# CODE OF ETHICS

## Medical Devices

2026

If you have any doubts or concerns about the application of this document, you can send them to: lineaeticadm@andi.com

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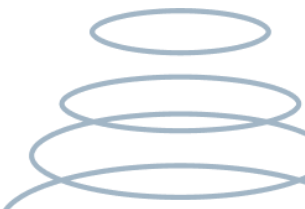
## 5.3. Procedures





# Preamble

The Chamber of Medical Devices and Health Supplies of the National Association of Businessmen of Colombia-ANDI-, calls for national and international companies, suppliers, manufacturers, distributors, and importers of Biomedical equipment, consumables, diagnostic reagents, software, among others, that serve to diagnose, prevent, monitor, treat, or relieve a disease.

The Chamber of Medical Devices and Health Supplies of the National Association of Businessmen of Colombia-ANDI-, aware of the impact generated by the relationships of the associated Companies with the agents of the Health System, Patients, health service providers and local and/or foreign government entities, ratifies its commitment to continue promoting good business and transparent ethical practices in the sector, better business environments for the Companies, better positioning, participation in international markets, and the safe and effective use of Medical Technology for the Patients 'benefit.

From the Chamber of Medical Devices and Health Supplies we promote a culture of business integrity in harmony with the advances of other local and international reference codes, and aligned with the Bogotá Principles of the Inter-American Coalition of Business Ethics in Health (2020), and the current regulation on the prevention of unethical conduct, corruption, transnational bribery, money laundering and terrorism financing.

This Code of Ethics serves as a self-regulation tool, guiding the relationships between companies in the sector, whether members of ANDI or not, and various stakeholders, thereby raising the standards of sectoral business ethics.

This version will enter into force as of January 1, 2026.

# Definitions

## A

**Stakeholders of the Health System:** It refers to any person, entity, or organization, public or private, that plays an active role in prescribing, recommending, using, purchasing, selling, or distributing medical technology products. It includes health system funders, distributors, logistics operators, service providers such as hospitals and clinics, scientific or professional organizations, academic institutions, and medical associations. It also encompasses Patients, caregivers, and Patient organizations to the extent that they interact directly with medical technology. Government officials or contractors involved in decisions related to Medical Technology are equally included.

**Medical Supplies:** Objects directly related to medical practice, which are beneficial to improve medical services and direct care of Patients.

**Educational Items:** Objects that have a genuine educational function with the intention of assisting in the medical care of Patients.

## A

**Associated companies:** Member companies of the Chamber of Medical Devices and Health Supplies of the National Association of Businessmen of Colombia-ANDI-

**Conflicts of Interest:** "A situation where business, financial, family, political or personal interests could interfere with the value judgment of personnel in the performance of their obligations to the organization" (NTC- ISO 37001 Anti-Bribery Management System, 2017).

## D

**Donation:** It is a voluntary and free contribution, in money or in kind, from one institution (donor) to another (donee), who accepts it. This implies that there should be no type of consideration for the donor.

**Due Diligence:** It refers, in general, to acting with the necessary care to reduce the possibility of being considered guilty of negligence and of incurring the respective administrative, civil, or criminal responsibilities; and, in particular, to the set of processes implemented for the adoption of sufficiently informed decisions.

which includes the full knowledge and identification of the counterparties and, in general, the interested parties, before and during the execution of a commercial agreement, transaction or contract.

## E

**Events:** These include congresses, symposia, courses, and other educational activities, both face-to-face and remote, that aim to support the advancement of medical science, educate healthcare professionals and patients, and facilitate independent medical research.

## P

**Product Information:** Any content and manner of disclosing the nature, origin, method of manufacture, components, uses, volume, weight or measurement, prices, manner of use, properties, quality, suitability or quantity, and any other characteristic or reference relevant to the products offered or put into circulation, as well as the risks that may arise from their consumption or use. This information must be timely, complete, truthful, independent, of quality, and supported by scientific evidence, as well as complying with the conditions of the respective sanitary registrations or marketing permits and Current legal technical standard.

## G

**Gifts:** Objects given to the Stakeholders of the Health System that do not meet the characteristics of Medical Supplies or Educational Articles.

**Patient Organization:** A non-profit entity, legally constituted and in operation, representing the interests and needs of Patients, their families, and caregivers, and that must act autonomously and independently. Some of its objectives:

a) Provide direct support to people affected by an illness.

b) Advocate for the rights of Patients before the Stakeholders of the Health System.

c) Educate and raise awareness about diseases.

d) Provide information to Patients in one or more therapeutic areas of interest.

## P

**Patient:** A person who receives health care, that is, who requires a service to promote, maintain, monitor or restore his or her health.

**Sponsorship (or Commercial Sponsorship):** Any payment or in-kind support provided to a third party, in exchange for advertising or promotion opportunities for the company.

**Patient Support Program:** Programs organized by a Partner Company or by a third party on behalf of the Company, aimed at Patients, caregivers of Patients, and families of Patients, who have previously and duly been prescribed by a health professional a Medical Technology marketed or manufactured by such Company. These programs will aim to promote patient adherence, as well as awareness and education about the disease, support in the follow-up of treatment, among others.

## B

**Brand Identity Reminders:** Objects of modest value that are used to remind a target group of the benefits and advantages of a product or brand and thus, increase their positioning. Brand identity reminders must be marked with the name of the Partner Company or the product they are promoting.

## M

**Medical Technology:** Any technological solution that is used to diagnose, treat, monitor, manage, and alleviate health conditions, disabilities, and meet a desired physical condition, including instruments, apparatus, machines, biomedical equipment, software, digital platforms, applications or software, as well as related services, solutions and therapies, used individually or in combination, for use in:

a) Diagnosis, prevention, monitoring, treatment, or relief of an illness;

b) Diagnosis, prevention, monitoring, treatment, relief, or compensation for an injury or deficiency;

c) Investigation, substitution, modification or support of the anatomical structure or physiological process;

d) Pregnancy diagnosis and conception monitoring, including in vitro fertilization procedures and assisted reproductive technologies;

e) Care during or after pregnancy, including newborn care;

f) Medical Technology Disinfection and Sterilization Products.

**Value Transfer:** The delivery in cash or in kind of goods or services to the Stakeholders of the Health System.

## F

**Fair Market Value:** It is the value for which a transaction is made in an open and competitive market, free from undue pressure. This can be determined by different criteria such as the sector, the nature or location of the services, the complexity, specialty, and knowledge and technical and/or scientific experience of the professional, considering historical data and/or independent market studies.

# 1

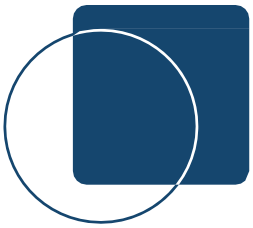
# Commitments Ethical and Transparent

The ANDI Chamber of Medical Devices and Health Supplies and the associated Companies are committed to maintaining ethical and transparent behavior, ensuring that medical decision-making is made seeking the greatest benefit for Patients and society in general.

This Code of Ethics constitutes the framework for ethical action and relationships that the Associated Companies are committed to promoting, always in compliance with national laws, respecting and adhering to international regulations, when applicable, in accordance with the following principles:

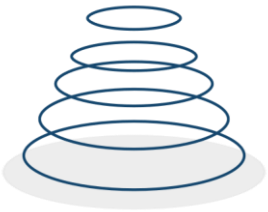
## Integrity

Our decisions and actions are honest, truthful, and fair to all parties. We are consistent with what we are, think, say, and do with all the people with whom we interact.



