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| | ***ALCANCE DIGITAL*** [Digital Bulletin] **Nº 84**<br>**LA GACETA**<br>**Diario Oficial** | Signed digitally by JORGE LUIS VARGAS ESPINOZA (FIRM)<br>Name of recognition (DN)<br>Serial number=CPF-02-0255-0227, sn=VARGAS ESPINOZA<br>Given Name = JORGE LUIS, c=CR<br>o=NATURAL PERSON, or= CITIZEN<br>Cn=JORGE LUIS VARGAS ESPINOZA (FIRM)<br>Date: June 26, 2012 17:03:24 – 06'00' |
| 34th Year | San José, Costa Rica, Wednesday, June 27, 2012 | Nº 124 |


# EXECUTIVE BRANCH

# DECREES

Nº 37185-S-MEIC-MTSS-MP-H-SP

REGULATION OF THE GENERAL LAW FOR THE CONTROL OF TOBACCO AND ITS HARMFUL EFFECTS ON HEALTH


**2012**
**Imprenta Nacional**
**La Uruca, San José, C. R.**

Unofficial Translation

**DAJ-1309-2012**

# EXECUTIVE BRANCH

## DECREES

### EXECUTIVE DECREE N° 37185-S-MEIC-MTSS-MP-H-SP

### THE PRESIDENT OF THE REPUBLIC, THE MINISTERS OF HEALTH, OF ECONOMY, INDUSTRY AND COMMERCE AND OF LABOR AND SOCIAL SECURITY, AND THE MINISTERS OF THE OFFICE OF THE PRESIDENCY, OF THE TREASURY AND PUBLIC SAFETY (*ad interim*)

In the use of the faculties conferred upon them by Articles 140 sub-paragraphs 3) and 18) and 146 of the Political Constitution; 27 and 28 of Law Nº 6227 of May 2, 1978, "General Law of Public Administration"; 1, 2, 4, 7, 338, 349 and 364 of Law N° 5395 of October 30, 1973, "General Law of Health"; 1 and 2 sub-paragraph c) of Law Nº 5412 November 8, 1973, "Organic Law of the Ministry of Health"; Law Nº 8289 of July 10, 2002, "Reform of the Organic Law of the Ministry of Health, No. 5412, to grant instrumental juridical personality to the Institute for Alcoholism and Addiction (*Instituto sobre Alcoholismo y Farmacodependencia*)"; Law No. 6054 June 14, 1977, "Organic Law of the Ministry of Economy, Industry and Commerce"; Law N° 7472 December 20, 1994, "Law for the Promotion of Competition and Effective Defense of the Consumer"; Law No. 7410 of May 26, 1994, "General Law of the Police"; Law No. 4762 of May 8, 1971, "Law for the Creation of the General Bureau of Social Adaptation"; Executive Decree No 22139-J, May 31, 1993, "Regulation of the Rights and Duties of those Deprived of Liberty"; Minimum Rules of the United Nations for the Treatment of Inmates, Geneva, 1955, approved by the General Assembly on November 22, 1969; 1, 2 and 5 of Law N° 1860 April 21, 1955, "Organic Law of the Ministry of Labor and Social Security"; Law No. 8655 of July 17, 2008; "Law for the Approval of the Framework Convention for Tobacco Control of the World Health Organization (WHO)"; Executive Decree Nº 34705 of August 14, 2008, "Ratification of the Republic of Costa Rica of the Framework Convention for Tobacco Control of the World Health Organization (WHO), signed on July 23, 2003" and Law No. 9028 March 22, 2012, "General Law for the Control of Tobacco and its Harmful Effects on Health."

**WHEREAS:**

1. The health of the public is a fundamental human right, as well as a public good protected by the State.

2. It falls within the competency of the Ministry of Health to define its policies, regulations, plans and the coordination of all public and private health-related activities.

3. The presence of harmful substances and carcinogenic agents in emissions caused by the burning of cigarettes and tobacco derivatives - which, in a slow but effective way, causes people's health to deteriorate – has been demonstrated through innumerable scientific studies.

4. The illnesses and deaths caused by the consumption of tobacco derivative products have reached epidemic proportions in many countries, and will only increase if effective measures to inhibit consumption are not put into practice.

5. The World Health Organisation (WHO - 2012) has established that tobacco is the direct or indirect cause of almost 6 million deaths a year, approximately a third of which occur in developing countries where, according to estimates, 8 million deaths will occur due to this addiction in the next 20 to 30 years if effective measures to reduce tobacco consumption and exposure to second-hand smoke are not put into practice.

6. The harm to health caused by the consumption of tobacco products and derivatives is considered one of the main public health problems at the global level, taking into account not only active smokers, but also the equally deleterious consequences for passive smokers, all the people voluntarily or involuntarily exposed to the effects of tobacco use.

7. The consumption of tobacco is directly related to illnesses such as chronic bronchitis, pulmonary emphysema, airway hyper-responsiveness, gastrointestinal problems, cardio and cerebral vascular disorders, and various types of cancer of the lung, mouth, kidney and bladder, among others. It also has a negative impact on fetal development, which can lead to premature birth and perinatal death.

8. On average, mortality among adult smokers is 1.7 greater in comparison to non-smokers.

9. The consumption of tobacco products and derivatives causes the illness and death of many people of productive age, which increases the costs of medical care and social welfare. Passive smokers also comprise a high percentage of those who are affected by the effects of this addiction.

10. One of the priority actions to prevent tobacco addiction in groups considered high-risk, and therefore vulnerable, such as children, young people, pregnant women, and the general public, is the dissemination of legislative measures adopted to protect the right of all people not to be affected by tobacco consumption.

11. An essential aspect of the State's policies in terms of public health is that of discouraging people who are underage from consuming tobacco products and derivatives, as well as eliminating their exposure to advertising, promotion and sponsorship of the aforementioned products.

12. It has been demonstrated that tobacco products and derivatives produce dangerous amounts of emissions for human health, and can also cause cardiovascular illnesses, as well as other conditions.

13. Given the carcinogenic nature of tar and other substances included in tobacco products and derivatives, it is necessary to regulate the consumption and exposure of the substances they contain.

14. There are studies on an international level that prove that the use of terms such as "low tar," "ultralight," "light" and "mild," give the impression that the product is less harmful, causing a greater increase in cigarette consumption.

15. It is evident that smokers (active and passive) incur direct costs in the area of social security, which is also likely to result in a cost to the health sector and to the economy in general, due to premature death, disabilities and related morbidity that necessarily require medical care.

16. According to the World Health Organisation, in the absence of effective regulation of tobacco, there will be serious consequences for public health, in light of the epidemic that tobacco use represents.

17. Disclosure of the risks caused by tobacco use, by itself, will not make this addiction disappear immediately, but rather the promulgation of the General Law for the Control of tobacco and its Harmful on Health was necessary. Nonetheless, there is a need for an entire process of socialization, with the participation of all social actors, focused on providing an effective, appropriate and comprehensive response to the set of problems tobacco use poses for public health.

18. It is imperative for the Ministry of Health, in keeping with the provisions contained in Law Nº 8289, to strengthen the creation of programs to quit consumption of tobacco products and derivatives for the entire population, as a result of which, in order to ensure proper implementation thereof, it becomes necessary to assign to the Institute for Alcoholism and Addiction (IAFA - *Instituto sobre Alcoholismo y Farmacodependencia*), the implementation of the guidelines for the operation of care programs for people with problems of addiction to tobacco or its derivatives.

19. The Executive Branch has carried forward a policy to promote simplification of administrative procedures by taking advantage of information technology in order to streamline private citizens' interactions with the Government, thus achieving speed and functionality in processing, reducing operating costs, all in accordance with the Law for the Protection of the Citizen from Excessive Administrative Requirements and Procedures, and its amendments, Law Nº 8220 of March 4, 2002.

20. In light of all of the considerations set forth, it has become necessary and timely to issue this regulation, in order to oversee and enforce compliance with the stipulations contained in Law No. 9028, the "General Law for the Control of Tobacco and its Harmful Effects on Health."

**THEREFORE,**

**DECREE**

The following:

**REGULATION FOR THE GENERAL LAW FOR THE CONTROL OF TOBACCO AND ITS HARMFUL EFFECTS ON HEALTH**

## CHAPTER I
## GENERAL PROVISIONS

**Article 1.- Purpose.**

The purpose of this regulation is to regulate, oversee and enforce the implementation of Law No. 9028, the "General Law for the Control of Tobacco and its Harmful Effects on Health," in order to protect the health of the public from the health, social, environmental and economic consequences of the consumption of tobacco products and derivatives, and from exposure to tobacco smoke.

**Article 2.- Objectives.**

The objectives of Law 9028 and this Regulation are as follows:

a) To reduce consumption of products made from tobacco.

b) To reduce to a minimum people's exposure to the harmful effects of smoke from products made from tobacco.

c) To reduce the health, social and environmental harm resulting from the use of tobacco.

d) To prevent people from starting to use tobacco, especially in the population of children and adolescents.

e) To foster promotion and education for health, as well as the dissemination of knowledge for present and future generations concerning the risks attributable to the consumption of products made from tobacco and due to exposure to tobacco smoke.

f) To fight the illegal trade in these products.

In light of the foregoing, no action contrary to the aforesaid objectives can be undertaken.

**Article 3.- Scope of application.**

The provisions of this regulation are a matter of public order and of general interest, and are therefore applicable to any natural or juridical person who may happen to be in the national territory.

**Article 4. Definitions and abbreviations.**

For the purposes of this Regulation and its implementation, the following definitions shall apply:

1. **Accreditation:** Procedure whereby the Ministry of Health, through the Institute for Alcoholism and Addiction, certifies compliance with the guidelines for the operation of programs to quit consumption of tobacco and its derivatives, as established in these regulations.

2. **Recreational activity:** Activity undertaken on the basis of a voluntary choice and that enables one to act upon one's various interests, pastimes or talents to stimulate their realization. They may be leisurely (passive activities) or recreational (active participation).

3. **Tax administrator:** General Office of Taxation of the Ministry of the Treasury.

4. **Work lodging:** Temporary facilities such as tents, for collective use, that serve to accommodate workers, with due conditions of safety and health, with the exception of houses intended exclusively for family occupation.

5. **Competent authority**: A body or institution of Government entrusted with carrying out the regulation, oversight, enforcement and execution of the provisions of the General Law for the Control of Tobacco and its Harmful Effects on Health, Law N° 9028, and its regulation.

6. **CCSS**: *Caja Costarricense de Seguro Social* [Costa Rican Social Security Fund].

7. **Correctional Institution:** Establishment in which punishments involving deprivation of liberty are executed, as well as measures set forth in the Penal Code and in special laws.

8. **Work Place:** Productive unit in an open or closed space that engages during working hours one or more workers who are employed or volunteers. Included are places connected or adjacent to the facilities, as well as vehicles that workers use in the performance of their work.

9. **To Certify:** A procedure whereby the IAFA issues a program resolution with approved status, complying with the guidelines established in this regulation.

10. **Quitting:** A process whereby health actions are conducted to quit consumption of tobacco products and tobacco derivatives.

11. **Cigarette:** Cut tobacco wrapped in fine paper, with or without a filter that is used for smoking. In addition to those that contain only tobacco, cigarettes can be prepared with blends of tobacco and tobacco substitutes, without taking into account the proportions of tobacco and tobacco substitutes present in a blend.

12. **Cigar or *puro*:** Rolled tobacco leaf that is lit on one end, either sucked or smoked at the other. May be prepared entirely with tobacco, or with mixtures of tobacco and tobacco substitutes present in a blend.

13. **Electronic cigarette:** Electronic nicotine dispensing systems (ENDS), constituting a category of products for consumption designed to release nicotine, after introducing the tip of a plastic or metal cylinder into the mouth, in a manner similar to a cigarette or a cigar, and inhaling with the aim of extracting a mixture of air and vapors from the device and releasing them into the respiratory system. Contains electronic vaporization systems, a power source and a charger, electronic controls and replaceable or rechargeable cartridges that contain nicotine. Included are devices, similar or otherwise, whose purpose is to supply nicotine to a person.

14. **Direct communication:** Communication that takes place between the tobacco industry and vendors or adult consumers of tobacco products and tobacco derivatives.

15. **Massive concentration:** Temporary event that brings together a number of people in unusual circumstances, under conditions of crowding or being packed closely together, in open or enclosed physical spaces that because of their characteristics as a site, whether structural or non-structural, causes or gives rise to a situation of risk or threat that requires preventive control measures for the use of the space and the conduct of the people.

16. **Oversight:** Activity of inspection that is conducted for the purpose of ensuring actual compliance with the regulations contained in the General Law for the Control of Tobacco and its Harmful Effects on Health, and this regulation.

17. **Survey questionnaire:** An instrument designed to capture data through open and closed questions. They are to be conducted in person, via e-mail, telephone or any other available medium.

18. **Tobacco derivatives:** Products made totally or partly from tobacco leaf as a raw material, as well as its waste, by-products and substitutes, whose purpose is to be smoked, sucked, chewed, sniffed or inhaled. They contain nicotine as a highly addictive psychoactive ingredient.

19. **Tobacco waste and by-products:** Stalks, leaf veins cuttings, particles and dust resulting from the manipulation and processing of tobacco leaf in the production of hand-rolled cigarettes, cigars (*puros*), *pitillos*, cigarettes and other tobacco products.

20. **Distributor:** Natural or juridical person, national or foreign, an entity of fact or of law, private or public, which acting in its own name or that of a third party, on its own or another's account, habitually engages in distributing or commercializing tobacco products and tobacco derivatives on a wholesale or retail basis.

21. **Space free of tobacco smoke:** An area where for reasons of public order, consuming or holding lit tobacco products and derivatives is prohibited, as is exposure to tobacco smoke.

22. **Space for public use:** This is understood to refer to a space of reduced size that does not occupy an area greater than five square meters.

23. S**pectacle:** An event organized by natural or juridical persons, for the purpose of bringing together the public to witness an enactment, representation, exhibition or projection of a religious, artistic, cultural or athletic nature.

