non-alcoholic beverages, alcoholic beverages, **food supplements,** cosmetic products, toiletries, tobacco, as well as raw materials and, where applicable, additives involved in their production **or any other product for human use or consumption that represents a health risk to the population;**

II. and **III.** **...**

...

Article 222.- ...

For the granting of sanitary registration to any drug, compliance with good manufacturing practices and the drug's production process, as well as the certification of its active ingredients, will be verified beforehand. These verifications **may not be carried out by authorized third parties and may only** be **performed** by the Ministry **of Health.** If applicable, the respective certificate issued by the competent authority of the country of origin will be recognized, provided that recognition agreements exist between the competent authorities of both countries.

Once the sanitary registration is granted, pharmacovigilance must be carried out in accordance with the applicable legal provisions.

Article 234.- For the purposes of this Law, the following are considered narcotics:

Acetyl-alpha-methylphentanyl.

ACETYLDIHYDROCODEINE.

ACETYLFENTANYL.

ACETYLMETHADOL (3-acetoxy-6-dimethylamino-4,4-diphenylheptane).

Acetorphine (3-O-acetyltetrahydro-7ÿ-(1-hydroxy-1-ethylbutyl)-6,14-endoethene-oripavin) also called 3-O-acetyl-tetrahydro-7ÿ- (1-hydroxy-1-methylbutyl)-6,14-endoethene-oripavin and, 5 acetoxyl-1,2,3,3ÿ , 8,9-hexahydro-2ÿ (1-(R) hydroxy-1-methylbutyl)3-methoxy-12-methyl-3; 9ÿ-etheno-9,9-B-iminooctanophenanthrene (4ÿ,5 bed) furan.

ACRILFENTANILO.

ALPHA-ACETYLMETHADOL (alpha-3-acetoxy-6-dimethylamino-4,4-diphenylheptane).

ALFAMEPRODINE (alpha-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine).

ALFAMETADOL (alpha-6-dimethylamino-4,4 diphenyl-3-heptanol).

ALPHA-METHYLFENTHANYL.

ALPHA-METHYLTHIOFENTANYL.

ALFAPRODINE (alpha-1,3-dimethyl-4-phenyl-4-propionoxypiperidine).

ALFENTANIL (N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4- (methoxymethyl)-4- monohydrochloride) piperidinyl]-N phenylpropanamide).

ALLILPRODINE (3-allyl-1-methyl-4-phenyl-4-propionoxypiperidine).

ANILERIDINE (ethyl ester of 1-para-aminophenethyl-4-phenylpiperidin-4-carboxylic acid).

SELFISH-FENTANILO.

BECITRAMIDE (1-(3-cyano-3,3-diphenylpropyl)-4-(2-oxo-3-propionyl-1-benzimidazolinyl)-piperidine).

BENZETIDINE (ethyl ester of 1-(2-benzyloxyethyl)-4-phenylpiperidin-4-carboxylic acid).

SENCILMORPHINA (3-selfishmorphine).

BETACETYLMETHADOL (beta-3-acetoxy-6-dimethylamino-4,4-diphenylheptane).

BETA-HYDROXIFENTANILO.

BETA-3-HYDROXY-3-METHYLPHENTANYL.

BETAMEPRODINE (beta-3-ethyl-1-methyl-4-phenyl-4-propionoxypiperidine).

BETAMETADOL (beta-6-dimetilamino-4,4-difenil-3-heptanol).

BETAPRODINE (beta-1,3,dimethyl-4-phenyl-4-propionoxypiperidine).

BENZYLPHENANYL BROMIDE.

FENTANYL BROMIDE.

BUPRENORPHINE.

DIOXAFETYL BUTIRATE (ethyl 4-morpholín-2,2-diphenylbutyrate).

BUTYRFENTANYL.

BUTIRILFENTANILO.

CANNABIS sativa, indica and americana or marijuana, its resin, preparations and seeds.

CARFENTANILO.

KETOBEMIDONE (4-meta-hydroxyphenyl-1-methyl-4-propionylpiperidine) or 1-methyl-4-metahydroxyphenyl-4-propionylpiperidine).

CYCLOPROPYLPENTANYL.

CLONITACENO (2-para-clorobencil-1-dietilaminoetil-5- nitrobencimidazol).

COCA (leaves of). (erythroxylon novogratense).

COCAINE (benzoylecgonine methyl ester).

CODEINE (3-methylmorphine) and its salts.

CODOXIME (dehydrocodeinone-6-carboxymethyloxime).

POPPY STRAW CONCENTRATE (the material obtained when poppy straw
It has entered a process for concentrating its alkaloids, at the moment it goes on sale).

DESOMORPHIN (dihydrodeoxymorphine).