## Transparency

We act in good faith and in order to ensure that the Stakeholders of the Health System openly share significant, sustainable financial relationships.

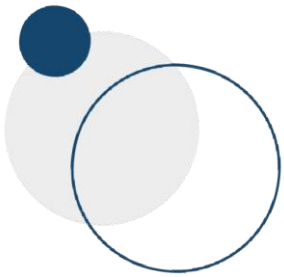


## Progress

Our relationships are aimed at advancing the field of medical technology, innovation, and patient care.

## Suitability

Our agreements meet proper business standards and are accurate and free from corrupt purposes.



## Independence

We understand that the decision-making process of stakeholders in the medical technology sector must be autonomous, objective, and impartial, always seeking the best interests of the Patient, recognizing everyone's right to high-quality healthcare, and differentiated care, according to individual needs.

### Responsibility

We promote a culture that supports social and ethical business practices, including protecting the safety, rights, and privacy of Patients and Health System Stakeholders.

### Education

We are aware of the importance of high-quality training and knowledge acquisition to help ensure the usage of medical technology safely and effective by Health System Stakeholders.

## 1.1. Anti-Corruption Declaration and Promotion of Free Competition

The ANDI Chamber of Medical Devices and Health Supplies and the associated companies are ZERO TOLERANT of unethical conduct, including those related to acts of corruption, private corruption and transnational bribery, as well as criminal conduct such as money laundering and terrorist financing. In this sense, we are committed to developing, implementing, and socializing the necessary programs that allow controlled and safe activities to be carried out.

Those of us who accept this Code of Ethics will respect the existing regulations for the promotion and defense of free and fair competition, committing ourselves all our actions will be carried out within the framework of respect and compliance with the law.

## 1.2. Adoption of the Code of Ethics

To ensure the effectiveness of this Code of Ethics, the associated Companies will be encouraged to adopt the following elements:

- Designate a senior executive responsible for leading the implementation and overseeing the Company's compliance with the Code of Ethics.
- Develop or adopt practical, useful, and substantial policies, guidance, and tools on how to integrate policies with the Code of Ethics.
- Provide effective and ongoing training and education on the Code of Ethics and Company policies consistent with this Code.
- Document the commitment to support the Code of Ethics of its governing bodies and board of directors, if applicable.
- To institute adequate internal monitoring, testing, and auditing mechanisms to assess continued compliance with the Code of Ethics.
- Create secure mechanisms for raising concerns and complaints about potential violations of the Code and encouraging employees to use them.
- Communicate the Code of Ethics, as well as related company policies, to third parties acting on behalf of the company, so that they may also comply with it.
- Comply with applicable regulations on the collection and use of Patient data, if any, categorically excluding its use as a means of inducement to obtain, retain, or conduct business or as any other illegal inducement or contrary to what is defined in this Code of Ethics.
- Conduct and maintain books and records that accurately and completely reflect transactions with Health System Stakeholders and government officials.
- Respond immediately to detected problems and take appropriate corrective action.
- Avoid situations of Conflicts of Interest. It is recommended that member companies guide their associates to report actual and potential Conflicts of Interest with Stakeholders in the Health System, as well as, whenever possible, adopt measures to eliminate or, at least, mitigate and/or provide transparency to such conflicts.
- Comply with the legislation of the country where they are carrying out their activities.

# 2

# Relationship with Stakeholders of the Health System

# 2.1. Events & Meetings

The purpose of continuous training in the proper use of Medical Technology, which is offered to the Stakeholders of the Health System, will aim to complement, update, and maintain the competencies of each occupation, profession or specialty and improving the provision of health services by strengthening human talent in health, always maintaining the independence of medical education and not being used as a means of inappropriate influence.

The Associated Companies may organize their own Events or support Events organized by third parties, whether face-to-face, remote or hybrid.

## 2.1.1. Common Arrangements for Events and Meetings

### 2.1.1.1. Meals

Since the relationship of a Company associated with Stakeholders of the Health System may need spaces for the presentation of results, sharing scientific, medical or educational information and some work days, they may require food. These meals must meet the following requirements:

- The purpose of the interaction should be the exchange of scientific, educational, or business information, and, accordingly, meals should be held in places that allow scientific discussions, where the exchange of professional information can be carried out in an easy and agile manner.

- The Partner Companies must not cover the costs associated with food or beverages for the Health System Stakeholders or employees of the health institution who are not part of such a meeting or who are not present. Nor will they assume food or beverage expenses of people accompanying the Health System Actor.

- Meals, as well as the locations and facilities where they take place, must not constitute an inducement or reward to prescribe, deliver, provide, supply, purchase, administer, recommend, or use a product or to assist Associated Companies in obtaining any other undue advantage.

- In the case of remote Events, meals may not be sent to the place where the Stakeholders of the Health System are located, such as their private home, hospital, private practice, or university.

- The food provided, i.e., the value of meals and beverages, including gratuities and taxes, may not exceed the percentages defined (per person) in the table below. These costs apply only to Colombia.

| | %CLMMW (Current legal monthly minimum wage) |
|---|---|
| SNACKS | 5% |
| BREAKFAST | 15% |
| LUNCH | 20% |
| DINNER | 25% |

#### 2.1.1.2. Prohibition of entertainment, recreation, and gambling activities

Within the framework of the Events, the Partner Companies must not organize or sponsor activities such as prizes, tournaments, raffles, and other random activities, as well as assemblies or meetings parallel to the Main Event.

This prohibition does not include the social or cultural activities of scientific Events such as the welcome reception or the closing lunch, which are usually part of the official programs of the Events.

#### 2.1.1.3. Visits to the production plant and places where medical technology is located

In the case of non-portable medical technology, difficult to transport, or when it is necessary to verify the manufacturing process of the product, the training may be carried out in the places where it is located.

Travel costs (lodging, transportation, and food, the latter in accordance with paragraph 2.1.1.1 of this Code) associated with a visit to a production plant or headquarters may be paid.

> The Associated Companies will not pay the costs for guests or companions of the Health System Stakeholders who do not have any valid reason to make this visit or participate in it.

### 2.1.2. Events organized by partner companies

The Companies Associated can organize Events of scientific, technical, educational, and/or promotional content, under the following guidelines:

- The program of the Event must not include entertainment activities, in accordance with the provisions of numeral 2.1.1.2 of this Code.

- In no event may any Value Transfer be offered or effected in favor of the guest to compensate for their time spent attending the meeting or the Event. The foregoing does not apply to the contracting of services of Stakeholders of the Health System, for which the associated Companies must comply with the provisions of numeral 2.4 of this Code.

- The Events belonging to the company must not be used to exert undue influence on the prescription, formulation, use, or purchase of Medical Technology.

- The Partner Companies may jointly create continuing education, training, or other medical education programs with duly accredited institutions, as long as they clearly indicate the Company's involvement.

#### 2.1.2.1. Travel & Lodging

Travel expenses and lodging costs related to meetings or company-owned Events, developed in this Code, may be granted as long as the following conditions are met:

- Hospitality may only include the actual expenses of travel, lodging, and food of the guest, which must be moderate and reasonable. Food expenses must comply with the provisions of numeral 2.1.1.1.

- Only expenses resulting from the day before the Event and up to one day after the end of the Event may be covered, provided that the itinerary so requires.

- The stay must be at the hotel hosting the Event or at hotels with a similar rate to the Event, in standard-level rooms. In these spaces, the Partner Company will not be able to pay additional expenses outside of the hotel lodging rate.

- Business class flights are not allowed; only economy class ones. As exceptions to this rule, as long as the internal policies of the associated company allow it, there are:
  - When there is a reasonable or justified impediment that requires the guest to travel in business class.
  - In the case of trips of six (6) or more continuous flight hours.