24. **Railroad stations**: Infrastructure constructed outside the public thoroughfare where a passenger railway terminal operates, and in which a series of services and facilities can be offered to the traveling public: bathrooms, access ramps, waiting areas, commercial areas, offices, ticket sales, zones for boarding and exiting trains.

25. **Manufacturer of tobacco products:** A natural or juridical person engaged in the manufacture of tobacco products.

26. **Smoking:** Inhaling and exhaling or blowing out smoke, gases or vapors of tobacco products and tobacco derivatives.

27. T**obacco smoke:** Emission released from the burning tip of a cigarette or other tobacco products, generally in combination with the smoke exhaled.

28. **IAFA:** *Instituto sobre Alcoholismo y Farmacodependencia* [Institute for Alcoholism and Addiction]

29. **Tobacco industry:** A natural or juridical person engaged in the manufacture, wholesale distribution and importation of tobacco products and tobacco derivatives.

30. **Health Report:** A technical-juridical instrument through which the health authorities attest to an infraction of the Law and its regulatory provisions by a natural or juridical person, that is promulgated for such purpose in connection with tobacco control.

31. **Importer of tobacco products: A** natural or juridical person in whose name tobacco products and tobacco derivatives are imported or brought into the country.

32. **The Law:** Law No. 9028 "General Law for the Control of Tobacco and its Harmful Effects on Health."

33. **Place attached and connected to a work place:** Sites or spaces that workers customarily use in the performance of their jobs, such as: hallways, elevators, stairways, vestibules, shared facilities, cafeterias, dining rooms, bathrooms, lounges and sheds.

34. ***Maquiladora* of tobacco products and tobacco derivatives: A natural or juridical person** that, having the necessary inputs, machinery and equipment, assembles, transforms, repairs, reconstructs, puts together or combines tobacco products and derivatives at the national level, which for purposes of the law is comparable to a manufacturer.

35. **MEIC:** *Ministerio de Economía, Industria y Comercio* (Ministry of Economy, Industry and Commerce).

36. **Bus stops:** A zone located on the public thoroughfare where boarding and exiting is authorized for passengers of buses that are duly authorized by the Council of Public Transportation of the Ministry of Public Works and Transportation (MOPT - *Ministerio de Obras Públicas y Transportes*). They are classified as:

    a. **Terminal stations:** places where services begin and end, where waiting times for buses are longer.

    b. **Transit stops:** places authorized within the service route for the specific purpose of users boarding and exiting, with shorter waiting times than at terminal stations.

37. **Taxi stops:** A zone located on the public thoroughfare where boarding and exiting is authorized for passengers of taxi services that are duly authorized by the Council of Public Transportation of the Ministry of Public Works and Transportation (MOPT - *Ministerio de Obras Públicas y Transportes*).

38. **Railway transit stops or platforms:** This refers to all areas located along the railway within the right of way, where boarding and exiting is authorized for public transport passenger trains duly authorized by the competent entity.

39. **Sponsorship of tobacco:** This refers to any kind of contribution to any event, activity or individual for the purpose, effect or possible effect of promoting, directly or indirectly, a tobacco product or the use of tobacco and tobacco derivatives.

40. **Water pipes or hookahs:** This is the actual device that permits smoking tobacco and its derivatives with different flavors, and which is made up of a series of tubes, a mouthpiece, a chamber where the vapors are concentrated, and a receptacle containing liquid. Similar devices used to concentrate tobacco vapors are included.

41. **Tobacco products:** These are products completely or partly prepared using tobacco leaf as raw material, and that are intended to be smoked, sucked, chewed or used as snuff.

42. **Advertising and promotion of tobacco:** This refers to any kind of communication, recommendation or commercial action with the purpose, effect or possible effect of promoting, directly or indirectly, a tobacco product or the use of tobacco and tobacco derivatives.

43. **Promotion of tobacco:** Any stimulation of the demand for tobacco products, which could include advertising and any action intended to attract the attention and awaken the interest of consumers and non-consumers of tobacco products or derivatives.

44. **Snuff:** This is a preparation of tobacco that is milled and usually aromatized, intended to be consumed via nasal inhalation.

45. **Tobacco:** A plant of the species ***Nicotiana Tabacum*** which can cause addiction if its leaves are consumed, either in natural form or when it has been industrially processed.

46. **Tobacco for a water pipe:** Composed of a blend of tobacco and glycerol, including oils and aromatic extracts, molasses or sugar, aromatic or flavoring agents.

47. **Air terminal or airport:** A flat place on the ground provided with a set of runways, facilities and services intended for regular air traffic.

48. **Port terminal or port:** A place on the coast or on the shores of a river which, owing to its natural or artificial characteristics, serves as a place for vessels to engage in loading and unloading operations, embarkation and disembarkation, of merchandise and people.

49. **Bus terminal:** This encompasses all infrastructure built away from the public thoroughfares where a terminal station for buses operates, duly approved by the Council of Public Transportation, and in which it is possible to offer a range of services and facilities to the traveling population, such as bathrooms, access ramps, waiting areas, freight shipment area, commercial areas, offices, the sale of tickets and zones for boarding and exiting.

50. **Tobacco substitutes:** All blends or products prepared to be smoked that include tobacco in some proportion.

51. **Vapor: A** gaseous fluid whose temperature is lower than its boiling point. Its pressure does not increase when compressed, but instead is partly transformed into liquid.

## CHAPTER II
## PROTECTION AGAINST TOBACCO SMOKE

**Article 5.- Smoke-free areas.**

It is prohibited to smoke or to hold lit tobacco products and derivatives that discharge smoke, gases or vapors, in any of their forms or in devices, including the electronic cigarette and the water pipe or hookah and similar devices used to concentrate or discharge smoke, gases or vapors of tobacco products and derivatives, in the following public and private spaces or places, that are established in the Law as spaces that are one hundred percent (100%) free of exposure to tobacco smoke:

a) Hospital or health care centers or establishments.

b) Work places, in accordance with what is set forth in Articles 4, sub-paragraph b) of the Law, and 4, sub-paragraph 8) of this regulation. This includes connected or attached spaces and vehicles that workers use in the performance of their job, as well as work lodgings. Excepted from this are houses intended exclusively for family residence, and open spaces that are found within the property at a distance not less than five (5) meters from the productive work unit or its attached and connected places.

c) Centers and departments of Government and entities of public law.

d) Public and private educational and training institutions.

e) Centers for social service, except open spaces set off by the General Office of Social Adaptation at correctional institutions. It should be understood that this exception is applicable solely to adults deprived of their liberty, not to visitors and public officials.

f) Shopping centers, casinos, nightclubs, discotheques, bars and restaurants.

g) Athletic facilities and places where spectacles and recreational activities of any kind are conducted. Included are all areas involved in activities with massive concentrations of people, holiday gatherings, parties, and the like, and parks in general.

h) Elevators and escalators.

i) Phone booths and areas for ATM machines and other spaces of reduced size for public use.

j) Service stations where gas is sold, and similar facilities.

k) Vehicles or modes of paid transportation for people, ambulances and aerial tramways.

l) Rail, maritime and aerial means of transportation having their origin and destination within the national territory.

m) Cultural centers, cinemas, theatres, lecture halls, centers for self help and support, exhibit halls, libraries, conference rooms, auditoriums and museums.

n) Areas or establishments where food is prepared, processed, cooked, sampled or sold, such as restaurants, bars and cafeterias.

o) Centers for amusement, leisure or recreation for minors.

p) All areas belonging to ports and airports.

q) Bus terminals, bus stops, taxi stops, railways stations and stops, as well as any means of

transport paid for by passengers that is duly authorized by the Council of Public Transportation.
r) Athletic facilities of shared use and places of common use where recreational activities are undertaken, on properties subject to the regime of property in condominium.

**Article 6.- Information for people with visual impairment.**

Any natural or juridical person representing premises that are one hundred percent (100%) free of exposure to tobacco smoke and derivatives, shall have the obligation to inform persons with visual impairment of the prohibition to consume tobacco or smoke in the public and private spaces or places indicated in the previous article.

**Article 7.- The rights of people and the duties of proprietors, managers, administrators, representatives and other persons with decision power for public and private spaces or places that are one hundred percent (100%) free of exposure to tobacco smoke and tobacco derivatives.**

a. People who are in any of the places mentioned above, who observe a client or worker of the place smoking or consuming tobacco products and derivatives, shall have the right to demand that the proprietor, manager, administrator, representative or other persons with decision power compel the offender to desist from such conduct.

b. It is the obligation of the proprietor or representative of the place to order the offender to desist from such conduct because it is harmful to health and therefore a violation of legal and regulatory provisions.

c. In the event that the offender is one of the people in charge of the premises or establishment, users may appeal to the competent authority to draw up the respective notice of sanitary violation, the sanitary incident report of the Constabulary, the police notice issued by municipal authorities, or any other document with a similar title issued by other competent authorities, or else users can file the appropriate complaint with the District Office of Health Administration at the local level, the Regional Bureau of Health Administration at the regional level, and the Office of Customer Services at the central level, all of the Ministry of Health.

d. If the offender should refuse to desist from such conduct, the proprietor, manager, administrator, representative or other persons with decision power shall request such person’s removal from the premises, and if necessary, may call upon the Constabulary, the Municipal Police or any other competent authority indicated in these regulations for assistance, who shall act in accordance with their competencies.

**Article 8.- Obligations of proprietors, legal representatives, managers, administrators and institutional directors of public and private facilities that are one hundred percent (100%) free from exposure to tobacco smoke and tobacco derivatives.**

Proprietors, legal representatives, managers, administrators and institutional directors of public and private facilities that are one hundred percent (100%) free of exposure to tobacco smoke and derivatives, must undertake actions conducive to compliance with these legal provisions, so that public institutions and private companies with autonomous service regulations, collective bargaining agreements, internal work regulations, or any other pertinent normative instrument, must incorporate the prohibition of smoking into their work place, as well as the respective disciplinary sanctions.

**Article 9.- Notices and signs in public and private places and spaces that are one hundred percent (100%) free from exposure to tobacco smoke and tobacco derivatives.**

Proprietors, legal representatives, managers, administrators and institutional directors of public and private places and spaces that are one hundred percent (100%) free of exposure to tobacco smoke and

derivatives, must prominently display notices or signs with the following message: “SMOKING PROHIBITED,” with the international symbol of smoking prohibition, and in the lower part of the notice, the message “SMOKE-FREE ENVIRONMENT, Law N° 9028.”

Notices or signs must comply with the following specifications:

a) The background of the notice must be white. The letters and symbol must be of the color established in Annex 1 of this regulation.
b) The minimum sizes for the notice or sign and its location must be:
    a. From 15 centimeters wide by 20 centimeters high or 30 centimeters wide by 40 centimeters high in indoor spaces of public and private facilities that are one hundred percent (100%) free of exposure to tobacco smoke and tobacco derivatives. They are to be placed at all main and secondary entrances, in bathrooms, dining rooms and covered parking areas.
    b. From 60 centimeters wide by 90 centimeters high or 90 centimeters wide by 120 centimeters high in outdoor spaces public and private facilities that are one hundred percent (100%) free of exposure to tobacco smoke and tobacco derivatives. At least two notices are to be posted for every ten thousand square meters (10.000 $m^2$), particularly in places that are more heavily frequented by people. In outdoor spaces of less than ten thousand square meters (10.000 $m^2$), at least one notice is to be posted.
    c. For vehicles or means of transport paid for by passengers, such as taxis, ambulances and aerial tramways, the size of the notice or sign may be of smaller dimensions than those indicated in sub-paragraph b) sub sub-paragraph i). They are to be posted in a place visible to passengers and that does not interfere with the visibility of the driver.
    d. For vehicles or means of transport paid for by passengers, such as buses, rail and maritime transportation, the size of the notice or sign must be of the dimensions indicated in sub-paragraph b) sub sub-paragraph i). They are to be posted in a place visible to passengers and that does not interfere with the visibility of the driver.
c) The base of the notice or sign is to be posted at a height of 1.7 meters from the floor. In activities involving massive concentrations of people, holiday gatherings, parties and the like, parks in general, athletic facilities and places where spectacles and recreational activities of any kind occur, in open or enclosed spaces; as well as in centers of amusement, leisure or recreations for minors, notices or signs must be posted at a height that allows for them to be visible, not less than 1.7 meters from the floor.
d) In those places that, owing to the nature of the activity are places with little illumination, notices must be illuminated in such a way that they are legible.
e) Notices or signs must be permanent and of a resistant material that does not easily deteriorate.

**Article 10.- Programs for quitting smoking.**

The Ministry of Health, acting through the IAFA, shall certify public and private programs dedicated to therapeutic care to enable people diagnosed as addicted to tobacco or its derivatives to quit.

In order to ensure the provision of appropriate services and treatments to combat addiction to tobacco and its derivatives, implementation of “Guidelines for the operation of treatment programs for people with problems of addiction to tobacco or its derivatives” contained in Annex 2 of this regulation, is hereby made compulsory.

The CCSS shall ensure the availability of programs for quitting smoking at the national level, and ensure diagnosis, follow-up, treatment and prevention of diseases associated with tobacco use.

Working people diagnosed with an addiction to tobacco or its derivatives have the right to receive therapeutic care in official programs of the IAFA, CCSS or any private program, so that the employer shall undertake to grant the permissions for attendance at the required sessions.

The IAFA, CCSS and any other establishment of health or that is engaged in duly approved programs to quit smoking, are required to issue the respective confirmation of attendance. The confirmation must indicate the name of the establishment, the name of the natural or juridical person responsible for the program to quit smoking, the name and identification of the user, the date, time of entry and exit, signature and stamp.

## CHAPTER III
## SWORN STATEMENT OF INGREDIENTS AND EMISSIONS OF TOBACCO PRODUCTS SOLD IN THE NATIONAL TERRITORY

**Article 11.-** Natural or juridical persons, importers and/or manufacturers of tobacco products and derivatives, including the electronic cigarette containing nicotine, must submit annually a sworn statement to the Ministry of Health stating the ingredients and emissions of nicotine, tar and carbon monoxide, as well as the methods of analysis used, for any tobacco products or derivatives that they commercialize in the country. The foregoing does not release the Ministry of Health from its duty to ascertain at any time the truth of what is stated in the Sworn Statement.