DESPROPYNOLYLFENTANIL.

DEXTROMORAMIDE ((+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)-butyl]morpholine) or [+]-3-methyl-2,2-diphenyl-4-morpholinobutyrylpyrrolidine).

DEXTROPROPOXYFENE (ÿ -(+)-4 dimethylamino-1,2-diphenyl-3-methyl-2 butanol propionate) and its salts.

DIAMPROMIDE (n-[2-(methylphenethylamino)-propyl]-propionanilide).

DIETHYLTHIAMBUTENE (3-diethylamino-1,1-di-(2'-thienyl)-1-butene).

DIPHENOXYLATE (ethyl ester of 1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid), or 2,2 diphenyl-4-carbethoxy-4-phenyl) piperidine) butyronitrile).

DIPHENOXINE (1-(3-cyano-3,3-diphenylpropyl)-4-phenylisonipecotic acid).

DIHIDROCODEIN.

DIHYDROMORPHINE.

DIMEFEPTANOL (6-dimetilamino-4,4-difenil-3-heptanol).

DIMENOXADOL (2-dimethylaminoethyl-1-ethoxy-1,1-diphenylacetate), or 1-ethoxy-1-diphenylacetate dimethylaminoethyl or dimethylaminoethyl diphenyl-alphaethoxyacetate. of

DIMETHYLTHIAMBUTENE (3-dimethylamino-1,1-di-(2'-thienyl)-1-butene).

DIPIPANONE (4,4-diphenyl-6-piperidine-3-heptanone).

DROTEBANOL (3,4-dimethoxy-17-methylmorphinan-6 ÿ,14-diol).

ECGONINE, its esters and derivatives that are convertible into ecgonine and cocaine.

ETHYL METHYLTHIAMBUTENE (3-ethylmethylane-1,1-di(2'-thienyl)-1-butene).

ETHYLMORPHINE (3-ethylmorphine) is dione.

ETONITACENO (1-diethylaminoethyl-2-para-ethoxybenzyl-5-nitrobenzimidazole).

ETORPHINE (7,8-dihydro-7 ÿ,1 (R)-hydroxy-1-methylbutyl 06 -methyl-6-14-endoetheno-morphine, denominated also (tetrahydro-7 ÿ;-(1-hydroxy-1-methylbutyl)-6,14 endoethene-oripavin).

ETOXERIDINE (ethyl ester of 1-[2-(2-hydroxyethoxy)ethyl]-4-phenylpiperidine-4-carboxylic acid.

FENADOXONE (6-morpholine-4,4-diphenyl-3-heptanone).

FENAMPROMIDE (n-(1-methyl-2-piperidinoethyl)-propionanilide) or n-[1-methyl-2- (1-piperidinyl)-ethyl] nphenylpropanamide.

PHENAZOCIN (2'-hydroxy-5,9-dimethyl-2-phenethyl-6,7-benzomorphane).

PHENMETRAZINE (3-methyl-2-phenylmorpholine 7-benzomorphan 1,2,3,4,5,6-hexahydro-8-hydroxy 6-11-dimethyl-3-phenethyl-2,6,-methane-3-benzazocine).

PHENOMORPHANE (3-hydroxy-n-phenethylmorphinan).

Phenoperidine (ethyl ester of 1-(3-hydroxy-3-phenylpropyl) 4-phenylpiperidine-4-carboxylic acid, or 1-phenyl-3-(4-carbethoxy-4-phenylpiperidine)-propanol).

FENTANYL (1-phenethyl-4-n-propionyl anilinopiperidine).

PHOLCODINE (morpholinylethylmorphine or beta-4-morpholinylethylmorphine).

FURAFENTANILO.

FURANILFENTANIL.

FURETIDINE (ethyl ester of 1-(2-tetrahydrofurfuryloxyethyl)-4-phenylpiperidine-4-carboxylic acid).

HEROIN (diacetylmorphine).

HYDROCODONE (dihydrocodeinone).

HYDROMORPHINOL (14-hydroxydihydromorphine).

HYDROMORPHONE (dihydromorphinone).

Hydroxypeptidine (ethyl ester of 4-meta-hydroxyphenyl-1 methyl piperidine-4-carboxylic acid) or ethyl ester of 1-methyl-4-(3-hydroxyphenyl)-piperidine-4-carboxylic acid.

ISOMETHADONA (6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone).

LEVOPHENACYLMORPHANE ((-)-3-hydroxy-n-phenacylmorphinan).

LEVOMETORFAN ((-)-3-methoxy-n-methylmorphinan).

LEVOMORAMIDE ((-)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)-butyl]-morpholine), or (-)-3-methyl-2,2-diphenyl-4-morfolinobutirilpirrolidina).