  In both cases, the Partner Company must check and document it in accordance with its internal policies.

- Hospitality of companions of any Actor of the Health System may not be paid.

- No excursions, recreational activities, or additional expenses such as laundry, room service, or other services will be paid.

- Lodging may not be granted in luxury hotels, resorts, or paradisiacal places.

- Procedures must be established that allow the verification of the attendance of the guest at the meeting or Event, recipient of hospitality.

### 2.1.3. Support for Educational Events organized by third parties

The purpose of continuous training in the proper use of Medical Technology, which is offered to the Stakeholders of the Health System, will have the purpose of complementing, updating, maintaining the competencies of each occupation, profession or specialty and improving the provision of health services by strengthening human talent in health, always maintaining the independence of medical education and not being used as a means of inappropriate influence. Associated Companies may support Events organized by third parties, whether face-to-face, remote, or hybrid.

Sponsorships may not be delivered directly to the Stakeholders of the Health System (individuals) so that they can attend educational events organized by third parties, except as described in numerals 2.1.3.1 and 2.1.3.2.

### 2.1.3.1. Educational Grants

The associated companies may grant subsidies for education to be used in the development of educational activities that primarily benefit the recipients of such activities. Support for Events that encourage the aforementioned must be carried out through the institution that is carrying out the training, so that it controls without any benefit over products, the program, the speakers, the methods, and educational materials, which must respond strictly to educational activities. The above-mentioned educational grants may be awarded under the following conditions:

- Educational subsidies will be awarded without any type of consideration in favor of those who grant them and without the purpose of unduly influencing the decisions of the recipient institution.
- The Event should be especially dedicated to the promotion of objective scientific and educational activities. They may not be granted for promotional, commercial, or non-educational activities.
- It must be granted to a legally constituted organization or institution. It must not be granted to an individual directly.
- The content of the program, including agenda, methods, and educational materials, will be in charge of the third party that organizes the Event.
- The selection of the exhibitor or exhibitors will be in charge of the third party that organizes the Event, who will also determine the payment of the fees.
- The program of the Event must not include entertainment activities, in accordance with the provisions of numeral 2.1.1.2 of this Code.
- The subsidy to the entity can be monetary or in kind, as long as it meets the objective of supporting the education of those attending the Event. In the case of meals and refreshments given during the execution of face-to-face Events, numeral 2.1.1.1 must be complied with.
- The subsidy must be documented.
- The value of the support must correspond to the Fair Market Value.

- Grants must not be awarded to: (i) induce the use of products of any Partner Company; (ii) the benefit of a particular person; (iii) support the normal operating activities of an institution or individual (e.g., to pay payroll expenses or office equipment); (iv) support a company's promotional activities.
- Support for participation in educational conferences must not be used to exert undue influence on the prescription, formulation, use, or purchase of Medical Technology.

### 2.1.3.2. Commercial Sponsorships

Within the framework of educational Events developed by third parties to promote the education of the Stakeholders of the Health System, the Partner Companies may make Commercial Sponsorships, i.e. payments to the organizer of the Event in exchange for educational, promotional and marketing benefits, such as stands or spaces to show their brand at the Event venue or digital environment (in the case of Virtual Events) or the organization of satellite symposia, within the limits of the law. This type of Sponsorship is allowed under the following conditions:

- Any booth or space should be separate from the rooms where educational conferences are held.
- The Event organizer must open commercial participation to all commercial houses that are willing to pay for their participation.
- It must be paid to the organization or institution organizing the Event. It must not be granted to a natural person.
- Any support provided for Commercial Sponsorship must be identified as such and processed separately and independently of an educational grant that the same Partner Company provides for the same Event.
- Any expenses that must be incurred to present the products or carry out product demonstrations in the space provided for the associated Company must be assumed by the associated Company independently, clearly indicating who makes the Sponsorship, including promotional material, speakers' fees, etc.

## 2.1.4. Product training

It is the responsibility of the associated companies, providers of medical technologies, to provide appropriate education and training on their products and services, referring to the obligation to train on safe and effective use. These training programs could include practice sessions.

The training must be given by qualified personnel with the appropriate technical experience. On the other hand, the recipients of the training must have a legitimate need to attend a training or education program organized by the company, namely the need to obtain instructions on medical technology.

The training of users must be carried out in scenarios that are appropriate and provide good results for the assimilation of information.

The places where the training takes place must be environments that favor the effective transmission of information. In addition to virtual settings, appropriate in-person locations may include clinical, educational, or conference settings. Programs that provide hands-on technical training and instruction in Medical Technologies must be conducted in training centers, medical institutions, laboratories, or other appropriate facilities. Meetings are not allowed in luxury hotels, resorts, or paradisiacal places.

## 2.1.5. Business and sales meetings

It is allowed to hold promotional meetings so that both the Stakeholders of the Health System and those in charge of choosing or selecting Medical Technologies know the characteristics, specificities, comparative advantages, and prices of a product, as long as the national laws that govern these practices are not violated.

These meetings will take place exclusively between the employees of the associated Companies and Stakeholders of the Health System.

All meetings should be held in appropriate locations where there is an environment conducive to the exchange of scientific information. Meetings are not allowed in luxury hotels, resorts, or paradisiacal places.

The Associated Companies may cover reasonable travel and lodging expenses, in accordance with the internal policies that the Companies have for this purpose, as well as the following guidelines:

- They may provide modest meals and occasional refreshments in connection with such meetings, meeting the criteria defined in paragraph 2.1.1.1 of this Code.

- They will not be able to pay for meals, snacks, travel, or guest accommodations of Health System Stakeholders or any other person who does not have a genuine professional interest in the information being shared at the meeting, including spouses, family members, or friends of Health System Stakeholders. Members must ensure that invitations to Events are not interpreted as extending to non-guests.

- All information related to this point must be documented, including the justification in terms of location, participants, and expenses in general.

## 2.2. Scholarships

Financial support can be provided to finance scholarships for students in health areas, observing the following criteria:

- There must be clarity in the criteria for providing these supports while maintaining independence, and undue influence on the beneficiary must not be sought.

- Payment of the amount will be made directly to the accredited educational institution and not directly to the recipient of such support.

- The applicant institution will be autonomous and must, independently, select the scholarship holders or beneficiaries.

- Scholarships must be formally requested by the institution.

- The scholarship must correspond to a program related to the areas of health care.

## 2.3. Scientific and Clinical Research

Support, monetary or in-kind, can be provided to institutions that allow research that provides valuable scientific and clinical information, which can lead to the development of better treatments, diagnoses, and health services. These contributions must not have any type of link with the purchase of medical technologies, as long as they comply with current legal regulations and with the following requirements:

- Have a written request that is sent to the partner Company to carry out the research, indicating the institution and the responsible professionals.

- Demonstrate the suitability of the professionals and institutions involved in the study.

- The support or payment made must be within the Fair Market Value.

- Have a research protocol that contains the necessary permits and authorizations to carry it out, the institution, and the list of researchers responsible for conducting the study, ensuring that its scientific support is preserved, so that it is not used to exert undue influence on the recommendations of the Stakeholders of the Health System.

- Be supported by a written agreement that takes into account, among others, the following aspects:

  - ☑ The name, objective, and timeframe of the research to be conducted.
  - ☑ Protocol compliance clauses.
  - ☑ The details of the forms and the allocation of resources.
  - ☑ The delivery of results through periodic and final reports.
  - ☑ The communication of the results, both to companies and to the scientific community, should inform about any adverse effects.