Any products, whether national or imported, that do not comply with the foregoing can be seized and destroyed by the health authorities, and in the case of importations, their removal from storage for entry into the country shall not be authorized, in which case the respective procedure is to be followed in accordance with the competencies of the Ministry of Health and the Ministry of the Treasury. If the submission of the form for the sworn statement is not done in person, the signature must be authenticated by a notary public.

**Article 12.-** The Ministry of Health shall prohibit the use of particular ingredients whenever it is demonstrated that, according to objective scientific criteria and international standards, they are increasing the total intrinsic toxicity and addiction to tobacco products and tobacco derivatives.

**Article 13.-** Producers and importers of tobacco products and derivatives must prepare and submit the sworn statement indicated in the foregoing Article 11, with its respective copy, of the ingredients and emissions from tar, nicotine and carbon monoxide, and the methods of analysis for each product, to the Office of Customer Services of the Ministry of Health, using the respective official form, as per Annex 4.

**Article 14.-** Modifications or reformulations of the tobacco products and derivatives indicated in the sworn statement submitted to the Office of Customer Services of the Ministry of Health, shall require a new sworn statement in which such new modifications or reformulations are registered.

**Article 15. –** To authorize removal from storage of imported tobacco products and derivatives, the person in question must have issued a sworn statement to the Office of Customer Services of the Ministry of Health, concerning the product that is to be imported. To this end, the Ministry of Health shall send to the Computer System of the National Customs Service the respective technical note.

## CHAPTER IV
## ADVERTISING, PROMOTION AND SPONSORSHIP OF TOBACCO PRODUCTS AND TOBACCO DERIVATIVES

**Article 16.- Advertising, promotion and sponsorship. –** Any kind of advertising, promotion or sponsorship of tobacco products and tobacco derivatives is prohibited.

**Article 17**.- Excepted from the foregoing are advertising and promotion by direct communication conducted by the tobacco industry with vendors and adult consumers of tobacco and derivatives, in accordance with the protocol established for such purpose in Annex 3 of this regulation.

**Article 18**.- Advertising and promotion of tobacco derivative products is only permitted inside places and events where access is restricted only to adults, and that have not been declared a space that is one hundred percent (100%) free from tobacco smoke and derivatives.

**Article 19**.- The use of advertising on vehicles intended for the distribution of tobacco products and tobacco derivatives is prohibited.

**Article 20**.- Advertising at points of sale, as well as the use of containers or dispensers displaying advertising of tobacco or its derivatives is prohibited.

**Article 21**.- It is prohibited to use the name, logo or emblem of a cigarette brand, as well as any kind of advertising, promotion or sponsorship of tobacco and derivatives, in activities relating to social responsibility undertaken by natural or juridical persons.

## CHAPTER V
## DISTRIBUTION, SALE AND DELIVERY OF TOBACCO PRODUCTS AND TOBACCO DERIVATIVES

**Article 22. –Regulation of the sale and provision of tobacco products and derivatives in particular places and spaces.**

The sale and provision of tobacco products and derivatives is prohibited at the following establishments:

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a) Hospital and health care centers or establishments, whether public or private.
b) Centers and departments of Government and entities of public law.
c) Public and private educational and training institutions.
d) Public and private centers for social service, except in Correctional Institutions, where sales are to be conducted in accordance with the provisions established by the General Office of Social Adaptation and places so authorized by it. The provision of tobacco products by persons visiting inmates shall be subject to regulations, procedures and controls issued by the General Office of Social Adaptation.
e) Athletic facilities and public places where spectacles and recreational activities of any kind are conducted.
f) Cultural centers, lecture halls, exhibit halls, libraries, conference rooms, auditoriums and museums.
g) Centers for leisure or recreation for minors.

The sanction set forth in Article 36 sub-paragraph c) sub sub-paragraph iii of the Law shall be applicable for any violation of the precepts established in this article.

**Article 23.- Other prohibitions concerning the sale and provision of tobacco products and tobacco derivatives.**

a) Sales to consumers via telephonic, digital, electronic, internet, postal or other media through which the identification of an adult cannot be verified in a clear and timely fashion, are totally prohibited, as well as purchases from street vendors, and the like.

b) The sale of tobacco products to minors is prohibited.

c) The sale of loose or individual cigarettes is prohibited, as is sale in packs containing less than twenty cigarettes.

d) It is prohibited to use vending or dispensing machines of tobacco products or derivatives.

e) The manufacture, importation and sale of food or toys with the shape or design of tobacco products is prohibited.

f) Wholesale or retail vendors of these products shall have the obligation to post at their own expense visible, clear and prominent posters inside places of sale indicating that the sale of tobacco products and derivatives to minors is prohibited. These notices must not bear logos, images or colors that make reference to brands or tobacco products. Permanent or occasional merchants selling tobacco products shall be obliged to demand presentation of an identity card, residency card, passport or other identification document at the time of sale.

g) The sale of tobacco products to the public must be done exclusively from shelves located at cash registers at points of sale within establishments, in such a way that they are not directly accessible to the end consumer.

## CHAPTER VI
## EDUCATION, PREVENTION AND COOPERATION

**Article 24.-** Pursuant to the provisions of Law No. 8289, the Ministry of Health, acting through the IAFA, shall create the National Education Program for Prevention and Information on the Consumption of Tobacco and its Derivatives, which shall in turn designate the agencies responsible for the execution of the program. The purpose of this Program is to foster promotion and health education, as well as the dissemination of knowledge for present and future generations of the risks attributable to the consumption of products made from tobacco, and resulting from exposure to tobacco smoke.

**Article 25.-** The IAFA shall coordinate with the Ministry of Public Education and other public entities involved with prevention, health and research, in order to compile and disseminate information, as well as educational and research programs associated with the National Education Program for Prevention and Information on the Consumption of Tobacco and its Derivatives. Part of the funding established in the Law for the IAFA shall be allocated towards this end.

**Article 26.-** With regard to educational programs developed by the IAFA, because these fall within the exclusive competency of the Superior Council of Education, they must be made known to the Council so that it can incorporate them into the Costa Rican educational system.

**Article 27.-** The Ministry of Public Safety, through the Bureau of Preventive Police Programs, shall assist the IAFA, on the basis of coordination, in the dissemination of these educational programs.

## CHAPTER VII
## TAXES ON TOBACCO PRODUCTS

**Article 28.- Taxable product.**

A "taxable product" shall be understood to refer to each cigarette, cigar or *puro* of tobacco and derivatives, tobacco in its natural state or any other presentation containing tobacco, and whether or not it is meant to be smoked, of domestic production or imported, included in tariff schedules 24.01 (LEAF TOBACCO OR UNPROCESSED; WASTE TOBACCO), 24.02 (CIGARS –*PUROS*- INCLUDING BLUNTS. LITTLE CIGARETTES – LITTLE CIGARS - AND CIGARRILLOS OF TOBACCO OR TOBACCO SUBSTITUTES) AND 24.03 (OTHER TOBACCOS AND TOBACCO SUBSTITUTES, PROCESSED; "HOMOGENIZED" OR RECONSTITUTED TOBACCO; TOBACCO EXTRACTS AND JUICES).

**Article 29.- Taxable Event for Tobacco Products.**

With regard to the taxable event for the tax created in Article 22 of Law No. 9028, called the "Tax on Tobacco Products," in the case of products of national manufacture, it shall occur at the time of sale at the factory level, at the time of the issue of the invoice, or the provision of the product, whichever event occurs first.

For importation or bringing into the country, at the time of acceptance of the customs declaration.

**Article 30.- Subjects liable to taxation.**

Manufacturers and *maquiladora* processors of products will be the payers of this tax, for national production, and for importation or bringing in the finished product, the natural or juridical person in whose name said product or derivatives are imported or brought in shall pay the tax.

Importers of raw materials will also be considered liable to this tax, as long as they are registered as payers of this specific tax with the Bureau of Taxation-Customs, through form D-140 entitled

"Declaration of registration, modification and de-registration," given that this tax is to be levied on the final product at the factory level.

**Article 31.- Determination of taxable income and calculation of tax.-**

In cases where tobacco products are cigars (*puros*), little cigars (*puritos*) and cigarettes of tobacco made from national or imported production covered by tariff schedule 24.02 of Law 9028, the taxable income is the number or amount of units of these products sold at the factory level or imported. For merchandise included in this sub-paragraph, the tax is to be determined by multiplying the taxable income by the tax rate.

For other tobacco derivatives, tobacco in its natural state and any other item containing tobacco, and whether or not it is intended for smoking, established in schedules 24.01 and 24.03, the taxable income is determined by dividing the net weight of the merchandise expressed in grams of tobacco by a factor of 0.6811 (which corresponds to the average weight in grams of tobacco content in one cigarette). The tax is to be calculated by multiplying the tax rate per cigarette by the result of the previous operation (taxable income), pursuant to what is set forth in the penultimate paragraph of Article 22 and Article 30 of the aforementioned Law No. 9028.

The taxable income of tobacco extracts and juices shall be established and announced via general resolution to be issued by the General Office of Taxation.

Tobacco products consisting of raw material for the manufacture of cigarettes, cigars or *puros*, whether imported or of national production, shall not be subject to this tax, as long as manufacturers establish before the Bureau of Taxation-Customs that they are duly registered as taxpayers of the specific tax established in the Law, through form D-140, entitled "Declaration of registration, modification and de-registration," given that this tax is to apply to the final product at the factory level.

The Bureau of Taxation shall issue a certificate of registration as a payer of this tax with such status. Said certificate shall constitute proof for the latter to present to its suppliers.

**Article 32.- Deadline for submission of declaration and payment of tax.**

Those who are liable to payment of this tax, in the case of national production, must submit their declarations of liquidation thereof within the first fifteen calendar days following the end of the respective month, unless the day on which it falls due is not a business day, in which case, it shall be understood as having been postponed until the next business day. The manufacturer shall file the declaration for all sales transacted in the month prior to the aforesaid deadline, and shall make payment of the tax simultaneously. Moreover, it should retain the verifying documents authorized by the Bureau of Taxation to support such declarations for the legal retention period.

For importation or bringing in of products, the General Bureau of Customs shall be the institution charged with collecting this tax.

**Article 33.- Establishment of a minimum level of taxation**.

The minimum level of taxation to be paid shall be established and announced annually via general resolution to be issued by the General Office of Taxation, pursuant to what is set forth in Article 31 of Law No. 9028.

**Article 34.- Allocation of Tax.**

Revenues received shall go into the General Fund of the Government of the Republic as current revenues with specific application, and are to be credited to a specific account for their control and subsequent distribution to the beneficiary entities, in fulfillment of what is set forth in Article 29 of the law. For the monthly transfer of funds, the actual collection for the previous month shall be considered, as well as the procedures applicable to the execution of transfers, in accordance with what is established in Article 43 of Law 8131, entitled "Law for the Financial Administration of the Republic and Public Budgets."

**Article 35. – Sanctions**.
Failure to fulfill the requirement to file the respective declarations and pay the tax on the part of the liable party shall empower the Bureau of Taxation to initiate an administrative procedure to impose sanctions, in accordance with what is established in the Code of Tax Standards and Procedures and the General Customs Law, as appropriate.

## CHAPTER VIII
## OVERSIGHT, ENFORCEMENT AND SANCTIONS
### SECTION I
### OVERSIGHT AND ENFORCEMENT

**Article 36. –** It shall be incumbent upon the Ministry of Health and other institutions concerned with oversight and enforcement of the provisions of the Law and its regulation to do the following:
.
The Ministry of Health shall regulate, oversee and enforce complete compliance with the Law and its regulation.

Health authorities duly identified, shall conduct inspections, sampling and analysis in keeping with the competencies that Law confers upon the Ministry of Health, in those places where infractions of the Law and its regulation could be perpetrated.

The Ministry of Economy, Industry and Commerce (MEIC), in conjunction with the Ministry of Health, shall enforce what is set forth in Chapters IV, V and VII of the Law, and such other provisions as may prove applicable, within the competencies that have been defined for it by the Organic Law of the Ministry of the Economy, Industry and Commerce, No. 6054 of June 23, 1977, and its regulation, Executive Decree No. 32475-MEIC of July 29, 2005.

The municipalities shall collaborate in the enforcement of provisions contained in Chapters II and VII of the Law and such other legislation as may prove applicable to them.

The Labor Inspectors of the Ministry of Labor and Social Security, shall have collaborating or auxiliary officials to assist them, in accordance with Article 88 of the Organic Law of the Ministry of Labor and Social Security for enforcement of the provisions contained in Chapters II and VII of the Law, and such other legislation as may prove applicable to them. Furthermore, the Council of Occupational Health shall collaborate in the prevention of consumption of tobacco products and derivatives, and of exposure to tobacco smoke.

The Ministry of Public Safety, through the General Bureau of the Constabulary, shall draw up the protocol of operational action that ensures its cooperation in the control, verification and execution of the Law and its regulation, in accordance with its competencies.

It is the responsibility of the municipalities to see to the cleaning up of waste on public thoroughfares from tobacco products and derivatives, in accordance with Law No. 8839 of July 13, 2010, the “Law for Comprehensive Waste Management.”

The implementation of a system of control shall be permitted to be applied to tobacco products and derivatives at the point of manufacture, for the purpose of conducting shared oversight with the Bureau of Taxation that will make it possible to achieve better fiscal control and discourage the illegal trade in tobacco and tobacco derivatives.” [*sic*]

**Article 37.-** At the requisition of the General Bureau of Customs or the Police of Fiscal Control, proprietors, administrators or personnel in charge of establishments selling tobacco products shall be compelled to submit invoices and allow officials from these agencies to inspect the inventories of

products on sale or in storage, for the purpose of confirming the documentary information stating the physical product inventories. In addition, they are obliged to allow the aforesaid inspections and to present the legal documents that confirm their inventories.