LEVORPHANOL ((-)-3-hydroxy-n-methylmorphinan).

METHADONE (6-dimethylamino-4,4-diphenyl-3-heptanone).

METHADONE, intermediate of (4-cyano-2-dimethylamino-4,4-diphenylbutane) or 2-dimethylamino-4,4-diphenyl-4-cyanobutane).

METAZOCIN (2'-hydroxy-2,5,9-trimethyl-6,7-benzomorphan 1,2,3,4,5,6, hexahydro-8-hydroxy3,6,11,trimethyl-2,6-methane-3-benzazocine).

METHYLDESORPHINE (6-methyl-delta-6-deoxymorphine).

METHYLDIHYDROMORPHINE (6-methyldihydromorphine).

METHYLPHENIDATE (methyl ester of alphaphenyl-2-piperidine acetic acid).

3-METHYLPHENTANYL.

3-METHYLOTHIOPHENTANYL.

METOPON (5-methyldihydromorphinone).

MYROFINE (myristilbenzylmorphine).

MORAMIDE, intermediate of (2-methyl-3-morpholine-1,1-diphenylpropane carboxylic acid) or (1-diphenyl-2-methyl-3-morpholine propane carboxylic acid).

MORPHERIDINE (ethyl ester of 1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid).

MORPHINE.

MORPHINE BROMMETHYLATE and other morphine derivatives with pentavalent nitrogen, including in particular n-oxymorphine derivatives, one of which is n-oxycodeine.

NICOCODINE (6-nicotinylcodeine or 6-codeine ester of pyridine-3-carboxylic acid).

NICODICODINE (6-nicotinic dihydrocodeine or nicotinic ester of dihydrocodeine).

NICOMORPHINE (3,6-dinicotinylmorphine) from the nicotinic di-ester of morphine).

NITAZENO.

NORACIMETADOL ((+)-alpha-3-acetoxy-6-methylamino-4,4-diphenylbeptane).

NORCODEINE (n-demethylcodeine).

NORFENTANIL.

NORLEVORFANOL ((-)-3-hidroximorfinan).

NORMETHADONE (6-dimethylamino-4,4-diphenyl-3-hexanone) or i, 1-diphenyl-1-dimethylaminoethyl-butanone-2 or 1-dimethylamino 3,3-diphenylhexanone-4).

NORMORPHINE (demethylmorphine or morphine-n-demethylate).

NORPIPANONE (4,4-diphenyl-6-piperidine-3-hexanone).

N-OXIMORFINA.

OCCFENTANIL.

YOUTH.

OXYCODONE (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).

OXIMORFONE (14-hydroxydihydromorphinone) or dihydroxyhydroxymorphinone).

POPPY STRAW, (Papaver Somniferum, Papaver Bracteatum, its straws and its seeds).

Para-fluorophentanyl.

PARA-FLUOROISOBUTYRFENTANILO.

PENTAZOCINE and its salts.

PETIDINE (ethyl ester of 1-methyl-4-phenyl-piperidin-4-carboxylic acid), or meperidine.

PETIDINA intermediario A de la (4-ciano-1 methyl-4- phenylpiperidine ó 1-methyl-4-phenyl-4-cianopiperidine).

PETIDIN intermediate B of the (ethyl ester of -4-phenylpiperidine-4-carboxylic acid or ethyl 4-phenyl-4-piperidin-carboxylic acid).

PETIDIN intermediate C of (1-methyl-4-phenylpiperidine-4-carboxylic acid).

PIMINODINE (ethyl ester of 4-phenyl-1-(3-phenylaminopropyl)-piperidine-4-carboxylic acid).

PYRITRAMIDE (amide of 1-(3-cyano-3,3-diphenylpropyl)-4-(1-piperidine)-piperidine-4-carboxylic acid) or 2,2-diphenyl-4-1 (carbamoyl-4- piperidine)butyronitrile).

PROHEPTACIN (1,3-dimethyl-4-phenyl-4-propionoxyazacycloheptane) from 1,3-dimethyl-4-phenyl-4-propionoxyhexamethyleneimine).

PROPERIDINE (isopropyl ester of 1-methyl-4-phenylpiperidine-4-carboxylic acid).

PROPIRAM (1-methyl-2-piperidino-ethyl-n-2-pyridyl-propionamide).

RACEMETORPHAN ((+)-3-methoxy-N-methylmorphine).

RACEMORAMIDE ((+)-4-[2-methyl-4-oxo-3,3-diphenyl-4-(1-pyrrolidinyl)-butyl]morpholine) or ((+)-3-methyl-2,2-diphenyl-4-morpholinobutyrylpyrrolidine).