- On the publication of the study results, the identity of the partner company that supported its implementation must be disclosed.

## 2.4. Contracts with Healthcare System Stakeholders

The Partner Companies may hire Health System Stakeholders as consultants or advisors to execute activities such as: speakers, moderators on educational topics, participation in expert meetings, and presentations at Partner Company Events. For which the following guidelines must be taken into account:

- There must be a legitimate need and a prior requirement for the contract.
- The relationship with the Actor of the Health System must be carried out through a written contract, which must include a detailed description of the services to be provided and the value of the fees (which must be within the limits of the Fair Market Value), as well as must be signed and formalized before the provision of the service.
- The number of Stakeholders of the Health System to be taken into account for the contracting of services must be fully justified due to aspects such as the program of the Event, the number of participants, and the number of sessions, among others.
- The Health System Actor hired must be the ideal one in knowledge, skills, and personal and professional aptitudes and their selection for the provision of services will be made exclusively based on their experience and qualifications to meet the needs presented.

- The work carried out by these Health System Stakeholders will be carried out in an appropriate place according to the type of services provided.
- Health System Stakeholders hired by a Partner Company to be speakers at an Event organized by third parties must disclose the name of the Partner Company that has hired them before starting their conference.
- The sales staff of the Partner Company may not unduly control or influence the decision to hire a particular Health System Actor; however, they may provide information about the capabilities and qualifications of a proposed Health System Actor for recruitment. The Partner Company should consider implementing appropriate controls to promote compliance with this guidance.

## 2.4.1. Payments to Healthcare System Stakeholders

- Compensation shall be determined in accordance with Fair Market Value and in no way in relation to the volume or value of past, present, or future business with such Health System Actor.

- Payments must be made in the name of the Health System Actor that has provided the service, applying local taxes and related legal requirements; Payments will never be made in cash.

- If it is within the contracting agreement, the associated Companies may pay or reimburse food expenses, according to the ceilings defined in numeral 2.1.1.1, and reasonable transportation and lodging expenses incurred by the Stakeholders of the Health System in connection with the provision of services. The above expenses must be documented and formally authorized.

## 2.4.2. Royalties and Intellectual Property

- Healthcare providers may develop intellectual property in connection with a product or technology development or an intellectual property licensing agreement, if they are active participants in such developments.

- Professionals involved in the development of a product or technology with their know-how can develop intellectual property licensing agreements.

- If a Health System Stakeholder provides a major contribution or is considered to be significant to the Partner Company, it must be properly documented to give the individual meritorious credit.

- The payment to a Health System Actor in exchange for their contributions as intellectual property should be based on factors that preserve the objectivity of decision-making and avoid inappropriate influence.

**Example**

1. That the health care professional purchases, orders, or recommends a medical product or technology from the company, or any product or technology produced as a result of the development project.
2. The commercialization of the product or technology is required at the time of marketing.

## 2.5. Medical Supplies

The Partner Companies may offer Medical Supplies, which must have established maximum quantities and ceiling values as follows:

- The associated companies may deliver up to two (2) Medical Supplies annually to the same Actor of the Health System.

- The Medical Supplies must not individually exceed an amount equivalent to twenty-five percent (25%) of the Current Monthly Legal Minimum Wage (CMLMW).

- In the case of Educational Articles, such as subscriptions to medical or scientific publications that facilitate the academic updating of the Health System Actor, they may not be given to the same professional more than once a year and may not exceed a value of two (2) Current Monthly Legal Minimum Wage (CMLMW).
- Its delivery must not be conditional on or encourage the purchase, use, or prescription of a product or, in general, imply an undue influence on the Actor of the Health System.
- The delivery must be documented and meet the requirements of the law.

## 2.6. Prohibition of Gifts and/or Gifts

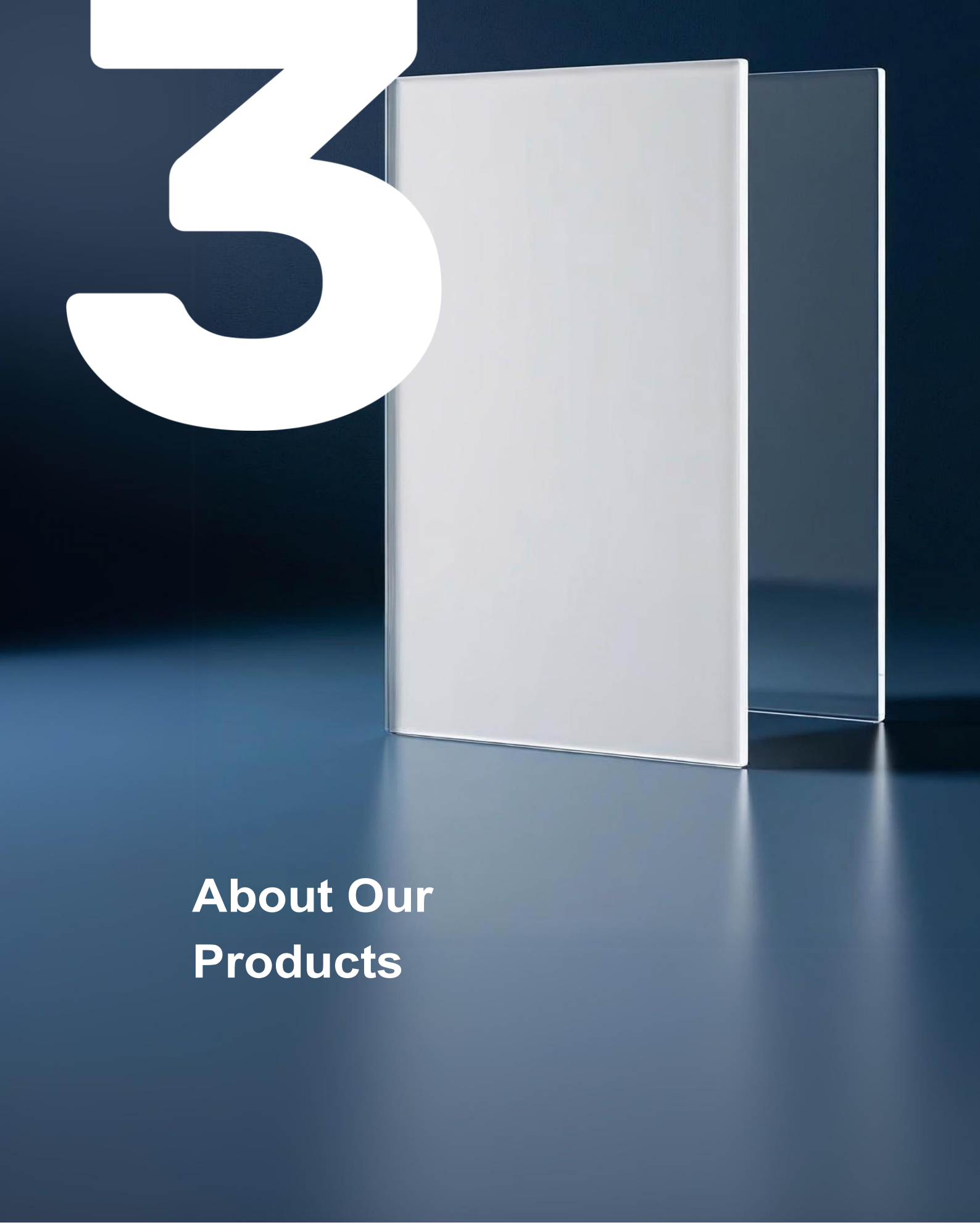
Neither the Partner Companies nor their members shall give or offer the Stakeholders of the Health System Gifts or Gifts for their personal benefit, such as cash (or its equivalent, such as vouchers and/or gift cards), tickets to shows or sporting events, electronic items, gift baskets, among others.