**Article 38.-** When the General Bureau of Customs or the Police of Fiscal Control ascertain that in facilities for the sale of tobacco products or vehicles for distribution, there are products that have not paid the respective taxes or customs duties, in whole or in part, they shall undertake a preventive seizure of such products and, following due process, as appropriate, they shall be subject to the provisions for imposing sanctions established in the General Customs Law, its amendments and related legislation, or in the Penal Code.

**Article 39.-** Upon conclusion of the proceeding for judicial or administrative resolution, the authority that has heard the matter shall order the destruction or return of the tobacco products, as appropriate. In the event of the destruction of the product, it shall be required to proceed in a manner pursuant to the requirements established by the Ministry of Health.

**Article 40.-** For the purposes of this regulation, the party legally responsible for any establishment or commercial facility engaging in the sale of tobacco products shall be responsible for the actions or omissions of its personnel and sub-contractors. Said liability does not restrict any other liability that may pertain directly to whomever may have performed or failed to perform the action that gave rise to the offense.

**Article 41.- Seizure of prohibited objects and tobacco products.**

In the event that a crime is established, and seizure of prohibited objects and tobacco products and derivatives occurs, the competent authority shall forward the respective documentation to the corresponding judicial authority within three days, and the latter shall order it to be stored in such location as the Ministry of Health shall have made available for the safeguarding of evidence until such time as said authority shall determine the appropriate procedure. If with the lapse of a period of three months following the conclusion of judicial proceedings, the legitimate proprietor does not appear in court to assert his rights, the jurisdictional authority shall order the Ministry of Health to destroy the goods, for which it shall have drawn up the appropriate documentation. When the destruction of these goods is undertaken, appropriate measures must be taken to avoid risks to health and the environment.

With respect to the authorization granted to the MEIC to carry out seizures of such tobacco products as may be found illicitly in the country, this activity must be subject to the legislation concerning this institution and the competencies defined by its Organic Law of the Ministry of Economy, Industry and Commerce, No. 6054 of June 23, 1977, and its regulation, Executive Decree No. 32475-MEIC of July 29, 2005.

**Article 42.- On seizure as a result of violations of this law and its regulation.**

When an infraction indicated in Article 36, sub-paragraphs c) sub sub-paragraphs ii), iii), iv), v), vi) vii) and viii), and sub-paragraph d) sub sub-paragraphs i), iii), iv) and v) of the law must be addressed, and there are grounds for any seizure of products related to tobacco, within three days the respective documentation must be forwarded to the appropriate District Office of Health Administration in order to institute the summary administrative procedure. If the infraction of the Law is proven, the health authority shall undertake the destruction of the seized goods, for which it must draw up the appropriate documentation. When the destruction of these goods is undertaken, appropriate measures must be taken to avoid risks to health and the environment.

With respect to the authorization granted to the MEIC to carry out seizures of such tobacco products as may be found illicitly in the country, this activity must be subject to the legislative provisions concerning this institution, pursuant to the competencies defined by its Organic Law of the Ministry

of Economy, Industry and Commerce, No. 6054 of June 23, 1977, and its regulation, Executive Decree No. 32475-MEIC of July 29, 2005.

## SECTION II
## OTHER INTERVENTIONS BY THE HEALTH AUTHORITIES

**Article 43.-** In fulfillment of what is ordered by the Law on the prohibition of smoking in spaces that are one hundred percent (100%) free of exposure to tobacco smoke and tobacco derivatives, the Ministry of Health shall also perform the following actions:

1. Schedule and conduct health inspections in public and private environments that are one hundred percent (100%) free of exposure to tobacco smoke and tobacco derivatives.

2. Publicize the provisions contained in these regulations to the general public through the use of the mass media, flyers, and other means.

3. Provide instruction for managers or those in charge of public and private establishments concerning the content of the Law and its regulation.

4. Coordinate with the competent authorities to provide training for their employees in connection with the provisions of the Law and its regulation.

## SECTION III
## PROCEDURE AND SANCTIONS

**Article 44.-** The things set forth in Article 36 of the Law constitute administrative infractions thereof. The infractions considered herein shall fall within the knowledge and competency of a permanent and collegial Executive Agency for Administrative Proceedings, which is to consist of an attorney and two staff members with technical competency for the conduct of the proceedings, designed by the Regional Director of the Health Directorate of the respective territorial jurisdiction, acting in the capacity of a Deliberative Body.
For purposes of administrative proceedings, the Executive Agency shall have all powers conferred upon it by Article 300 of the General Law of Public Administration.

**Article 45.-** Conduct of the administrative proceeding to impose sanctions, as well as execution of any sanctions that may be imposed due to non-compliance with customs procedures for tobacco products and derivatives stated in Article 36 sub-paragraph d) sub sub-paragraph ii), are to be carried out by the National Customs Service, in accordance with the administrative procedures legally established in the customs legislation in force. The National Customs Service shall notify the Ministry of Health of the established resolution in order for it to be listed in the National Registry of Offenders.

The sanction stated in Article 36 sub-paragraph d) sub sub-paragraph ii of Law No. 9028, shall be applicable, unless the infraction is subject to a heavier sanction pursuant to the General Customs Law.

**Article 46.-** For implementation of the competencies assigned to the Ministry of Health, and in order to seek greater effectiveness and efficacy in the processing of matters relating to infractions of the Law and its regulation, a Summary Proceeding is to be instituted, as established in Chapter Two, Title Six of the General Law of Public Administration, and set forth in Article 39 of the Law.

**Article 47**.- A procedure that may give rise to the imposition of any of the administrative sanctions stated in the Law may be initiated at the request of the parties, or based on a court order, as appropriate.

**Article 48**.- Complaints concerning violations of the Law may be submitted verbally, or written in hard copy or digital format submitted to the District Office of Health Administration at the local level, to the Regional Bureau of Health Administration at the regional level, and to the Office of Customer Services at the central level, all in the Ministry of Health.

Written or verbal complaints must contain the following information:

1. Full name of the complainant, number of ID card or any other identity document, and place or medium for receiving notifications.
2. Reasons or grounds of fact.
3. Signature of the complainant and the person receiving the complaint.
4. The complainant may submit testimonial and/or documentary evidence. Evidence may be submitted in any technological format, including videos and digital photos.

When complaints are submitted verbally, the health authority must record the information called for in this article, through an incident report that is to be drawn up for such purpose.
Furthermore, the health authority must take note of anonymous complaints submitted, and verify the truth of the complaint through such means as it may have at its disposal.

**Article 49.-** Once the complaint has been received at the District Office of Health Administration, the Regional Bureau of Health Administration or the Office of Customer Services, as appropriate, steps will be taken to assess its admissibility in terms of its adherence to the formal requirements contained in the preceding article. If the complaint is deficient in any of the requirements contained in the preceding article, the aforementioned organizational unit shall grant only once, in writing, an extension of ten business days, pursuant to Article 264 of the General Law of Public Administration, in order for the person submitting the complaint to provide the necessary clarifications.

Non-compliance with the measure, or failure to justify such non-compliance, shall result in the dismissal of the matter.

If the complaint is deemed admissible, within three business days the Regional Bureau of Health Administration or the Office of Customer Services shall forward it to the District Health Office in order to have the respective inspection performed and the corresponding report issued, which must be sent within three business days, and with no further processing addressed to the Executive Agency established in this regulation.

**Article 50.-** The health report, the police report of the Constabulary, the police incident report issued by municipal authorities, the report of the authorities of the MEIC or any other document of similar character issued by other public authorities, shall give rise to the initiation of *ex-officio* summary administrative proceedings. To such end, the authority issuing the report must forward it in hard copy or digital format to the District Office of Health Administration of the corresponding territorial jurisdiction, within a period of five business days. For its part, the District Office of Health Administration, shall have a period of three business days, to forward the report to the Executive Agency.

**Article 51.-** The Executive Agency shall conduct itself in accordance with the principles of due process and exhaustive verification of the actual truth of the facts, and with what is set forth in Chapter Two, “Summary Proceedings,” of Title Six, of the General Law of Public Administration. Pursuant to Article 344 of the General Law of Public Administration, there shall be no appeal allowed within the summary proceeding, except under the following circumstances:

.

a) Summary dismissal of petition or complaint.

b) Refusal to convene a hearing to conclude the proceeding.

c) Final ruling.

When a final ruling is concerned, the period for appeal shall be three business days, and twenty-four hours in the other cases, both deadlines counting from the business day following notification of the ruling. Appeals must be resolved by the Deliberative Body within eight days following its submission.

**Article 52.-** If the complexity or technical nature of the case should so warrant, the Executive Agency may seek advisory guidance from technicians expert in the matter, or from any professional with technical expertise for such purpose.

**Article 53.-** The Executive Agency shall issue a recommendation to the Deliberative Body, based on verification of the actual truth of the facts under investigation. In each case it shall recommend sanctions that are appropriate, or else the closing of the case file when there are no grounds or sufficient evidence for the imposition of sanctions.

**Article 54.-** Within the period established in Article 325 of the General Law of Public Administration, the Deliberative Body shall bring the proceedings to a close through a final ruling, ordering closing of the case file when there are no grounds or sufficient evidence for the imposition of sanctions, or if the infraction of the provisions of the Law is ascertained, it shall impose the appropriate monetary sanction, which must be paid within a period of thirty business days counting from the notification of the final ruling, without impairment to the closing of the establishment by the Ministry of Health and the municipalities, in accordance with Article 36 of the Law, except for what is set forth in Article 45 of this regulation, which is regulated by the provisions of the General Customs Law.

**Article 55**.- The execution of any final ruling that imposes a monetary sanction must be preceded by two consecutive notifications; for such purpose, the final ruling must contain the first notification.

The second notification must be delivered within three business days following the first notification; both notifications must be addressed to the offender, who must undertake to settle the terms of the final ruling, under penalty of closure of the establishment in the event of failure to comply with such obligation within the prescribed period.

**Article 56.-** The resulting amount that must be paid to settle the established sanction must be deposited in a collection account to be opened for such purpose in the name of the Ministry of Health, and every month, within the first 5 business days of each month, funds collected under this heading are to be transferred to the account of the General Fund of the Government of the Republic, in order to pay for expenditures on oversight and enforcement, in accordance with what is set forth in the Law.

The funds collected are to be executed by budgetary programs of the Ministry of Health or transfers to other entities to provide support for oversight and enforcement efforts for the fulfillment of the Law.

For oversight and enforcement efforts, the Ministry of Health may hire the staff required for such purpose.

**Article 57.-** If the offender should fail to comply with the obligation to pay the monetary sanction imposed, the head of the Ministry of Health shall issue a certificate of indebtedness, which for such

purpose shall constitute an executive order, which shall become executory in the respective jurisdictional venue.

**Article 58.-** The Administrative Division of the Ministry of Health, through the Financial Office of Goods and Services, shall draw up and update the monetary amounts established for the various fines in relation to the minimum wage, pursuant to Article 2 of Law 7337 of May 5, 1993, "Creating the Category of Minimum Wage for Special Crimes in the Penal Code."

**Article 59.-** For purposes of the application of this Law, with the final ruling of the summary proceeding, or a judicial resolution imposing a monetary sanction, the Regional Director of the Health Directorate of the respective territorial jurisdiction, or such person as the latter may designate, shall be charged with inserting the respective information in the National Registry of Offenders and, within a period not greater than two business days counting from the request, issuing a certification indicating the status of the interested party in relation to the fines established under the Law.

## SECTION IV
## THE NATIONAL REGISTRY OF OFFENDERS

**Article 60.-** The Ministry of Health shall implement the National Registry of Offenders, which shall be charged with maintaining a record of offenses and sanctions committed by violators of the Law, which must be maintained for a maximum period of up to four years, unless the offenders shall have failed to pay the fine, in which case they shall remain in the registry.

Institutions of the State that grant permits or licenses to operate any establishment or commercial activity, must verify in the National Registry of Offenders whether a person subject to administrative sanction is up to date in the payment of fines.

In situations involving the renewal of sanitary operating permits, the Ministry of Health shall verify in the National Registry of Offenders whether the interested party is up to date in the payment of fines, of which it must provide certification in the establishment's administrative case file.

## CHAPTER IX
## FINAL AND TRANSITORY PROVISIONS

**Article 61. – Additions.**

a) A section THREE BIS is to be added to Annex No. 4 "SWORN STATEMENT FOR PROCESSING APPLICATION FOR SANITARY OPERATING PERMITS FOR THE FIRST TIME OR RENEWALS" from Executive Decree No. 34728-S of May 28, 2008, "General Regulation for Granting Sanitary Operating Permits by the Ministry of Health," so that it shall be amended to read as follows:

> "THREE BIS: That complies with what is established in Law No. 9028 of March 22, 2012, the "General Law for the Control of Tobacco and its Harmful Effects on Health" and its regulation."

b) A point five is to be added to the end of Article 24 of Executive Decree No. 34728-S of May 28, 2008, "General Regulation for Granting Sanitary Operating Permits by the Ministry of Health," so that it shall be amended to read as follows:

> "Article 24.- Requirements for renewal.
>
> (…)

5. To be up to date in payment of fines for violation of Law No. 9028 March 22, 2012, “General Law for the Control of Tobacco and its Harmful Effects on Health” and its regulation.”

c) An Article 25 bis is to be added to Executive Decree No. 34728-S del May 28, 2008, “General Regulation for Granting Sanitary Operating Permits by the Ministry of Health,” so that it shall be amended to read as follows:

“Article 25 bis.- Verification in the National Registry of Offenders:

The authorities of the A.R.S. shall verify in the National Registry of Offenders that the party in question is up to date in the payment of fines for violations of Law No. 9028 March 22, 2012, the “General Law for the Control of Tobacco and its Harmful Effects on Health”; for which it shall be required to include confirmation thereof in the administrative case file of the establishment.”

**Article 62**.- **Derogations.**

Executive Decree No. 25462-S of August 23, 1996, published in *La Gaceta* No. 182 of September 24, 1996, “Regulation of the Law Regulating Smoking,” and its amendments, is hereby rescinded.