RACEMORPHAN ((+)-3-hydroxy-n-methylmorphinan).

SUFENTANIL (n-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl]propionanilide).

TEBACON (acetyldihydrocodeinone or acetyldmethyldihydrothebaine).

THEBAINA.

TILIDINE ((+)-ethyl-trans-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylate).

TIOFENTANILO.

TRIMEPERIDINE (1,2,5-trimethyl-4-phenyl-4-propionoxypiperidine), and

Isomers of the narcotics in the above list, unless expressly excluded.

Any other derivative or preparation containing substances listed above, their chemical precursors, and, in general, those of an analogous nature, and any other substance determined by the Ministry of Health, **through the Federal Commission for Protection against Sanitary Risks** or the General Health Council. The corresponding lists will be published in the Official Gazette of the Federation.

Article 245.- ...

I. **...**

Any other product, derivative or preparation that contains the substances indicated in the above list and when expressly determined by the Ministry of Health, **through the Federal Commission for Protection against Sanitary Risks** or the General Health Council, their chemical precursors and in general those of an analogous nature.

II. Those that have some therapeutic value, but constitute a serious problem for public health, and which are:

AMOBARBITAL.

AMPHETAMINE.

BUTORFANOL.

CHAIN.

CICLOBARBITAL.

DEXTROANFETAMINA (DEXANFETAMINA).

DIHYDROERGOCRISTINA.

FENETYLINE.

Phencyclidine.

HEPTABARBITAL.

MECLOCUALONE.

METHAQUALONE.

METHAMPHETAMINE.

NALBUFINE.

NICERGOLINA.

NORPSEUDOEPHEDRIN.

PENTOBARBITAL.

PSEUDOEFEDRINA.

SECOBARBITAL.

TETRAHYDROCANNABINOL, which are or contain in concentrations greater than 1%, the following isomers: ÿ6a (10a), ÿ6a (7), ÿ7, ÿ8, ÿ9, ÿ10, ÿ9 (11) and their stereochemical variants.

And its salts, precursors and chemical derivatives.

III. **...**

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AMPHEBUTAMONE (BUPROPION)

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TRAMADOL

IV. Those that have broad therapeutic uses and constitute a minor problem for public health, and are:

GABOB (GAMMA AMINO BETA HYDROXYBUTYRIC ACID).

GAMMA HYDROXYBUTYRIC ACID (GHB).

ALOBARBITAL.

AMITRIPTYLINE.

APPROVAL.

BARBITAL.

BENZOPHETAMINE.

BENZQUINAMIDA.

LEAVE.

BUSPIRONA.

BUTABARBITAL.

BUTALBITAL.

BUTAPERAZINE.

BUTETAL.

BUTRIPTILINA.

CARBROMAL.

CHLORIMIPRAMINE.

CHLOROMEZANON.

Chloropromazine.

CLORPROTIXENO.

DEANOL.

DESIPRAMINE.

ECTILUREA.

ETINAMATO.

PHENELCINA.

FENFLURAMINA.

PHENOBARBITAL.

FLUFENAZINE.

FLUMAZENIL.

GAMMA BUTYROLACTONA (GBL).

HALOPERIDOL.

HEXOBARBITAL.

HYDROXYCINE.

Imipramine.

ISOCARBOXYCIDE.

LIEUTENANT.

LITHIUM CARBONATE.

PROTEIN.

INSPIRATION.

I KNOW.

METILFENOBARBITAL.

METHYLPARAFFINOL.

METIPRILONA.

NALOXONE.

NORTRIPTILINA.

PARALDEHYDE.

PENFLURIDOL.

SODIUM PENTOTHOTHAL.

PERFENAZINE.

PIPRADROL.

PROMAZINA.

PROPYLHEXEDRINE.

SULPIRIDE.

TETRABENAZINA.

TETRAHYDROCANNABINOL, which are or contain in concentrations equal to or less than 1%, the following isomers: ÿ6a (10a), ÿ6a (7), ÿ7, ÿ8, ÿ9, ÿ10, ÿ9 (11) and their stereochemical variants.

TIALBARBITAL.

TIOPENTAL.

TIOPROPERAZINE.

THIORIDAZINE.

TRAZODONE.

TRAZOLIDONA.

TRIFLUOPERAZINA.

VINILBITAL.

And its salts, precursors and chemical derivatives.

V. ...

Article 259.- The establishments **provided for** in article 257 of this Law must have **a person** responsible for the identity, purity, safety **and carry out the pharmacovigilance** of the products.

...

Article 262 Bis.- Once the sanitary registration of medical devices is granted, technovigilance must be carried out, which consists of monitoring the safety of medical devices, through the set of activities that aim to identify and evaluate incidents and adverse incidents, produced by medical devices in use, as well as the identification of the risk factors associated with them, in accordance with the applicable legal provisions.