In this sense, the associated Companies must not deliver articles, objects, subsidies, or similar that do not comply with the provisions and limits established in numeral 2 of this Code.

## 2.7. Brand Reminders

Associated companies may provide brand reminders, which must comply with maximum quantity and value limits as follows:

- Brand reminders must not individually exceed an amount equivalent to ten percent (10%) of the current legal monthly minimum wage (SMMLV), and in total must not exceed fifty percent (50%) of the current legal monthly minimum wage (SMMLV) within a one-year period. This amount includes taxes.
- Brand reminders may not be given in cash or cash equivalents.
- Their provision must not be conditional upon, nor serve as an incentive for, the purchase, use, or prescription of a product.



# About Our Products

# 3.1. Product Information

To ensure the safe and efficient use of Medical Technology, help solve a clinical picture or improve health services, the Partner Companies may provide information on studies, technical information, medical conditions, health products, therapies, and economic data to the Stakeholders of the Health System. This information must always apply the general standards of health or therapeutic education, be true, independent, complete, balanced, and consistent with the approved use.

- It must be consistent with the conditions of the respective sanitary registrations, permissions, and the technical and legal standards in force. The foregoing does not restrict the right to inform the scientific community and the general public about scientific and medical progress, including the status of the process of induction of that product into the country's health service.

- It must adhere to the truth with up-to-date scientific evidence that demonstrates it, not exaggerate its use, nor induce deception or error, so it must be clear, legible, and accurate so that the receiver of the information can form his or her own opinion about its therapeutic value.

- The scientific evidence used must be recent, complete, and not distorted, biased, or omit relevant information. If the scientific evidence refers to published studies, these should be cited accurately, and the use of tables and graphs should be presented verbatim using the data publication standards.

- When presenting product information in comparison with other products, competition rules must be followed. The products being compared must not be denigrated or defamed. The comparison should be based on scientific information that is accessible to the competitor, verifiable, comparable, and relevant.

## 3.2. Products for Evaluations and Demonstrations

The products for evaluation and demonstration can be delivered to the Stakeholders of the Health System at no cost and to improve the care of Patients. The products can be delivered at no cost, taking into account that:

- Items must be marked "sample with no commercial value" or "product free of charge."
- The quantities of the products must be reasonable, and their delivery must be duly justified and supported.
- These products are delivered to the Health System Stakeholders for evaluation or demonstration and are not for sale or personal benefit.
- These products may not be offered or given as an inducement or reward to prescribe, administer, recommend, pay for, or supply any Medical Technology or service of the Partner Company. Its delivery should not be a condition for the realization of a sale or be understood as compensation for a service.
- Associated companies must have protocols in place to ensure that products delivered for demonstration and evaluation are not fraudulently used for health system recoveries.
- The associated companies must have adequate control and monitoring systems for the products that are delivered to the Stakeholders of the Health System and that are in the hands of the sales representatives, as well as their subsequent reports.

### 3.2.1. Products for Demonstration

Products manufactured, imported, or marketed by the Partner Companies that are used for the practical demonstration or training of Health System Stakeholders on the safe and effective use of such products.

- Its sale is prohibited.
- They cannot be used in humans.
- The quantity of Demonstration Products must not exceed what is reasonably necessary for the Health System Actor to acquire the necessary experience in the handling of the product.

## 3.2.2. Products for Evaluation

They can be: (a) Single-use products for evaluation (sample), or (b) Multi-use products for evaluation.

### 3.2.2.1. Single-use products for evaluation (sample)

Medical technology or diagnostic products used by healthcare professionals during the diagnosis or treatment of a Patient that are supplied to healthcare professionals or institutions for evaluation. Examples include:

- Medical technologies that are used for only one Patient.
- Single-use accessories, disposables, or consumables used with Medical Technology.
- Reagents, tests, consumables, or disposables that are used with diagnostic equipment.

### 3.2.2.2. Multi-purpose products for evaluation

Durable and reusable products manufactured, imported or marketed by the associated Companies, which are provided to the Stakeholders of the Health System so that they can evaluate them and learn about their functionality and benefits. Examples include equipment, instruments, diagnostic software, or surgical equipment.

For multi-use products for evaluation, the following conditions must be met:

- The conditions for the evaluation of these products must be established in advance and in writing, specifying the duration of the evaluation period, which may not exceed ninety (90) days.

- Partner Companies must maintain ownership of the products during the evaluation period, and must have a process in place to retire them within fifteen (15) business days after the end of the evaluation period, unless the Health System Stakeholder purchases or leases the products.

# 4

# Interactions with Third Parties

# 4.1. Donations

Partner Companies may make charitable monetary or product donations, for charitable or social purposes, in accordance with their internal policies. In addition, they must be aligned with national standards.

These practices should not be used to evade responsibilities, generate Conflicts of Interest, benefit a particular Stakeholder the Health System or as an illegal incentive.

The materialization of a Donation by a Partner Company must comply with the following steps:

- Formal written request for the Donation, by the requesting entity.
- Donations must be open and transparent. For all purposes, the information corresponding to donations is not considered reserved. The Partner Companies will ensure that the entity receiving the Donation discloses the Donation.
- Verification of the internal area of the associated Company that evaluates compliance with the requirements of the applicant, having as a principle that donations must be made to non-profit organizations authorized to receive them under the stipulations of local regulations.
- Donations should not be delivered to Stakeholders of the Health System or to individuals who are part of the recipient entity. These will be delivered to legally constituted entities after validation of their existence and verification of compliance with their corporate purpose.
- Approval for the execution of the Donation by a non-commercial area.
- These must not represent the obtaining of commercial advantages or conditioning of past, present, or future sales.
- The associated companies must implement analysis methodologies for the delivery of donations, to identify situations that attract attention and allow timely measures to be taken.

- For Medical Technology that enters the country through Donation, they must meet the established legal requirements.
- The Donation must be formalized in documentation, with the donor partner Company keeping a copy of these documents. The documentation must state the recipient of the Donation and the intended use of the Donation.
- Associated Companies must not directly or indirectly make contributions to political parties in exchange for obtaining inappropriate advantages and/or exerting undue influence that favors the prescription or purchase of Medical Technology.

## 4.2. Interaction with Patient Organizations, Patient Support Programs, and Patients

### 4.2.1. Products for Demonstration

Within the framework of interaction with Patient Organizations, ethical and transparent relationships are promoted based on the following guidelines:

Mutual respect:

Any collaboration between Partner Companies and Patient Organizations must be based on mutual respect, promoting an environment of trust and cooperation.

Independence and autonomy:

Patient Organizations must maintain their independence and autonomy in decision-making, free from undue external influences.

Prohibition of promotion of Medical Technologies:

Partner Companies shall not request Patient Organizations to specifically promote Medical Technologies, ensuring that such relationships are not used for commercial purposes or to promote Medical Technology.

Ethical use of supports:

The supports granted to the Patient Organizations shall not be used to induce the prescription or promotion of Medical Technologies, ensuring that such supports are exclusively for educational, research, or general support purposes to the mission of the Patient Organization.

Diversification of financing sources: Funding for Patient Organizations should come from a variety of sources. No member company may be the sole financial sponsor of an organization, guaranteeing the plurality of resources and avoiding any dependence that compromises the independence of the organization.