Executive Decree No. 20196-S of December 13, 1990, published in *La Gaceta* No. 21 of January 30, 1991, the “Regulation concerning Control of Advertising and Smoking Cigarettes,” is hereby rescinded.

**TRANSITORY PROVISIONS:**

**TRANSITORY PROVISION I**

The tobacco industry and vendors of tobacco products and derivatives shall have a period of twelve months counting from the publication of this regulation to conclude advertising contracts signed prior to the entry into force of the Law. Once the advertising contracts elapse, they cannot renewed, and the appropriate measures must be taken to remove the advertising.

**TRANSITORY PROVISION II**

The tobacco industry and vendors of tobacco products and derivatives shall have a period of twelve months counting from the publication of this regulation to comply with the prohibition established in sub-paragraph a) of Article 18 of the Law, with respect to the distribution and sale of previously packaged packs of cigarettes containing less than twenty units. Once this period elapses, importing, distributing or selling products in packages of less than twenty units will no longer be allowed.

**TRANSITORY PROVISION III**

For the creation of the National Education Program for Prevention and Information on the Consumption of Tobacco and its Derivatives, the IAFA shall have a period of one year counting from the publication of this regulation.

**TRANSITORY PROVISION IV**

For the creation of the National Registry of Offenders, the Ministry of Health shall have a period of one year counting from the publication of this regulation. Nonetheless, the Ministry shall implement a basic compilation for the registry of offenders, which shall be accessible on the website of the Ministry of Health.

**TRANSITORY PROVISION V**

To draft the protocol for operational action to ensure cooperation in the oversight, verification and execution of the Law and its regulation, the Ministry of Public Safety, through the General Bureau of the Constabulary, shall have a period of three months counting from the publication of this regulation.

**TRANSITORY PROVISION VI**

The proprietors, legal representatives, managers, administrators and people in charge of institutions referred to in Article 8 of this regulation shall have a period of three months counting from the publication of this regulation to comply with the obligation established in that provision.

**TRANSITORY PROVISION VII**

Persons responsible for public and private programs to quit smoking shall have a period of six months counting from the publication of this regulation to acquire certification for these programs.

**TRANSITORY PROVISION VIII**

Natural or juridical persons, importers and/or manufacturers of tobacco products and derivatives, including the electronic cigarette that contains nicotine, shall have a period of three months counting from the entry into force of this regulation to submit the first sworn statement to the Ministry of Health indicating the ingredients and emissions of nicotine, tar and carbon monoxide, as well as the methods of analysis used for tobacco products and derivatives sold in this country.

**Article 63.-** This shall take effect as of its publication.

Issued in the Office of the Presidency of the Republic.--San José, on the twenty-sixth day of June, Two Thousand and Twelve.

**LAURA CHINCHILLA MIRANDA**

**CARLOS RICARDO BENAVIDES JIMENEZ**
**MINISTER OF THE OFFICE OF THE PRESIDENCY**

**DAISY MARIA CORRALES DIAZ**
**MINISTER OF HEALTH**

**SANDRA PISZK FEINZILBER**
**MINISTER OF LABOR AND SOCIAL SECURITY**

**CELSO GAMBOA SANCHEZ**
**MINISTER OF PUBLIC SAFETY (*ad interim*)**

**EDGAR AYALES**
**MINISTER OF THE TREASURY**

**MAYI ANTILLON GUERRERO**
**MINSTER OF ECONOMY, INDUSTRY AND COMMERCE**

1st time.—O. C. Nº 14143.—Application Nº 31956.—C-2375750.—(D37185-IN2012064525).

Unofficial Translation

# ANNEX 1
# SIGN / OFFICIAL LABEL
# ART DESIGN

| | | Measurements | | | | | **Typeface:** CG Triumvirate Bold |
|---|---|---|---|---|---|---|---|
| | | | cm | | | | |
| | A<br>A1<br>A2<br>A3<br><br>SMOKING<br>PROHIBITED<br>[GRAPHIC]<br>ENVIRONMENT FREE<br>OF TOBACCO SMOKE<br>LAW 9028<br>A4<br>A5<br>A6 | A | 15 | 30 | 60 | 90 | **Colors:**<br><br>Red pantone 185C or similar<br><br>Red in accordance with INTE 31-07-01-00 standards<br><br>Symbol in accordance with INTE 31-07-02-00 standards. |
| | | A1 | 15.6 | 29 | 58 | 87 | |
| | | A2 | 13.5 | 27 | 53 | 81 | |
| | | A3 | 9 | 17 | 34 | 52 | |
| | | A4 | 3 | 6 | 14 | 19 | |
| | | A5 | 12 | 24 | 49 | 73 | |
| | | A6 | 13 | 27 | 53 | 79 | |
| | | B | 20 | 40 | 90 | 120 | |
| | | B1 | 5 | 10 | 21 | 30 | |
| | | B2 | 1.75 | 3.5 | 6.75 | 10 | |
| | | B3 | 0.5 | 1 | 2.5 | 3 | |
| | | B4 | 10 | 19.5 | 45 | 60.5 | |
| | | B5 | 0.9 | 2 | 4 | 5 | |

# ANNEX 2

## "GUIDELINES FOR OPERATION OF PROGRAMS FOR CARE OF PEOPLE WITH PROBLEMS OF ADDICTION TO TOBACCO OR ITS DERIVATIVES"

1º—Que es función del Estado a través de sus instituciones velar por la protección de la salud de la población y garantizar el bienestar de los ciudadanos.

2º—Que la reforma de la Ley Orgánica del Ministerio de Salud Nº 5412, para el otorgamiento de personalidad jurídica instrumental al Instituto sobre Alcoholismo y Farmacodependencia, Ley Nº 8289 del 10 de julio de 2002, publicado en *La Gaceta* Nº 147 del 1° de agosto de 2002, confiere a esta institución, que tendrá a su cargo la dirección técnica, el estudio, la prevención, el tratamiento y rehabilitación de la dependencia al alcohol, el tabaco y otras drogas lícitas o ilícitas, y será el responsable de coordinar y aprobar todos los programas tanto públicos como privados, relacionados con sus fines; deberá gestionar la suspensión o el cierre de tales programas, si incumplen los lineamientos estipulados al efecto.

3º —Que por Decreto N° 34784.MSP-S, "se declara el consumo de drogas que producen dependencia, como un problema de salud pública, y por ende, se declara de interés público y nacional todas las actividades que se realicen para la prevención e investigación de su utilización o consumo, así como para el apoyo de las personas propensas a su consumo, establece también que las dependencias del sector privado y público, dentro de su marco legal respectivo, podrán contribuir con sus recursos económicos, en la medida de sus posibilidades y sin perjuicio del cumplimiento de sus propios objetivos a las organizaciones sociales que brinden apoyo a las personas que se encuentran dentro de las redes del consumo de drogas que producen dependencia"

4º —Que se hace necesario y oportuno dictar la normativa atinente al funcionamiento de los programas de atención a las personas con problemas de dependencia al tabaco o sus derivados.

5º —El Instituto sobre Alcoholismo y Farmacodependencia (IAFA) velará por la correcta aplicación de la presente Normativa.

**Disposiciones Generales**

**1**. **Objeto y Ámbito de aplicación**: La presente normativa tiene por objeto regular la prestación de los servicios de atención en los programas de cesación de fumado, de las personas dependientes de los productos de tabaco y sus derivados, en congruencia con el respeto por los derechos universales. Es de acatamiento obligatorio para el funcionamiento de todos los programas públicos y privados, en el territorio nacional.

**2. Definiciones:** Para efectos de esta normativa, se establecen las siguientes definiciones:

**Accesibilidad:** Atención al alcance de todas aquellas personas que requieran tratamiento, de manera oportuna y durante el tiempo necesario para su recuperación.

**Acceso a recurso humano**: Tener disponibilidad del recurso humano, para la ejecución de las actividades, puede ser contratado (de planta), por servicios profesionales, por convenio entre instituciones u organizaciones y voluntariado, los cuales deben cumplir con las funciones establecidas, en congruencia con el programa.

**Aprobación del programa**: Procedimiento, mediante el cual el IAFA, evalúa la congruencia entre el programa escrito y su ejecución, por lo que certifica el cumplimiento de los lineamientos para el funcionamiento de los programas, que se establecen en la presente normativa.

**Aval de la propuesta metodológica:** Procedimiento, mediante el cual, el IAFA, brinda el visto bueno, al programa escrito, a fin de que se inicien los trámites, para la apertura o renovación de permisos ante las Instituciones correspondientes. (Municipalidad y Ministerio de Salud).

**Certificar:** Procedimiento mediante el cual el IAFA, emite resolución del programa con el estatus de aprobado, al cumplir con los lineamientos establecidos en esta normativa.

**Dependencia física:** estado de neuroadaptación producido por la administración repetida de una sustancia, que determina la necesidad de continuar con su consumo, para evitar el síndrome originado por su privación, conocida como síndrome de supresión.

**Desempeño Ocupacional:** se entiende como el desempeño o realización de actividades de auto cuidado y auto mantenimiento, productivas, educativas, lúdicas y de ocio, permiten a un sujeto participar como un miembro que contribuye a su entorno personal, social, cultural y económico

**Derechos universales:** derechos y libertades reconocidos de forma universal, que incluyen a toda persona, por el simple hecho de su condición humana, para la garantía de una vida digna.

**Enfermedad:** se fundamenta en las alteraciones neurofisiológicas, estructurales y funcionales, que provocan la continua búsqueda de la drogas. Las modificaciones o ajustes neuroadaptativos producidos por la nicotina, son permanentes y constituyen la base neurobiológica de la dependencia al tabaco.

**Evaluación diagnóstica:** referida a la definición del proceso salud-enfermedad. La evaluación orienta la decisión en cuanto al tratamiento, de acuerdo a tres posibilidades:
a. Tratamiento intensivo inmediato. Cuando se detecta la existencia de peligro inminente para la vida de la persona.
b. Tratamiento ambulatorio cuando hay peligro potencial pero no inminente.
c. Orientación y motivación al cambio.

**Equidad:** otorgar a las personas igualdad de oportunidades para alcanzar el máximo potencial individual y colectivo.

**Fumar:** acto de inhalar y exhalar humo de un producto de tabaco e incluye el hecho de estar en posesión o control de un producto de tabaco en combustión que genere emisiones.

**Fumador:** un fumador (activo), es la persona que ha consumido diariamente durante el último mes cualquier cantidad de cigarrillos, incluso uno.

**Intervenciones farmacológicas**. La utilización de fármacos específicamente diseñados y registrados para el tratamiento de la cesación de tabaco, los padecimientos comórbidos como consecuencia del consumo de tabaco y para la prevención de la recaída.

**Intervención terapéutica.** Conjunto de acciones por parte del equipo de atención, orientadas a fomentar en las personas afectadas por el tabaquismo, la motivación a emprender y mantenerse en un programa de tratamiento. Puede incluir no solo al consumidor sino también a miembros de la familia, vinculados con dicho padecimiento.

**Manejo de medicamentos**: Procedimientos que optimizan la forma en que los medicamentos son utilizados por los usuarios y servicios de salud. Abarca todos los aspectos desde la prescripción hasta la forma en que los medicamentos son aplicados o tomados por las personas.

**Manejo del Síndrome de Abstinencia**. Conjunto de medidas terapéuticas destinadas a corregir o compensar las alteraciones del funcionamiento normal y el malestar del sujeto, que aparecen como consecuencia de la reciente reducción significativa o de la supresión absoluta del consumo de tabaco, cuyo uso viene siendo generalmente intenso y en grandes dosis.

**Lineamientos de aprobación y seguimiento de programas**: Condiciones requeridas para el funcionamiento de los programas de cesación de fumado dirigido al tratamiento de las personas dependientes de tabaco y sus derivados.

**Patrón de Consumo.-** Características del consumo de tabaco, los años de fumar y cantidad de cigarrillos.

**Programa privado**: Creado, administrado y financiado total o parcialmente por personas físicas o jurídicas, con o sin fines de lucro.

**Programa público**: Creado, administrado y financiado total o parcialmente por el Estado, sin fines de lucro.

**Programa de tratamiento:** Conjunto de procesos, procedimientos y actividades destinados a brindar una evaluación, diagnóstico, tratamiento, seguimiento, prevención de la recaída y atención de problemas físicos y emocionales asociados.

**Plan de tratamiento:** Resume las metas u objetivos que se espera obtener con el mismo, constituye una guía o "mapa de ruta", elaborada por el equipo responsable del programa, adaptada a las necesidades del paciente.

**Recaída:** Restablecimiento del patrón de consumo previo, dada la naturaleza crónica y recurrente de la dependencia al tabaco.

**Síndrome de privación:** si a las 24 horas de haber dejado de fumar una persona presenta 4 de los siguientes síntomas de abstinencia, los cuales le ocasionan molestias o alteraciones. Clínicamente significativas en las áreas emocional, física, familiar, social y laboral.

**Tabaquismo o dependencia a la nicotina**: Es una enfermedad crónica y recurrente, de base biológica y psicológica; es un desorden cerebral que no difiere de otras enfermedades. De las múltiples sustancias que contiene el tabaco, la nicotina es el determinante más importante para el consumo y la dependencia física. Su abstinencia produce diversos síntomas conocidos como síndrome de privación.

**Tratamiento:** Una o más intervenciones estructuradas, para tratar los problemas de salud y de otra índole causados por el abuso de drogas y aumentar u optimizar el desempeño personal y social. Según el comité de expertos de la OMS en Farmacodependencia, el término "tratamiento" se aplica al proceso que comienza cuando las personas con problemas de consumo de sustancias psicoactivas, entran en contacto con un proveedor de servicios de salud o de otro servicio comunitario y puede continuar a través de una sucesión de intervenciones concretas hasta que se alcanza el nivel de salud y bienestar más alto posible.

**Lineamientos**

Se establecen las condiciones requeridas para el funcionamiento de los programas de tratamiento para las personas con dependencia al tabaco.

**A. Acceso, Disponibilidad y Admisión**

A.1. Los servicios deben ser accesibles por medios ordinarios de transporte público, tanto para el paciente, como para el personal que labora en el programa.