CHAPTER XII TER

Electronic cigarettes, vapes and other similar systems or devices

Article 282 Ter.- For the purposes of this Law, the following is understood: electronic cigarettes, vapes and other analogous systems or devices, any mechanical, electronic or any other technological apparatus or system used to heat, vaporize or atomize liquid toxic substances, gels, salts, waxes, dry aerosols, resins, waxy oils or other new synthetic formulations, with or without nicotine, that can be inhaled by the consumer.

Article 282 Quater.- The acquisition for commercial purposes, preparation, production, manufacture, mixing, conditioning, packaging, transport for commercial purposes, storage, import, export, trade, distribution, sale and supply of electronic cigarettes, vapes and other analogous systems or devices, including those that are disposable or single use, is prohibited throughout the national territory.

The prohibition does not apply to its consumption and possession when it is not intended for the activities or purposes indicated in the previous paragraph.

All acts of marketing, advertising or propaganda for the consumption of electronic cigarettes, vapes and other similar systems or devices are prohibited, through any printed, digital, television, radio or any other means of communication.

Article 282 Quinquies.- The health authority may carry out the verification, the application of security measures and the sanitary disposal of electronic cigarettes, vapes and other analogous systems or devices.

The foregoing is independent of any actions that may be taken by other authorities in their respective jurisdictions. respective area of competence.

Article 313. ...

I. and **II.**	**...**
III.	To establish and direct health policies regarding donation, procurement and transplantation of organs, tissues, **stem cells, as well as the provision of blood, blood products and blood derivatives,** for which it will rely on the National Transplant Center, and the National Blood Transfusion Center;
IV.	**...**
V.	To develop and carry out, in coordination with the public institutions of the National Health System and with the governments of the federal entities, permanent awareness campaigns on the importance of organ, tissue and **stem** cell donation for transplantation purposes, as well as blood and **blood products** for transfusions and other therapeutic uses.

Article 314.- ...

I. to **III.**	**...**
IV.	**Repealed**
V. a **XI.**	**...**

XI Bus. **Blood products, the various preparations of blood that have therapeutic utility, include units of whole blood, its components and mixtures thereof;**

XII. and **XIV. ...**

XIV Bis. Transfusion, the therapeutic procedure consisting of the application of blood or **blood products** to a human being;

XV. y **XVI. ...**

XVII. Disposition, the set of activities related to the obtaining, extraction, analysis, preservation, preparation, supply, use and final destination of organs, tissues, **blood products, stem** cells , products and corpses of human beings, for therapeutic, teaching or research purposes;

XVIII. of **XXIV. ...**

XXV. Preservation refers to the use of chemical agents **and, where appropriate,** the modification of environmental conditions during the extraction, packaging, transfer or transplantation of organs, tissues, **blood products** or cells, with the purpose of preventing or delaying their deterioration;

XXVI. ...

XXVII. Traceability refers to the ability to locate and identify organs, tissues, **blood products ,** and cells at any time from donation and, where applicable, through therapeutic use, processing, or final destination;

XXVIII. Blood products, those products obtained from certain **blood products,** especially plasma, through physicochemical or biological processes, for therapeutic, diagnostic, preventive or research applications;

XXIX. **Stem cell bank, the establishment authorized to obtain, collect, analyze, process, preserve, apply, transfuse and provide stem cells;**

XXX. **Stem cell collection center, the establishment authorized for obtaining and collecting stem cells, including donor care, safekeeping and shipment of stem cells obtained for analysis to a stem cell bank;**

XXXI. **Regenerative medicine is the field focused on the repair, replacement, or regeneration of cells, tissues, or organs to restore damaged function resulting from any cause, including congenital defects, acquired disease, and trauma. It utilizes a combination of technological approaches ranging from tissue engineering to evidence-based therapeutic applications that ensure the highest degree of therapeutic recommendation, going beyond traditional transplantation and replacement therapies.**

XXXII. **Residual plasma refers to any plasma that, based on scientific evidence and technological advances, lacks the characteristics to be used for clinical purposes in transfusion through the blood network, which can be fresh plasma, frozen plasma, and plasma devoid of labile factors.**

Article 316.- The establishments referred to in the previous article will have a responsible health person, who must be notified **of their registration, modification and deregistration** before the Ministry of Health.

Facilities that perform organ, tissue, and **stem** cell procurement must have an Internal Coordination Committee for organ and tissue donation, chaired by **the Director** General or their immediate subordinate who is **a physician** with a high level of academic and professional expertise in the field. This committee will be responsible for selecting the healthcare facility with an authorized transplant program to which the organs, tissues, and **stem cells will be sent,** in accordance with the provisions of this Law and other applicable legal regulations.