## 4.2.2. Interaction with Patient Organizations

It is allowed for the associated Companies to interact with the Patient associations while maintaining ethics and transparency, taking into account the following guidelines:

- The independence of Patient Organizations, autonomy, responsibility, respect, and solidarity must be guaranteed.
- The associated Companies may carry out actions aimed at raising awareness among Patient Organizations on issues related to health, diagnosis, prevention, and treatment of pathologies.
- Partner Companies must enter into direct agreements with Patient Organizations or through third parties. The agreements will account for the type of collaboration, dates, sponsored activities, the direct or indirect support, the source of funding, and other non-economic contributions that are made.
- Support for Patient Organizations must be made public and documented.
- No type of relationship should be used to obtain an undue advantage in terms of use, purchase or recommendation of Medical Technology. The Partner Companies will not solicit the Patient Organizations to specifically promote any Medical Technology.

- In accordance with existing regulations, the appropriate and responsible use of the personal data of Patients or Patient Organizations with which the Partner Companies have a relationship must be ensured.
- It is not allowed to give money or direct monetary subsidies, in cash or equivalents, to Patients.
- Each one of the financial aids granted by a Company associated with a Patient Organization must be made in its own name, by means of a bank transaction (never in cash), and duly registered in the accounting books of the associated Company.
- No Partner Company may apply to be an exclusive provider of funds to a Patient Organization.
- The Partner Company shall adopt strictly technical, objective, adequate, and expressly documented criteria for the evaluation (due diligence) and selection of the Patient Organizations to which it will provide support.
- The Partner Companies shall ensure that the Patient Organizations maintain absolute independence in relation to the object of the support, namely, not to use the support for purposes that do not directly benefit the Patients associated with it; use of support for awareness-raising actions on issues related to health, diagnosis, prevention, and treatment of pathologies.

### 4.2.3. Interaction with Patient Support Programs

The Associated Companies may provide Patient Support Programs (hereinafter, Programs), provided that the following conditions are met:

- The process of diagnosis, assessment, and formulation of the patient has been previously carried out within the framework of the health system.
- These are health conditions that merit the existence of a Program.
- The Program must be properly reviewed, approved, and documented by the Partner Company.

- The Patient's involvement and permanence in the Program must come from his/her interest and duly documented free consent.
- The existence of the program must be public knowledge.
- The dissemination of the Patient programs to the Stakeholders of the Health System may be carried out through the medical visit representatives, but the interaction with the Patient can only be carried out through the medical or specialized support areas of the associated Companies. The commercial and sales areas of the Partner Companies must be excluded from direct contact with the Patient.
- The Programs may be disclosed to the Patient Organizations when they so request, always respecting their autonomy and independence. In any case, the treating physician is the only one who may recommend the linkage of the Patient to the Program.
- All decisions related to the treatment of the Patient are solely the treating physician's and the Program may not intervene in those decisions.
- The associated Companies must have documented guidelines or procedures for linking and relating to the Patient.
- Employees of Partner Companies should not receive remuneration and/or bonuses for meeting goals in relation to the number of Patients participating in the Programs.
- Partner Companies can raise awareness of Patients' illnesses through recommendations on special care for their illness, healthy habits, or lifestyle changes through the Program.

This information must not include promotional or advertising messages from brands, specific Medical Technologies of the associated Companies, or be used as a commercial means for recruiting Patients, except as permitted by the current rules and regulations, according to the classification of the medical device.

- The Programs may not be used to deliver Medical Technology without the prior existence of a medical prescription. They also cannot be used to deliver Gifts, or to perform any form of illegitimate Value Transfer .

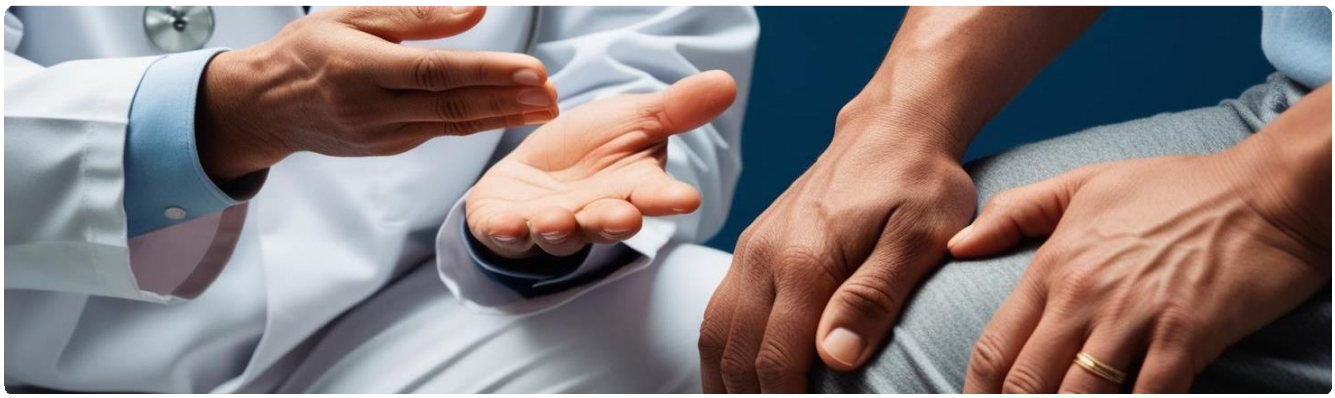
- Partner Companies may not offer or provide payments in cash or in kind to Health System Stakeholders for referring Patients to Patient Support Programs, nor may they offer such programs to Health System Stakeholders solely for their personal or financial benefit.
- The accompaniment and support of the Patient will be ordered by their treating physician, without the Program assuming behaviors that threaten or replace the doctor-patient relationship. In no case will the professional who provides the patient support service be the same prescriber.
- All Patients who enter a Support Program must previously provide their consent to participate in it, which must be recorded in a verifiable medium. It is forbidden to make use of the Patient's consent and data to promote Medical Technology. This information should not be a factor in the calculation and granting of incentives or bonuses within the Partner Company.
- Financial aid for education, research, or medical treatment is permitted, as long as it is within the framework of a Patient Support Program.

#### 4.2.3.1. Patient Support Program Items

The Associated Companies may deliver or offer through health institutions or professionals' non-promotional items of moderate value in the development of their Patient support programs that do not exceed a cost of ten percent (10%) of a Current Monthly Legal Minimum Wage (CMLMW) provided that the item delivered is directly and closely related to the activities implemented in such Programs and does not contain the brand of the product. Products for evaluations and demonstrations are excluded from the Articles of Patient Support Programs, to which the provisions of numeral 3.2 apply.

### 4.2.4. Interaction with Patients

It is permitted for the associated Companies to interact with Patients while maintaining ethics and transparency, as long as the rules and regulations in force allow it, according to the classification of medical devices for human use and under the following guidelines:



- Partner Companies can raise awareness of Patients' illnesses through recommendations on special care for their disease, healthy habits, or lifestyle changes; as well as actions aimed at raising awareness among patients on issues related to health, diagnosis, and prevention.
- It is not allowed to give money or direct monetary subsidies to Patients.
- In accordance with national laws, the appropriate and responsible use of the personal data of Patients with whom the Partner Companies have a relationship must be ensured. The Partner Companies must implement special security measures for the processing of personal data of a sensitive nature, in accordance with current legislation.
- In the after-sales stage of Medical Technology that is not for the exclusive use of health professionals or prescribed by them, and by virtue of quality problems or defective products, the associated Companies may offer services of verification, calibration, maintenance, and supply of supplies, exchange of Medical Technology for quality assurance, as well as the training required for the correct use, operation and basic maintenance of the Medical Technology, directly to the Patient.
- When the interaction with Patients is intended for them to provide information about their experience with the disease and/or the Medical Technology, the initial contact with the Patient may be made by the Patient Support Program if the Patient has authorized it. Otherwise, the contact will be made through a Patient Organization, a health professional or a health service provider, from which the partner Company must obtain authorization from the Patient for the correct handling of their personal data. Regarding the expenses of meals, transportation and/or lodging on the occasion of the presentation of said testimony, they may be paid directly by the associated Company and must comply with the provisions of numerals 2.1.1.1 and 2.1.2.1, respectively, of this Code.