A.2. Cada proveedor de servicios debe contar con un horario visible de atención al público, congruente con el tipo de servicios que ofrece.

A.3. La admisión al programa debe contar con valoración médica hecha por profesional autorizado e incorporado al respectivo Colegio Profesional. Esta valoración, debe garantizar que los servicios ofrecidos corresponden a las prioridades de atención de la persona, vinculados directamente con el tabaquismo.

A.4. Previamente a la admisión en el programa, se debe proveer al paciente y su familia, información exhaustiva y asequible sobre los servicios ofrecidos, nombre del personal responsable, tipo de tratamiento, su proceso y duración. Tal información debe ser provista por personal calificado y dejar documentada en el expediente.

A.5. Para la admisión al programa no podrá existir discriminación alguna a nivel general:

a) de tipo racial, étnico, cultural, ideológico, político, religioso o filosófico;

b) relativas a padecimientos físicos o psiquiátricos que afecten o hayan afectado a la persona dependiente de tabaco,

c) relativas a su condición socioeconómica,

d) relativas a los antecedentes de tratamiento

e) relativas a su condición legal o antecedentes penales

**B. Evaluación**

B.1. El programa debe garantizar la evaluación inicial integral de la personas, que permita detectar los trastornos físicos, emocionales, situación social y desempeño laboral, para establecer las prioridades de intervención en un plan de tratamiento.

B.2. El programa debe efectuar la evaluación diagnóstica integral, de cada persona, en todas las áreas eventualmente afectadas por el tabaquismo, que incluya la historia de consumo, junto con los antecedentes comórbidos físicos y mentales, así como examen físico completo. Tal evaluación debe ser hecha por personal calificado, según el área de competencia

**C. Contenido, Prestación y Organización del Servicio**

C.1. Toda persona, debe contar con un plan de tratamiento. El mismo debe diseñarse por profesionales calificados, y adaptarse a las necesidades y demandas del paciente, debe tomar en cuenta:

a) el patrón de consumo de tabaco,

b) la severidad de la dependencia,

d) la condición física y psiquiátrica,

e) la condición psicológica,

f) la situación social y familiar.

g) las áreas ocupacionales y funcionales afectadas

C.2. La evolución y seguimiento del paciente, debe estar acompañada por el equipo técnico, en función del plan de tratamiento. Cualquier modificación al plan individual debe realizarse de común acuerdo con el paciente y siempre debe buscar la superación del tabaquismo.

C.3. El programa debe garantizar, que las personas responsables de la atención se capaciten, al menos una vez al año.

C.4. El programa, debe incluir la atención a los familiares afectados indirectamente por el tabaquismo en el paciente.

C.5. El programa debe garantizar los medios necesarios para proveer una atención inmediata y calificada a cualquier paciente que sufra de complicaciones asociadas a la condición por la cual está siendo atendido.

C.6. El programa debe garantizar la equidad de género.

C.7. El programa debe garantizar espacios para la exploración y desarrollo de habilidades para la vida, que promuevan el desarrollo integral, dentro de un ambiente controlado que se debe basar en el enfoque de derechos.

**D. Egreso, Referencia y Seguimiento**

D.1. El plan de tratamiento debe especificar los criterios para establecer si el paciente logra los objetivos propuestos, que deben ser congruentes con el tipo de programa que se desarrolla.

D.2. Cuando el equipo técnico detecte necesidades, que no pueden ser suplidas por el programa vigente, el paciente debe ser remitido al servicio que requiere según su necesidad. Toda referencia a otro servicio o programa debe constar en el expediente.

D.3. Se debe implementar una estrategia de seguimiento, orientada a la prolongación del estado de abstinencia del consumo de tabaco, mediante la prevención de recaídas.

**E. Expediente**

E. 1. Debe existir un expediente para cada paciente. Deben incluirse todos los documentos que provean información pertinente sobre el tratamiento y su condición, así como el consentimiento informado. Se han de consignar los siguientes datos:

Datos generales, situación de salud, historia clínica, diagnósticos, tratamientos recibidos, examen físico, exámenes de laboratorio, entre otros

Situación específica relacionada con el motivo de ingreso al programa: Boletas de referencia, fecha de inicio, resultados de las valoraciones de los diversos miembros del equipo, historial de consumo de drogas que incluye el tabaco, enfermedades en general, manejo de medicamentos, diagnóstico inicial, instrumentos aplicados, resultados de estudios específicos de laboratorio y especialidades médicas.

Tratamiento: Planes de tratamiento individual, registro periódico y actualizado del proceso de tratamiento de la persona, duración o extensión del tratamiento, fecha y motivos de finalización, referencias a otros servicios. Plan de seguimiento y su evolución.

E.2. El programa, debe garantizar a la persona, el acceso a la información contenida en el expediente, cuando así lo requiera. La misma debe ser dada acorde a las condiciones de salud en que estas personas se encuentran, y estar debidamente reglamentado.

**F. Derechos de las Personas**

F.1. Todo programa y las acciones que de él se deriven deben estar enmarcadas en un enfoque de derechos. Regirán a este fin la Declaración Universal de los Derechos Humanos y todo tratado o convenio que, en esta materia, haya sido reconocido por el país.

F.2. Todo programa debe garantizar el cumplimiento de los derechos de las personas, descritos en los artículos 2 y 3 de la Ley No. 8239 y de cualquier otra que la sustituya o modifique.

F.3. Los pacientes, deben estar informados de la naturaleza y características del tratamiento, así como de los riesgos que entraña y los beneficios que pueden esperar del mismo. La información que se les facilite debe ser comprensible, exhaustiva y, en presencia de trastornos médicos, acorde a las condiciones de salud en que se encuentren.

F.4. Se prohíbe someter a pacientes, a cualquier tipo de amenaza, coerción o enajenación, ya sea de carácter físico, químico o psicológico, con el fin de modificar su conducta, o retener a una persona en un programa, cuando su vida no corra peligro.

F.5. Todo programa debe garantizar la confidencialidad respecto a la enfermedad adictiva del paciente. Se prohíbe el uso de simbología, signos externos o atuendos que revelen el padecimiento de la persona. Así, como cualquier actividad vinculada con ventas y recolectas de dinero, en las que se exponga la integridad física de la persona.

F.6. Se prohíbe toda actividad o procedimiento que sea violatorio de la vida íntima o espacios privados del paciente.

F.7. Se prohíbe cualquier tipo de prestación laboral directa o indirecta por parte del paciente, que exija subordinación, si no esta regulada formalmente como lo establece la Ley vigente en esta materia.

F.8. Los usuarios del programa, tienen derecho a plantear ante autoridad competente su inconformidad por los servicios recibidos.

F.9. El programa debe contar con un reglamento interno que regule las relaciones entre pacientes, el personal responsable de la atención, los familiares y allegados, que satisfaga los derechos consagrados en la legislación vigente, relativa a los derechos de las personas.

**G. Recursos Humanos y Financieros**

G.1. El programa debe garantizar la presencia, de personal calificado para ejercer la Dirección Técnica, durante el horario de funcionamiento, donde se ofrece la atención.

G.2. El programa debe tener acceso de personal calificado, para la intervención terapéutica de las personas dependiente de tabaco.

G.3. El programa debe garantizar el personal necesario, en programa de atención a las personas con problemas de dependencia al tabaco o sus derivados, tal como profesionales en medicina, psicología, enfermería, terapia física, terapia respiratoria, terapistas cardiacos, trabajo social, nutrición, consejeros certificados en la materia.

G.4. El programa debe garantizar, que el personal profesional se encuentra debidamente autorizado por el colegio profesional respectivo, para el ejercicio legal de su actividad profesional en el país.

G.5. El programa debe garantizar que el personal no profesional, se encuentra debidamente certificado en el país, para el ejercicio legal de su actividad, por la instancia técnica formalmente establecida en la materia.

G.6. El programa debe contar con un manual de lineamientos, procedimientos técnicos y administrativos, que no sea violatorios de derechos.

G.7. El programa debe especificar los mecanismos de supervisión y evaluación del personal para asegurar la adecuada prestación de los servicios.

G.8. Se debe hacer una evaluación periódica de los resultados del programa, para determinar la eficiencia y eficacia del mismo (evaluación del programa).

G.9. El personal que brinda la atención directa a la población debe conocer todos los aspectos del programa: metodología, metas, objetivos, indicadores, actividades y aspectos administrativos del mismo.

G.10. El programa debe considerar, en la selección del personal, las características de género de la población atendida hacia la que se dirigen los servicios.

G.11. Se debe contar con planes, que garanticen la sostenibilidad financiera del programa.

**H. Manejo de Medicamentos**

H.1. El programa debe contar con un plan de manejo de medicamentos, cuando se prescriben los mismos.

H.2. El plan de manejo de medicamentos debe ser supervisado por personal de salud capacitado en esta materia.

H.3. Toda persona que ingrese al programa con una prescripción médica o con un esquema de tratamiento, debe tener continuidad en su terapéutica, sólo puede ser interrumpida por recomendación médica con previa valoración.

H.4 Queda prohibido suspender algún medicamento prescrito médicamente, sin la valoración previa y autorización del profesional en medicina, que forme parte del equipo del programa; dicha suspensión debe quedar por escrito en el expediente.

**Aplicación de los lineamientos**

1.

**Calificación del funcionamiento del programa.** Para determinar el nivel de cumplimiento de los lineamientos expuestos en el presente documento y sus apéndices y complementos, se utilizarán los criterios que se resumen en el siguiente cuadro:

| **Estatus** | **Calificación** | **Puntaje mínimo** | **Puntaje máximo** |
|---|---|---|---|
| Aprobado | Excelente | 91% | 100% |
| | Bueno | 81% | 90% |
| Reprobado | Deficiente | 70% | 80% |
| | No apto | 0% | 69% |

Se utilizarán las siguientes categorías para calificar los programas, según el puntaje general y estatus logrado:

***1.1 Estatus APROBADO:*** *El funcionamiento del programa queda autorizado.*

***1.1.1 Calificación EXCELENTE:*** *El programa cumple con todas o casi todas los lineamientos y recomendaciones técnicas, anteriormente establecidas, para ofrecer una atención satisfactoria a la población usuaria. (Puntaje general de 91% a 100%)*

***1.1.2 Calificación BUENO:*** *El programa cumple, en un nivel mínimo, con los lineamientos y recomendaciones técnicas, anteriormente establecidas, para ofrecer una atención aceptable a la población usuaria. (Puntaje general de 81% a 90%)*

***1.2 Estatus REPROBADO:*** *El funcionamiento del programa queda desautorizado, porque las condiciones y desempeño del mismo no garantizan una atención de mínima calidad, a la población usuaria.*

***1.2.1 Calificación DEFICIENTE:*** *El programa incumple con una cantidad tal de los lineamientos o recomendaciones técnicas anteriormente establecidas, que no se puede garantizar una atención de mínima calidad a la población usuaria. Sin embargo, es susceptible de mejoras para obtener el estatus de APROBADO. De no cumplir con las mejoras requeridas en el plazo de uno a tres meses, se reprueba el programa para su funcionamiento. (Puntaje general de 70% a 80%).*

***1.2.2 Calificación NO APTO:*** *El programa incumple una cantidad tal de los lineamientos o recomendaciones técnicas anteriormente establecidas, que se desaconseja el funcionamiento del programa; por el riesgo que implica para la seguridad y atención de las personas usuarias del servicio. Sin embargo, es susceptible de mejoras para obtener el estatus de APROBADO. De no cumplir, con las mejoras requeridas, en un plazo de treinta días hábiles, se reprueba el programa para su funcionamiento. (Puntaje general inferior al 70%).*

**2. Metodología de cálculo.**

Para obtener el puntaje general correspondiente al programa, se aplicará el cuestionario de evaluación, que es parte de esta normativa, en lo sucesivo llamado Instrumento.

Cada ítem del Instrumento descrito en el apéndice N° 4, debe valorarse según los siguientes criterios:

a) Valor 1**:** El programa cumple de forma satisfactoria el ítem.

b) Valor 0**:** El programa no cumple el ítem.

c) NA: Significa “no aplica” y se asignará si el ítem evaluado no corresponde al tipo de programa.

A cada sección del Instrumento, que corresponde a un párrafo del apartado de lineamientos, se le asignará un puntaje parcial que se obtendrá de la siguiente manera:

Si aplican todos los ítemes: Se sumarán los valores de los ítemes de la sección y se dividirá entre el total de estos.

Si no aplican todos los ítemes: Se sumarán los valores de los ítemes que sí aplican al programa y se dividirá entre la totalidad de éstos.

Para obtener el puntaje general del programa que permite establecer su calificación, se han de promediar los puntajes de todas las secciones del Instrumento. Todas las secciones tendrán igual ponderación.

**Interpretación de resultados.**

3.1 Los programas que reciban una calificación de NO APTO, incumplen los lineamientos oficiales para brindar sus servicios, por lo que deben presentar en diez días hábiles, un plan intensivo de mejoras de cada ítem reprobado, factible de cumplir en treinta días hábiles, para optar por la APROBACION, de no lograrlo, se les asignará el estatus de REPROBADO, con calificación de NO APTO para funcionar.

3.2 En caso que la calificación asignada a un programa sea de DEFICIENTE, se concederá un plazo de uno a tres meses, según la cantidad de ítemes incumplidos, para proceder a su corrección. Si al cabo del plazo concedido no ha superado la calificación, se puede conceder por única vez una prórroga por la mitad del plazo anterior, a fin de que alcance la calificación que permita otorgarle el estatus de APROBADO. Una vez agotada la prórroga anterior, de no

alcanzar el puntaje para lograr el estatus de APROBADO, el programa será considerado como NO APTO para funcionar.

3.3 Cuando la puntuación asignada al programa evaluado corresponda a las calificaciones de BUENO o EXCELENTE, se le otorgará el estatus de APROBADO, pudiendo ajustar los ítemes pendientes en el plazo que le señale el IAFA.

DISPOSICIONES FINALES

1. La aprobación de los programas, que prestan servicios a las personas con problemas de dependencia al tabaco o sus derivados, se otorgará por un período máximo de dos años, al determinar la congruencia entre la propuesta metodológica del programa (escrita), previamente avalada por el IAFA y el funcionamiento técnico o ejecución del programa.