...

...

Establishments that perform transfusions, blood disposal, **blood products** and **stem cells,** must have a Transfusion Medicine Committee, **and, where appropriate, a Stem Cell Transplant Committee or Subcommittee, as appropriate, which will meet in ordinary quarterly sessions and in extraordinary sessions when required, in which the total number of adverse events and reactions to donation, transfusion and transplants will be reported, subject to the provisions issued for this purpose by the Ministry of Health.**

Healthcare facilities that transfuse blood and **blood products** must
to have a Transfusion Medicine Committee.

Healthcare facilities that **perform stem cell transplantation, infusion, and disposal procedures must have a Stem Cell Transplant Committee, which will meet regularly on a quarterly basis and extraordinarily when required, and will report all adverse reactions to the transplant and, where applicable, to the infusion, subject to the provisions issued by the Ministry of Health.**

...

...

Article 316 Bis 1.- To guarantee the timely availability of blood, **blood products and stem cells,** the establishments referred to in article 315 of this Law that do not have blood banks, processing centers and stem cell banks, must enter into an agreement with a blood bank establishment, processing center or stem cell bank respectively.

Article 319.- The following shall be considered illicit disposal of organs, tissues, **stem cells,** corpses, **blood and blood products** that which is carried out without being authorized by law.

Article 321 Bis.- The donation **of stem cells obtained from placental blood and umbilical cord blood must at all times have an informed consent letter from the pregnant woman, guaranteeing the full will, freedom and confidentiality, in accordance with the applicable legal provisions.**

Article 322.- ...

...

...

...

In all cases, care must be taken to ensure that the donation adheres to the principles of altruism, non-profit status, and feasibility. These conditions must be stated in the minutes prepared for this purpose by the respective internal committee. In the case of blood, **blood products ,** and stem cells, the provisions issued by the Ministry of Health will apply.

Article 323.- ...

I. **...**

II. For donation of blood, **blood products** and living stem cells.

Article 327. The trade of organs, tissues, **stem cells, blood, and blood products is prohibited, except for the activities referred to in Chapter III BIS of Title Fourteen of this Law.** Donation of **these** shall be governed by the principles of altruism, non-profit status, and confidentiality; therefore, their procurement and use shall be strictly free of charge.

...

Article 332.- ...

Organs and tissues may not be taken for transplants from living minors, except in the case of **stem cell or** bone marrow transplants, for which the express consent of the minor's legal representatives will be required.

...

...

CHAPTER III BIS

Disposal of blood, **blood products,** blood derivatives and stem cells

Article 340 Bis.- The donation of blood, blood products and stem cells is a free, voluntary, altruistic act, oriented towards repetition, which is carried out without commercialization or profit, and will be governed by the following principles:

I. **Human value and social responsibility;**

II. **Permanent need;**

III. **Early childhood learning;**

IV. **Repetitive nature;**

V. **Process not based on gender differences and non-discriminatory;**

WE. **Guarantee of safety, quality and warmth for donors;**

VII. **Confidence in the proper handling of blood and blood products resulting from fractionation, and**

VIII. **Greater good for the Mexican population.**

Article 340 Ter.- The Ministry of Health will determine the disposal of existing residual plasma in the country, for industrialization purposes to obtain blood products for the benefit of the population.

Article 340 Quater.- The Ministry of Health will establish the bases and modalities to which the National Health System will be subject, regarding the provision of blood and blood products to address contingencies, emergencies and extraordinary situations.

Article 341.- The disposal of blood, blood **products** and stem cells, for therapeutic purposes will be in charge of the following establishments:

A) ...

I. to **III.** ...

IV. Blood and **blood products** distribution center ;

V. and **VI.** ...

B) y **C) ...**

Establishments that carry out blood transfusions, as well as the **use of stem cells for therapeutic purposes, must implement a hemovigilance system, as well as be part of the biovigilance system implemented by the Ministry of Health.**

The establishments indicated in sections A), B) and C) of this article, within the scope of the authorized activities, will inform the Ministry of Health about the acts of use and disposal of blood, blood products and stem cells, through the official forms or means and within the time limits established by said Ministry for this purpose.

Article 341 Bis.- The Ministry of Health and the governments of the federal entities, within their respective spheres of competence, shall promote the donation of blood, blood **products** and stem cells, to assist in the treatment or cure of patients who require them; likewise, the Ministry of Health shall establish the bases and modalities to which the National Health System will be subject in this regard.

...