# 4.3. Guidance for Ethical Relationships with Sales and Marketing Intermediation Partners

The Chamber of Medical Devices and its associated Companies are committed to the active collaboration of third-party sales and marketing intermediaries, such as distributors, wholesalers, distribution or sales agents, marketing consultants, brokers, commission agents, or independent sales representatives (Sales and Marketing Intermediaries), as well as Health System Stakeholders and other interested parties, both governmental and non-governmental.

This commitment aims to implement policies and procedures that promote transparency in operations and strengthen trust in the country's health system, in accordance with the Bogotá Principles of the Inter-American Coalition for Business Ethics in the Medical Technology Sector, which include the following elements:

## I Implementation of Codes of Ethics and Compliance Programs

They guide the guidelines under which all the participants of the system and their third-party members must carry out the activities.
These policies and programs must contemplate:

- Policies and procedures for adopting an anti-bribery and anti-money laundering and countering the financing of terrorism (AML) system - which must be in writing, published, and disseminated at all levels of the associated Company, as well as to its third parties.
- Implementation of controls that prevent the entry of illicit money into the system, and carrying out prevention activities to prevent the involvement of third parties.

- Have systems for identifying illicit records with a possible third party, involved in issues of fraud, extortion, judicial processes related to drug trafficking, among others, which must be duly related to the internal processes of the associated companies.
- There must be a protocol of response or action by the associated Company for cases in which the illicit acts are identified in third parties.
- It is important to detail and prohibit all forms of bribery or illicit money proceeds by any person or entity representing the name of the company.
- In areas of cross-cutting or common risk, such as travel, gifts, hospitality, entertainment, grants or donations, research and capital equipment, more detailed measures should be included, which allow vulnerability to be identified and measures to be implemented to control it.

## R Risk Assessment

Associated companies, sales and marketing intermediaries, and third parties must implement systems for the evaluation of risks that may materialize inside and outside the operation, to know and control them.

Associated Companies must evaluate:

- Local risk through published corruption indices, as well as specific risk profiles of planned or used third-party sales and marketing intermediaries.
- The local and international legal requirements that must be met and implemented.
- Information provided by third-party sales and marketing intermediaries for potentially unusual arrangements, such as high commissions, high degree of interaction with government officials, marketing budgets, healthcare providers, corporate affiliation or ownership, and/or offshore payment accounts.

- Information available from public sources or employees for potential issues associated with third-party sales and marketing intermediaries.

Sales and Marketing Intermediaries must:

- Know and support risk assessments of companies before and during participation in activities carried out on behalf of the company.
- Assess and communicate local and international legal requirements.
- Disclose potentially unusual agreements.
- Maintain accurate records for review.

The risk system of the Associated Companies and third-party sales and marketing intermediaries must include specific procedures to identify, manage, and mitigate these risks, ensuring transparency and regulatory compliance in all transactions.

# D Due Diligence

This must be risk-based and contemplate actions that are carried out prior to the execution or renewal of agreements or contracts to identify, prevent and mitigate risks related to the market in which the sales and marketing intermediary is involved to operate, as well as any specific activity that the sales and marketing intermediary carries out on behalf of the associated Company. Due diligence measures will also be taken during the execution of the agreements or contracts with the sales and marketing intermediary, at the frequency determined by the associated Company and in accordance with the risks identified.

Due diligence must guarantee the associated Company that its actions, carried out in the face of bribery and the prevention of money laundering and terrorist financing, will protect it or release it from a judicial process that is imposed on a third party involved in illicit matters.

## W Written Contract

Associated Companies and sales and marketing intermediaries must reach a mutual agreement that includes controls and implementation of anti-corruption policies and prevention of money laundering and terrorist financing, such as:

- Compliance with international and local laws, ethical principles and policies of the Partner Company.
- The ability to conduct independent audits and monitoring, including access to relevant books and records.
- The power to/possibility to terminate an engagement for non-compliance with international and local laws, ethical principles and policies of the Partner Company.
- The right to apply Due Diligence measures during the execution of the agreements.

## T Training and Education

Associated Companies and sales and marketing intermediaries must carry out training and communication programs at all internal and external levels of the operation, on compliance with applicable local and international laws and to publicize the ethical principles and policies of the company. These trainings will be conducted in the most appropriate language for participants and attendance must be recorded.

## M Monitoring / Auditing

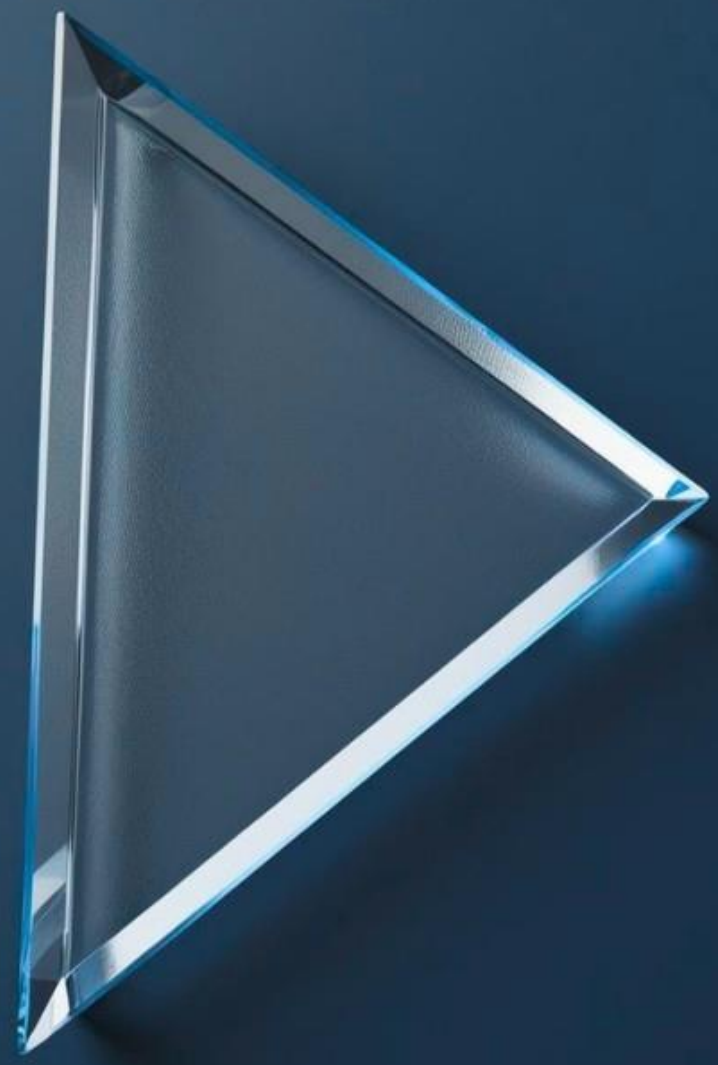
The sales and marketing intermediaries of the associated Company, and of third parties, must ensure through the evaluation of audits compliance with local and international laws, ethical principles and the policies of the Company, as well as the relevant contractual terms and regular certification of the personnel of the Company's sales and marketing intermediaries.