2. Los programas deberán ser renovados, previa solicitud y presentación de la propuesta metodológica, al menos con tres meses de anticipación a su vencimiento. Su renovación estará condicionada al cumplimiento de los requisitos vigentes en esta materia.

3. Todos los programas estarán sujetos a la supervisión y seguimiento periódico por el IAFA, mediante las visitas que estime oportunas. Al constatar cambios en el programa que impliquen una variación negativa en la calificación asignada, se procederá a una nueva aplicación de la normativa para recalificarlo, aunque no hayan transcurrido los dos años de plazo.

4. Todos los programas que cuenten con el estatus de APROBADOS, pueden realizar seminarios, talleres y actividades de capacitación a la población general, previa aprobación del programa por parte del IAFA, para garantizar la idoneidad de esas actividades, en la materia que le compete a esta Institución.

5. .El IAFA debe gestionar la suspensión o cierre de los programas si incumplen la normativa estipulada al efecto, o cuando razones de interés sanitario o social así lo aconsejen, previa coordinación con el Ministerio de Salud y otros entes vinculados con la población.

**APENDICE**

Los documentos contenidos en este apéndice, son parte integrante de la presente normativa y se enumeran a continuación:

1.
Procedimiento para solicitar la aprobación de un programa

Guía para la elaboración de la propuesta metodológica del programa

Matriz de planificación

Instrumento de evaluación del programa

Unofficial Translation

## APPENDIX N° 1.

## PROCEDURE FOR PROGRAM APPROVAL

Para cumplir la aprobación de un programa de atención a las personas con problemas de dependencia al tabaco o sus derivados, se debe cumplir el siguiente trámite:

1.
Presentar carta de solicitud, dirigida a la dependencia encargada de la Aprobación de Programas Públicos y Privados, en el Instituto sobre Alcoholismo y Farmacodependencia, con la propuesta metodológica del programa. Consultar apéndice N° 2, con formato para la presentación del documento.

2.
La dependencia responsable de la Aprobación de Programas, realiza la revisión de la propuesta metodológica, tomando en cuenta los lineamientos generales de la presente normativa, así como aspectos técnicos que se relacionan con el tabaquismo. En el plazo de treinta días emite el informe técnico respectivo.

3.
Si la propuesta metodológica del programa, cumple con los lineamientos requeridos, se emite resolución con el aval o visto bueno, del programa escrito.

3.1
Cuando se trata de un programa que se presenta por primera vez al IAFA, el aval referido en el numeral tres, se realiza por un período máximo de seis meses, con el fin de que los responsables del programa realicen los trámites relacionados con permisos de funcionamiento ante el Ministerio de Salud y Municipalidades, y cuando corresponde, para realizar gestiones en la consecución de recursos para la ejecución del programa.

4.
Una vez que el programa cuenta con el permiso de funcionamiento del Ministerio de Salud, en el plazo de dos meses, posterior al otorgamiento del mismo, el IAFA, verifica la coherencia de la propuesta escrita y la ejecución del programa, mediante la evaluación del cumplimiento de los lineamientos expuestos en el presente reglamento. Se emite la resolución que certifica al programa con el estatus de Aprobado o Reprobado.

5.
Cuando se trata de un programa que se presenta para renovación, el aval referido en el numeral tres, se realiza por un período máximo de dos años. Y en el plazo máximo de un mes posterior al otorgamiento del mismo, el IAFA, verifica la coherencia de la propuesta escrita y la ejecución del programa, mediante la evaluación del cumplimiento de los lineamientos expuestos en el presente reglamento. Se emite la resolución que certifica al programa con el estatus de Aprobado o Reprobado.

6.
Cuando la propuesta metodológica del programa, (nuevo o en renovación) no cumple con los lineamientos requeridos, mediante informe técnico se señalarán las correcciones pertinentes para que el plazo de treinta días hábiles, los responsables del programa, replanteen la propuesta y se presente al IAFA, para continuar con la revisión. De no presentarse la misma en el periodo establecido, se procederá a archivar el expediente, por lo que se deberá iniciar el proceso.

**APPENDIX N° 2.**
**GUIDE FOR DRAFTING METHODOLOGICAL PROPOSAL FOR PROGRAM**

## PRESENTACIÓN

La guía que se presenta, proporciona pautas básicas que puedan orientar en la elaboración de un programa de atención para las personas con problemas de dependencia al tabaco o sus derivados, teniendo en cuenta, que este esquema debe utilizarse adaptándolo a las exigencias según la modalidad de intervención.

La propuesta, constituye una herramienta para la planificación del trabajo durante un periodo determinado. En el documento, se debe reflejar la transparencia del programa que se plantea, además de ser claro y flexible.

## ESTRUCTURA Y CONTENIDO

En este apartado, se orienta como deberá elaborarse la propuesta metodológica del programa, para la revisión y aval por parte del IAFA. Se recomienda tomar en cuenta, los protocolos que se enumeran a continuación y todos los que establezca el IAFA en esta materia:

-
Instituto sobre Alcoholismo y Farmacodependencia: “Guía de Intervención para el Tratamiento de la Dependencia al Tabaco”. San José, 2011.

-
Instituto sobre Alcoholismo y Farmacodependencia. Estrategia para dejar de fumar. San José, 2012

-
Instituto sobre Alcoholismo y Farmacodependencia: “Síndromes de Intoxicación y Abstinencia a drogas psicoactivas: recomendaciones para su manejo”. San José, 2000

**I.**
**Identificación:**

El documento de la propuesta del programa de tratamiento incluye un apartado donde figuran los datos principales del mismo.

**Datos generales**

Nombre de la Organización (cuando corresponde):_____

Nombre del programa: _____

Presidente (a) de la organización o representante legal, cuando corresponde: ----------

Director(a) del programa: ----------

Dirección: (Especificar para notificaciones).

Medios de contacto: Teléfono Fax correo-e

Personería jurídica vigente: _____

Miembros de la Junta Directiva y Fiscalía, cuando corresponda:

Nombre Cédula Puesto que ocupa Teléfono

**II.**
**Justificación:**

Se deben describir las principales razones que motivaron a plantear el desarrollo del programa para atender las necesidades de la población dependiente de tabaco. Se debe responder a la pregunta ¿por qué?

a. Explicar la prioridad y urgencia del problema para el que se busca solución.
b. Justificar por qué el servicio que se plantea es la propuesta de solución viable para resolver ese problema.

**III. Marco Conceptual y filosófico**

En el proceso de planificación de un programa, las diversas teorías y modelos descriptivo-explicativos, con evidencia científica, son el soporte de la propuesta. Se debe tomar una posición teórica y conceptual, para poder construir con una base sólida de conocimiento el programa.

**IV. Antecedentes:**

.

**de la organización** ( cuando corresponde)

Se deben indicar las acciones que se hayan ejecutado para contribuir a la superación de las necesidades de un determinado grupo o sector de población. Describir brevemente si se han desarrollado trabajos similares o que complementan el programa que proponen y resultados de los mismos.

**de la problemática.**

Se debe explicar la elección de los problemas a resolver, hacer referencia a la información recolectada durante un tiempo determinado, previo a la elaboración de la propuesta. Tomar en cuenta las situaciones del entorno o cambios en éste, que haya afectado a la población que se pretende beneficiar.

Documentar las características principales de la población a la cual se dirigirán el programa. Incorporar datos de las investigaciones recientes, tanto locales como nacionales y otros ámbitos si es del caso, respecto de la problemática del consumo de tabaco; las cuales pueden ser consultadas en el IAFA, otros centros de salud y fuentes bibliográficas.

Incluir la descripción de los recursos existentes en la comunidad, según sea el caso, con los cuales podrá contar como red de apoyo en la ejecución del programa: profesionales, centros de tratamiento, clínicas y demás dispositivos sanitarios.

**V. Cobertura geográfica de atención**

**a) Localización física**

Consiste en determinar el área geográfica, en dónde se proyecta realizar el programa. Indicar la ubicación de las instalaciones, tomando en cuenta la distribución geográfica, por provincia, cantón, distrito y barrio. Se debe responder a la pregunta ¿Dónde se quiere hacer?

**b) Población beneficiaria**

Se responde a la pregunta ¿A quiénes va dirigido el programa de atención?. Indicar si el servicio tomará en cuenta la demanda local, nacional o internacional.

Definir la población a atender por género, por edades y proyectar la capacidad a instalar.

**Objetivos**

**Objetivo general:**

Se refiere a una aspiración o propósito que se desea lograr en un plazo determinado, como respuesta o solución a los problemas, necesidades o carencias de la población.

Los objetivos o resultados, expresan un cambio concreto y medible de lo que se alcanzará en un tiempo con la población determinada.
El objetivo general es la forma mediante la cual el programa define que es lo que se pretende lograr. Estos deben ser flexibles, realistas y claros. Un objetivo general puede tener uno o más objetivos específicos.

El objetivo debe expresarse en verbo infinitivo (atender, capacitar, construir, entre otros), de manera precisa y concisa en términos de resultados medibles y alcanzables.

La estructura del objetivo puede conformarse a partir del siguiente orden de preguntas:

¿Qué?: ¿qué vamos hacer?, contempla la propuesta que se piensa implementar.

¿Cómo?: ¿cómo lo vamos a hacer?, será el modelo mediante el cual se pretende poner en funcionamiento el programa.

¿Para qué?: ¿para qué lo vamos a hacer?, constituye el fin por el cual se desarrolla el programa.

**b) Objetivos específicos:**

Deben guardar coherencia y vinculación con los objetivos generales del programa.
Están referidos a los logros del programa. Expresan los resultados que se esperan alcanzar con las personas beneficiarias. Por tanto, pueden ser estructurados según las diferentes fases o etapas que presenta el programa.

El objetivo específico, debe expresarse en verbo infinitivo. De los objetivos específicos se derivan las metas.

**c) Metas**

Las metas son la expresión de los fines en términos cuantitativos (números) y cualitativos (calidad) con las cuales se indicará el logro de los mismos, en tiempo cantidad y calidad. Las metas se vinculan con niveles de producción a alcanzar de cada objetivo, de que calidad es lo que queremos lograr, y en qué tiempo se van a conseguir los resultados esperados o el avance de la gestión.

Estas constituyen el punto final de referencia de lo que será el proceso de evaluación del programa, proyectando los logros o desaciertos.

Por lo que, deben plantearse de manera clara y realista en coherencia con los objetivos, los cuales pueden contener más de una meta. Las metas se concretan por medio de las actividades.

.

**Indicadores**

Los indicadores, se orientan a medir el grado de cumplimiento de las metas propuestas, en relación con las realizadas.

Su medición, se realiza generalmente, comparando el número total de los beneficios realizados o ejecutados, con el número de los programados; según como se haya formulado la meta.

.

**Actividades**

Son las acciones concretas que realiza el personal del programa para alcanzar los objetivos específicos. Implica la definición y ejecución de tareas y procedimientos.

## VII. Método y técnicas

Se trata de especificar el instrumental metodológico y técnico que se utilizará para realizar las diferentes actividades, la elección de métodos y técnicas, es el dar preferencia a aquellos que facilitan, promueven o posibilitan la participación de las

partes (personal y población beneficiaria) en el desarrollo del programa. Se contempla en este ítem, ¿cómo lo vamos a hacer?
Qué áreas y fases de intervención tiene el programa, independientemente del modelo de intervención. Describir las fases o etapas que conforman el programa, con el recorrido terapéutico, tiempos definidos por cada fase, así como los criterios establecidos para trascender cada una de las fases, según corresponda con el programa, en este apartado se debe retomar la fase de inserción, seguimiento y prevención de recaídas.

Lo que materializa la realización de un programa, es la ejecución secuencial e integrada de diversas actividades y tareas. Para ello debe explicarse la forma que suceden, complementan y coordinan las diferentes tareas, el modo de lograr el encadenamiento correcto de las mismas, evitando desajustes que influyan en la realización del mismo.

Entre ellas se citan, entrevistas individuales, terapias grupales, individuales, ocupacionales (laborales, recreativas y educativas), consejería, atención a la familia y otras que el programa establezca como reuniones de autoayuda y grupos de apoyo. Consultar apéndice N°3, con matriz de planificación.

Se recomienda crear una sección o apartado adjunto, en el que pueden incorporar todos los documentos aclaratorios, como instrumentos de trabajo, manuales de funciones y responsabilidades, perfiles profesionales, reglamentos y demás instrumentos relacionados con la propuesta.

**VIII. Recursos:**

En este apartado se requiere una descripción, lo más amplia posible, de los recursos con los que se cuenta y los que requiere conseguir, para ejecutar el programa y cumplir con sus fines. Se debe garantizar la sostenibilidad del programa, e indicar el costo por persona, cuando corresponde.
.

**Recursos Humanos**

**Para determinar el recurso humano se responde a la pregunta ¿quiénes lo van a hacer?.**

Para ejecutar el programa, hay que disponer del personal necesario, y calificado para realizar las diversas tareas con las personas usuarias del servicio, entre el que se enumera a profesionales en medicina, psicología, enfermería, terapia física, terapia respiratoria, terapistas cardiacos trabajo social, nutrición, consejeros certificados en la materia.

Especificar las características de las personas que participarán en la ejecución del programa, (personal administrativo, técnico, profesional, voluntariado).

Deben indicar calidades de este personal, experiencia laboral, capacitación demostrable en la materia correspondiente y funciones que desempeñarán y otros datos que se consideren necesarios; así como el apoyo de recurso humano externo, si es el caso, para cumplir con las actividades y los objetivos propuestos.

**b) Recursos Materiales**

Los recursos materiales: son las herramientas, equipo tecnológico, instrumentos, infraestructura física, mobiliario, transporte, etc., necesarios para llevar a cabo el programa. Se responde a la pregunta ¿con qué se va a hacer?

**c) Recursos Financieros**

Se responde a la pregunta ¿con qué se va a costear?