Article 342 Bis 1.- Residual plasma **may be allocated by the Ministry of Health to industrial processing for the production of blood products. Therefore, health facilities that supply residual plasma,** as well as facilities that receive it for the production of blood products, must be authorized in accordance with Articles 198, Section I, and 315 of this Law. They shall also be subject to the provisions issued by the aforementioned Ministry.

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The export of residual plasma for industrial processing may only be carried out when the national supply has been guaranteed and in accordance with what is established by the Ministry of Health and the applicable legal provisions.

The importation of plasma may only be carried out when the units have complied in the country of origin with all the requirements established in this Law, to guarantee the absence of markers of infectious agents transmitted by transfusion and the applicable legal provisions.

Article 342 Bis 3.- The National Blood Transfusion Center shall be in charge of the National Blood and Stem Cell Registry, which will integrate and keep updated the information relating to the availability of blood, **blood products** and stem cells and will include the following:

I. and **II.** ...

III. Information regarding the disposal of blood, **blood products** and stem cells carried out in the country;

IV. and **VI.** ...

Article 342 Bis 4.- The Ministry of Health will issue and supervise compliance with the selection criteria that are necessary to guarantee the protection of the autologous and allogeneic donor, both of whole blood, blood products and stem cells, and of the recipient, taking into account the existing epidemiological and demographic characteristics, and the applicable technical and scientific conditions.

Article 371.- The competent health authorities will issue the respective authorizations when the applicant has satisfied the requirements indicated by the **corresponding provisions and specifications** and covered, where applicable, the fees established by the tax legislation.

The foregoing is without prejudice to the health authority, upon becoming aware that the products or services that generate danger, risks or damage to health may deny the corresponding authorization.

For the purposes of the provisions of the preceding paragraph, the Ministry of Health may analyze and issue the corresponding opinion for each product, for which it may rely on the opinion of expert persons recognized by the competent institutions.

The opinion referred to in the previous paragraph does not prevent the Ministry of Health, if after its issuance it becomes aware that a product represents a risk to health, from prohibiting its manufacture, storage, import, distribution or sale and initiating the revocation of the corresponding authorization if it has been given.

Article 375.- ...

I. a **V.** ...

WE. The entry into or exit from the national territory of human tissues, including blood, **blood products, stem cells** and blood derivatives;

VII. and **X .** ...

...

Article 376.- The following require sanitary registration: medicines, narcotics, psychotropic substances and products containing them; medical devices with the exception of those determined as low risk and which do not require sanitary registration by the health authority, as well as pesticides, plant nutrients and toxic or hazardous substances.

The registration may only be granted by the Ministry of Health **and** will be valid for 5 years, without prejudice to the provisions of Article 378 of this Law. This registration may be extended for periods **of 10 years,** at the request of the interested party, under the terms established by the regulations.
If the interested party does not request the extension within the established period or changes or modifies the product or raw material manufacturer without prior authorization from the health authority, the latter will proceed to **cancel** the corresponding registration.

For the purposes of the preceding paragraph, cancellation of registration shall be understood as the administrative procedure carried out by the Federal Commission for Protection against Sanitary Risks, resulting from not requesting an extension within the established period or from non-compliance with the provisions applicable to the granting of an extension of the sanitary registration.

For the purposes **of this article,** the Executive Branch, through the Ministry **of Health,** shall establish, by means of general provisions, the requirements, tests, and other requirements that must be met by medicines, health supplies, and other products and substances mentioned in
This article.

Article 396.- ...

I. Verification visits by personnel expressly authorized by the competent health authority to carry out physical, **documentary or electronic** verification of compliance with the law and other applicable provisions, and

II. ...

Article 414 Bis.-

a) Herbal remedies, food supplements or cosmetic products that have been improperly advertised or promoted as medicines or to which therapeutic qualities or effects have been attributed, presenting them as a definitive solution in the preventive or rehabilitative treatment of a certain ailment, not being medicines and without **having** a sanitary registration to be considered as such;

b) The cosmetic products referred to in Article 271 Bis of this Law, **and**

c) **Electronic cigarettes, vapes and other similar systems or devices, as well as toxic substances, including solutions, mixtures, and additives used for that purpose.**

...

Article 431.- The competent health authorities may make use of the necessary legal measures, including the assistance of **public security institutions of the three levels of government within the scope of their competencies,** to achieve the execution of the sanctions and security measures that are appropriate.

Article 456 Bis.- Anyone who carries out by any means any of the conduct referred to in Article 282 Quater of this Law, shall be punished with one to eight years of imprisonment and a fine equivalent to one hundred to two thousand times the daily value of the Unit of Measurement and Update.

Transitional

First.- This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

Second.- The inclusion in the classifications provided for in article 245 of this Law of the following CATINE, substances: DIHYDROERGOCRISTINE, NICERGOLINE, NORPSEUDOEPHEDRINE, PSEUDOEPHEDRINE, AMPHEBUTAMONE (BUPROPION), TRAMADOL, GAMMA HYDROXYBUTYRIC ACID (GHB), BENZQUINAMIDE, GAMMA BUTYROLACTONE (GBL), will come into force one hundred and eighty calendar days after the publication in the Official Gazette of the Federation of this Decree.

Third.- All provisions that conflict with the provisions of this Decree are hereby repealed.

The Regulations of the General Health Law on Social Protection in Health, published in the Official Gazette of the Federation on April 5, 2004, are hereby repealed.

Fourth.— The Ministry of Health shall integrate the information of the National Master Plan for Health Infrastructure and High-Technology Equipment within a period not exceeding one hundred and eighty calendar days after the entry into force of this Decree. The initial integration of this Plan shall not affect works in progress, nor those associated with priority programs or strategic projects.

Fifth.- The Ministry of Health shall issue the guidelines referred to in Article 60 Octies of this regulation within a period of no more than ninety calendar days after the entry into force of this Decree.

Upon the entry into force of this Decree, the Agreement establishing the General Criteria for the Development of Health Infrastructure, published in the Official Gazette of the Federation on May 4, 2022, shall be rendered ineffective.

Sixth. Certificates of needs issued prior to the effective date of this Decree shall retain their original validity. The Ministry of Health shall incorporate the information contained in said certificates into the National Master Plan for Health Infrastructure and High-Technology Equipment.

The procedures for certificates of needs pending completion on the date of entry into force of this Decree must be resolved within a period of no more than fifteen working days from the entry into force of this instrument, in accordance with the legal provisions applicable at the time of their initiation, and be integrated into the National Master Plan for Health Infrastructure and High Technology Equipment.

Seventh.- The National Medical Arbitration Commission shall carry out the necessary procedures for the issuance and, where appropriate, modification of the internal regulations governing the implementation of alternative dispute resolution mechanisms in matters of health services contemplated in this regulation within a period not exceeding one hundred and eighty calendar days after the entry into force of this Decree.

Eighth.- Health authorizations related to electronic cigarettes, vapes and other similar systems or devices, which have been granted prior to the entry into force of this Decree, will be without effect.

The Federal Commission for Protection against Sanitary Risks will notify the holders of said authorizations so that they immediately cease all activities related to said devices.

Ninth.- The provision provided in article 10, last paragraph, of this regulation, to promote the participation of natural or legal persons who prove that they have, in national territory, investment in the production chain of medicines, medical devices and other health supplies, or with the start of installation of factories, laboratories or warehouses that are part of said chain, or those that develop scientific research or when it is a matter of acquisitions of innovative products in health matters in the consolidated contracting procedures of medicines, medical devices and other health supplies, will be applicable to the contracting procedures that are carried out from the fiscal year 2026 and whose medicines, medical devices and other health supplies are scheduled for delivery from 2027.

Tenth.- The Sixteenth Transitory Provision of the Decree that amends and adds to the Law is repealed
General Health published in the Official Gazette of the Federation on May 15, 2003.

Eleventh.- The expenses generated by the implementation of this Decree will be covered by the budgets of the spending entities involved in this, therefore no increases in resources will be authorized in the current fiscal year or in subsequent years for such purposes.

For subsequent fiscal years, the respective resource provisions must be made in the draft budgets of the corresponding spending entities without increasing their regular operating expense or personal services budget.

Twelfth.- The Health Services of the Mexican Social Security Institute for Well-being (IMSS-BIENESTAR) within a maximum period of thirty working days, counted from the entry into force of this Decree, will carry out the necessary actions to modify, in terms of the applicable legal provisions, the contract of the public trust called “Health Fund for Well-being”, in accordance with the provisions of this Decree.

Once the modification to the contract has been formalized within the following thirty business days, the Technical Committee must approve the operating rules of the Health Fund for Well-being, in accordance with the provisions of this Decree.

Mexico City, December 10, 2025.- Rep. Kenia López Rabadán, President.- Sen. Laura Itzel Castillo Juárez, President.- Rep. Magdalena del Socorro Núñez Monreal, Secretary.- Sen. María Martina Kantún Can, Secretary.- Signatures.

In compliance with the provisions of section I of Article 89 of the Political Constitution of the United Mexican States, and for its due publication and observance, I issue this Decree at the Residence of the Federal Executive Power, in Mexico City, on January 13, 2026.- **Claudia Sheinbaum Pardo,** President of the United Mexican States.- Signature.- **Rosa Icela Rodríguez Velázquez,** Secretary of the Interior.- Signature.