Consiste en una estimación de los recursos económicos, indicar las fuentes reales de financiamiento para la ejecución del programa. Entre ello se contemplan, aportes del

estado, de empresas privadas, de la familia, de la población beneficiaria cuando corresponde, y recursos propios.
Se recomienda establecer un calendario financiero, en el que se debe indicar cada actividad en la ejecución del programa y cuáles son los recursos financieros necesarios para llevarla a cabo.

Hay que precisar también, la forma en que se irán obteniendo los recursos, asegurando el ritmo de operación del programa, de modo que haya una permanente revisión y nivelación entre gastos e ingresos.

**IX Evaluación :**

La Organización debe evaluar el programa, al menos una vez al año. Se trata del proceso que permite medir, los resultados obtenidos en el desarrollo del mismo. Esta ha de ser integral, puesto que debe abarcar todos los aspectos de la propuesta programática.

Los resultados deben describirse lo más concretamente posible y en términos verificables. Son los productos tangibles que el programa debe producir.

Se debe responder a la pregunta ¿qué vamos a lograr?

Los resultados permitirán, cuando corresponde, desde la parte directiva y técnico-administrativa, tomar las medidas correctivas si fuera del caso, o bien reafirmar la propuesta metodológica.

## APPENDIX N° 3.

## PLANNING MATRIX

| **GENERAL OBJECTIVE(S)** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Objetivos Específicos | Metas | Indicador | Actividades | Técnicas a utilizar en cada actividad | Tiempo estimado para el desarrollo de la actividad | Recurso Humano responsable | Recursos materiales necesarios para la ejecución de la actividad | Coste estima de cad activid |
| 1. | | | | | | | | |
| 2. | | | | | | | | |
| 3. | | | | | | | | |
| 4. | | | | | | | | |

## APPENDIX N°4

## PROGRAM EVALUATION INSTRUMENT

## GENERAL DATA

Nombre del programa:

Responsable legal:

Cantidad de pacientes activos: Hombres Mujeres

Ubicación geográfica: Provincia Cantón Distrito

Dirección:

Medios de contacto Teléfono Fax Correo –electrónico:

**ESCALA DE VALORES:**

**Valor 1:** El programa cumple de forma satisfactoria el ítem.

**Valor 0:** El programa no cumple el ítem.

**NA:** No aplica, y se asignará si el ítem evaluado, no corresponde con el programa.

| A. ACCESO, DISPONIBILIDAD Y ADMISIÓN Lineamiento | No. Ítem | Ítem | Valor | Fuente de verificación | Observaciones |
|---|---|---|---|---|---|
| **A.1** | **1** | | Acceso a las instalaciones del programa | Entrevista a usuarios y Equipo | |
| **A.2** | **2** | | Horario al público cumple con requerimientos | Entrevista a usuarios Verificar documentos | |
| **A.3** | **3** | | Existencia de valoración médica previa indicando prioridades de atención | Verificar documentos Entrevista a usuarios Entrevista a equipo | |
| **A.4** | **4** | | Se brinda información al paciente y allegados sobre el programa; por profesionales calificados. | Verificar documentos y entrevista a usuarios | |
| **A.5** | **5** | | Admisión sin restricciones o razones discriminatorias | Verificar documentos Entrevista a usuarios | |
| **Total de puntos** | | | | | |
| **Ítemes que aplican** | | | | | **5** |
| **Puntaje parcial** | | | | | |

| B. EVALUACIÓN DEL PACIENTE Lineamiento | No. Ítem | Ítem | Valor | Fuente de verificación | Observaciones |
|---|---|---|---|---|---|
| B.1 | 6 | | Realización de evaluación inicial integral para detectar trastornos físicos, neurológicos, psiquiátricos, situación social y desempeño ocupacional. | Verificar documentos Entrevista Equipo técnico | |
| B.2 | 7 | | Realización de evaluación diagnóstica integral, en todas las áreas eventualmente afectadas, por personal calificado. | Verificar documentos Entrevista Equipo técnico | |
| **Total de puntos** | | | | | |
| **Ítemes que aplican** | | | | **2** | |
| **Puntaje parcial** | | | | | |

| C. CONTENIDO, PRESTACIÓN Y ORGANIZACIÓN DE LA ATENCIÓN lineamiento | No. Ítem | Ítem | Valor | Fuente de verificación | Observaciones |
|---|---|---|---|---|---|
| C.1 | 8 | | Realización de plan individual de tratamiento, por profesionales calificados. | Verificar documentos Entrevista a usuarios y equipo técnico. | |
| C.2 | 9 | | Monitoreo periódico de la evolución del paciente,acompañada por el equipo técnico, de acuerdo al programa y su duración. | Verificar documentos Entrevista a usuarios y equipo técnico. | |
| C.3 | 10 | | Conocimiento del programa y su aplicación por parte del personal del equipo técnico. | Verificar actividades Entrevista a usuarios Entrevista a equipo técnico | |
| C.4 | 11 | | Disponibilidad de atención para familiares afectados. | Verificar documentos Entrevista a equipo técnico y usuarios | |
| C.5 | 12 | | Disponibilidad de medios, para proveer la atención inmediata de complicaciones asociadas al padecimiento. | Verificar documentos Entrevista a usuarios y equipo técnico | |
| C.6 | 13 | | Diseño y ejecución del programa considera la equidad de género. | Verificar documentos | |
| C.7 | 14 | | Diseño y ejecución del programa, consideran espacios para la exploración y desarrollo de habilidades, con enfoque de derechos. | Verificar documentos Verificar actividades Entrevista a equipo técnico | |
| **Total de puntos** | | | | | |
| **Ítemes que aplican** | | | | **7** | |
| **Puntaje parcial** | | | | | |

| D. EGRESO, REFERENCIA Y SEGUIMIENTO Lineamiento | No. Ítem | Ítem | Valor | Fuente de verificación | Observaciones |
|---|---|---|---|---|---|
| D.1 | 15 | | Especificación de criterios de | Verificar documentos y Entrevista a equipo | |

| | | | |
|---|---|---|---|
| | | cumplimiento de los objetivos terapéuticos, en plan de tratamiento. | técnico |
| **D.2** | **16** | Referencia de la población al servicio requerido, segúnnecesidades, no suplidas por el programa. | Verificar documentos Entrevista equipo técnico |
| **D.3** | **17** | Implementación de la fase de seguimiento y prevención de recaída. | Verificar documentos Entrevista a equipo técnico. |
| **Total de puntos** | | | |
| **Ítemes que aplican** | | | **3** |
| **Puntaje parcial** | | | |

| **E. EXPEDIENTE Lineamiento** | **No. Ítem** | **Ítem** | **Valor** | **Fuente de verificación** |
|---|---|---|---|---|
| **E.1** | **18** | | Existencia de expediente, con la información requerida | Verif docu Equip |
| **E.2** | **19** | | Acceso del paciente, a la información contenida en el expediente | Verif Entre |
| **Total de puntos** | | | | |
| **Ítemes que aplican** | | | | |
| **Puntaje parcial** | | | | |

| F. DERECHOS DEL USUARIO Lineamiento | No. Ítem | Ítem | Valor | Fuente de verificación | Observaciones |
|---|---|---|---|---|---|
| **F.1** | | **20** | Programa y todas sus acciones, enmarcado dentro de un enfoque de Derechos Humanos. | Verificar documentos | |
| **F.2** | | **21** | Cumplimiento de derechos del paciente consagrados en Ley 8239 | Verificar documentos | |
| **F.3** | | **22** | Información al paciente de los responsables del tratamiento, naturaleza y características del mismo. | Verificar documentos y entrevista a usuarios Entrevista a personal técnico | |
| **F.4** | | **23** | Ausencia de coacción para modificar conductas o retener al paciente, cuando su vida no corra peligro. | Verificar documentos Entrevista a usuarios Entrevista a equipo técnico | |
| **F.5** | | **24** | Confidencialidad relativa a la condición de enfermedad adictiva del paciente. | Verificar documentos Verificar actividades | |
| **F.6** | | **25** | Derecho a la vida privada del paciente. | Verificar documentos | |
| **F.7** | | **26** | Ausencia de prestaciones laborales, en cumplimiento con la ley vigente | Verificar documentos Verificar actividades | |
| **F.8** | | **27** | Derecho a plantear inconformidades sobre los servicios recibidos | Verificar documentos Entrevista a usuarios y equipo técnico | |
| **F.9** | | **28** | Vigencia de reglamento que regula las relaciones de convivencia | Verificar documentos Entrevista a usuarios y equipo técnico | |
| **Total de puntos** | | | | | |
| **Ítemes que aplican** | | | | | **9** |
| **Puntaje parcial** | | | | | |

| G. RECURSOS HUMANOS Y FINANCIEROS Lineamiento | No. Ítem | Ítem | Valor | Fuente de verificación | Observaciones |
|---|---|---|---|---|---|
| **G.1** | **30** | | Presencia de personal calificado en la Dirección Técnica, congruente con horario de funcionamiento del programa | Verificar documentos<br>Entrevista a usuarios<br>Entrevista a equipo técnico | |
| **G.2** | **31** | | Acceso de personal calificado para la intervención terapéutica de la población usuaria del programa. | Verificar documentos<br>Entrevista a usuarios<br>Entrevista a equipo técnico | |
| **G.3** | **32** | | Personal requerido, congruente con el tipo de programa. | Verificar documentos | |
| **G.4** | **33** | | Personal profesional está autorizado por colegios respectivos y cumple requisitos específicos | Verificar documentos | |
| **G.5** | **34** | | Personal no profesional, está certificado y cumple requisitos específicos | Verificar documentos | |
| **G.6** | **35** | | Manual de lineamientos y procedimientos técnicos y administrativos. | Verificar documentos | |
| **G.7** | **36** | | Mecanismos de supervisión y evaluación del programa | Verificar documentos | |
| **G.8** | **37** | | Evaluación periódica de resultados del programa | Verificar documentos | |
| **G.9** | **38** | | Conocimiento detallado del programa por parte del equipo | Entrevista equipo técnico | |
| **G.10** | **39** | | Selección del personal coherente con población atendida | Verificar documentos | |
| **G.11** | **40** | | Vigencia de planes de sostenibilidad financiera. | Verificar documentos | |
| **Total de puntos** | | | | | |
| **Ítemes que aplican** | | | | | **11** |
| **Puntaje parcial** | | | | | |

## ANNEX 3

## PROTOCOL:
## ADVERTISING AND PROMOTION BY DIRECT COMMUNICATION BETWEEN MANUFACTURERS AND VENDORS OR CONSUMERS OF TOBACCO PRODUCTS AND TOBACCO DERIVATIVES

**Justification**: This protocol is issued in accordance with what is established in l, Article 12 of the General Law for the Control of Tobacco and its Harmful Effects on Health.

**Purpose**: To regulate the reach of advertising and promotion of tobacco products and derivatives by direct communication of the tobacco industry with vendors and consumers.

**Definitions:**

a) **Direct communication**: Refers to any communication that takes place between the tobacco industry and vendors or adult consumers of de tobacco products and derivatives.

b) **Consumers**: Persons who consume tobacco products and derivatives .

c) **Tobacco industry:** Any natural or juridical person engaging in the manufacture, wholesale distribution and importation of tobacco products and derivatives.

d) **Promotion of tobacco**: any stimulation of the demand for tobacco products, which may include advertising and any act intended to attract the attention and provoke the interest of consumers and non-consumers of tobacco products or tobacco derivatives.

e) **Advertising and promotion of tobacco**: This is understood to refer to any kind of communication, recommendation or commercial action with the purpose, effect or possible effect of promoting, directly or indirectly, a tobacco product or the use of tobacco.

f) **Vendors of tobacco products:** Natural or juridical persons engaging in any commercial activity for the purpose of wholesale or retail sale of tobacco products and tobacco derivatives, as well as products related to their consumption.

**Provisions:**

In order for the tobacco industry to be able to communicate directly with vendors and consumers to undertake actual advertising or promotion of tobacco products and derivatives, it must be ascertained that such advertising is between adults and consumers of tobacco products and derivatives.

When communication is with vendors or consumers of tobacco products and derivatives, use may only be made of face to face service in people’s homes.

Unofficial Translation

# ANNEX 4

| [EMBLEM] | REPUBLIC OF COSTA RICA<br>MINISTRY OF HEALTH | Sequence No.: |
|---|---|---|

**SWORN STATEMENT OF INGREDIENTS AND EMISSIONS OF TOBACCO PRODUCTS AND TOBACCO DERIVATIVES**

**1. MANUFACTURING COMPANY OR IMPORTER**

| 1.1. Company title or full name | | 1.2. Juridical Card No. or ID Card No. |
|---|---|---|
| 1.3. Phone(s): | | 1.4. e-mail |
| 1.5. Means of delivering notifications | | 1.6. Signature(*) |

**2. LEGAL REPRESENTATIVE OF MANUFACTURING COMPANY OR IMPORTER**

| 3.1 [*sic*] Full name | | 3.2 ID Card No. |
|---|---|---|
| 3.3 Phone(s) | 3.4 Fax for notifications | 3.5 e-mail |
| 3.6 Exact address for notifications | | 3.7 Signature(*) |

**3. CIGARETTE DATA**

| 3.1 NAME OF PRODUCT AND BRAND | |
|---|---|
| 3.2 PRESENTATION OF PRODUCT | |

**4. LEVELS OF NICOTINE, TAR AND CARBON MONOXIDE**

| | | |
|---|---|---|
| NICOTINE | | |
| TAR | | |
| CARBON MONOXIDE | | |
| INGREDIENTS<br>(attach signed sheet) | | |

**5. METHOD(S) OF ANALYSIS USED**

**FOR EXCLUSIVE USE OF THE MINISTRY OF HEALTH**

**6. DATE OF RECEIPT:**

**7. NAME AND SIGNATURE OF OFFICIAL RECEIVING IT**

(*) This information has the character of a sworn statement, with knowledge of the sanctions with which the Penal Code punishes the crime of perjury. By signing this document, the legal representative swears an oath that everything declared herein and the documents attached are true, and furthermore signs this document aware of the meaning, scope and import of these statements.