The personnel of the associated companies, who perform functions in the areas of Sales, Marketing, Education, Distributors, Direct Relationship with Stakeholders of the Health System or Patients, General Management, Legal & Compliance, Regulatory, Purchasing or equivalent areas, must take the courses and training established by the ANDI Medical Devices Chamber.

## A Appropriate Corrective

Where audits or supervision identify breaches of international and local laws, ethical principles, partner Company policies or relevant contractual terms, the party involved must implement appropriate corrective measures. These actions must conform to applicable international and local laws, to address any unacceptable or unethical conduct.

# 5



# Implementation of the Code (Dispute Settlement Mechanism)

# 5.1. Government and Administration Bodies

For the implementation of this Code, the following bodies are created:

### 5.1.1.

**Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies**

### 5.1.2.

**Executive Secretariat**

### 5.1.3.

**External Decision Panel**

5.1.1.

# Ethics Committee

It is the advisory body of the Chamber of Medical Devices and Health Supplies of ANDI, in charge of protecting the spirit and philosophy of the Code of Ethics, its permanence, improvement, development and interpretation. of undue external influences.

## A. Conformation

It will be composed of the members of the Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies Officials from the ANDI Chamber of Medical Devices and Health Supplies will also be part of it, who will have a voice, but not a vote.

## B. Functions

The Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies will have the following functions:

- To ensure the application of the Code and its regulations.
- To strive for unity of criteria in relation to the application of the Code and its regulations.
- Periodically review the provisions of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies and propose modifications for approval by the Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies.
- Provide advice, guidance and training in relation to the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies and its regulations, which may be presented in the form of pedagogical guides, training or any other useful form for the fulfillment of this purpose.
- To answer general queries that arise on the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies its regulations, by any natural or legal person. The answers to such general inquiries may not deal with particular aspects, nor refer to ongoing matters or complaints.

5.1.1.

## Ethics Committee

It is the advisory body of the Chamber of Medical Devices and Health Supplies of ANDI, in charge of protecting the spirit and philosophy of the Code of Ethics, its permanence, improvement, development and interpretation. of undue external influences.

- To issue circulars addressed to the members of the ANDI Chamber of Medical Devices and Health Supplies, informing them of the matters that correspond to them in accordance with this Code.
- Examine the resumes of the candidates presented by the ANDI Chamber of Medical Devices and Health Supplies, to be part of the External Decision Panel and the Executive Secretariat, as indicated in the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies.
- To issue an annual report of activities for the Board of Directors and the Ordinary Annual Assembly of the Chamber.
- Any other function that corresponds to it by virtue of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies.

### C. Meetings

The Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies shall meet in an ordinary manner at least biannually and, extraordinarily, when general consultations are made or when the needs, in the opinion of the Ethics Committee itself, warrant it.

It must also meet extraordinarily when the Executive Directorate of the ANDI Chamber of Medical Devices and Health Supplies deem it appropriate.

For the purposes of both ordinary and extraordinary meetings, the ANDI Chamber of Medical Devices and Health Supplies will indicate the date, time and place of the meeting and will summon the members.

5.1.1.

## Ethics Committee

It is the advisory body of the Chamber of Medical Devices and Health Supplies of ANDI, in charge of protecting the spirit and philosophy of the Code of Ethics, its permanence, improvement, development and interpretation. of undue external influences.

Both face-to-face and virtual meetings may be held, as long as attendance and virtual presence can be accredited, by any technologically valid means and the quorum indicated in the following paragraph is met.

### D. Quorum and Majorities

Deliberative quorum: the attendance of a plurality of member companies of the Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies that represents at least ten percent (10%) of the total members belonging to said Chamber or linked to it will constitute a quorum to deliberate. on the date of the meeting.

Decision-making majority: the decisions of the Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies may be validly adopted if they have the favorable vote of the majority of the attending companies, virtually or in person.

### E. Memoirs

From each meeting of the Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies, a written account of the decisions adopted, the responses to the general queries formulated and the proposals presented will be kept, which will be circulated through the ANDI Chamber of Medical Devices and Health Supplies.

5.1.2.

# Executive Secretariat

It is the administrative and independent body hired by the ANDI Chamber of Medical Devices and Health Supplies to fulfill the functions of a procedural nature derived from the complaints made in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI.

## A. Requirements

For the appointment of the Executive Secretariat of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies, the following requirements must be met:

- Be a legal or natural person.
- Independence and absence of contractual ties of any nature with the companies and entities belonging to or affiliated with the ANDI Chamber of Medical Devices and Health Supplies, their related or related companies, as well as their directors, during the three (3) years prior to their appointment.
- Accredited knowledge and experience in self-regulation systems, compliance programs and corporate governance, as well as understanding of the normative and regulatory framework in matters of transparency, ethics and anti-corruption, at the national level and international reference.
- Knowledge of the Medical Devices and Health Supplies sector or related subjects.
- High standards of ethics and integrity.

## B. Designation

The ANDI Chamber of Medical Devices and Health Supplies will present to the Board of Directors of the same, the candidates for Executive Secretariat, after convening and verifying compliance with requirements.

5.1.2.

## Executive Secretariat

It is the administrative and independent body hired by the ANDI Chamber of Medical Devices and Health Supplies to fulfill the functions of a procedural nature derived from the complaints made in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI.

The Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies will adopt the decision and the ANDI Chamber of Medical Devices and Health Supplies, will enter into the binding contract on behalf of the entity.

### C. Period

The Executive Secretary will be hired for an initial term of one (1) year with the possibility of extension for the same period or a shorter term, after validation by the Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies.

### D. Fees and Operation

The fees of the Executive Secretariat will be determined by the Directorate of the ANDI Chamber of Medical Devices and Health Supplies and established in the contract to be signed, following the following criteria:

- Costs per Complaint: Include the costs that must be incurred for the practice or collection of evidence and the notification to the parties of the decisions adopted by the External Decision Panel and other procedural actions that require it.

- The complainant must bear the fees incurred during the complaint process, which will be reimbursed to the complainant if the accused is sanctioned.

5.1.2.

# Executive Secretariat

It is the administrative and independent body hired by the ANDI Chamber of Medical Devices and Health Supplies to fulfill the functions of a procedural nature derived from the complaints made in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI.

## E. Functions

The Executive Secretariat shall have the following functions:

- Receive and evaluate the admission of complaints and their annexes in accordance with the requirements established in the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies and, subsequently, refer them to the study of the External Decision Panel.
- To receive and collect the monies corresponding to the fees decreed for the members of the External Decision Panel and for the Executive Secretariat itself, to render an account thereof and deposit them in the account indicated by the ANDI Chamber of Medical Devices and Health Supplies.
- To act as a facilitator – mediator between complainant and defendant, within the processing of complaints, in the stage prior to settlement.
- Verify that the members of the External Decision Panel, appointed by the parties within the process of resolving the complaints made, comply with the requirements set forth in this chapter and do not incur in grounds for disqualification or recusal. In the event of presentation, communicate in writing to the ANDI Chamber of Medical Devices and Health Supplies, in order to guarantee compliance with the relevant provisions of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies.
- Proceed to the draw for the corresponding election of the members who will make up the External Decision Panel, according to the established procedure and with the presence of a delegate from the ANDI Chamber of Medical Devices and Health Supplies.

## 5.1.2.

## Executive Secretariat

It is the administrative and independent body hired by the ANDI Chamber of Medical Devices and Health Supplies to fulfill the functions of a procedural nature derived from the complaints made in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI.

- Convene the External Decision Panel within the terms indicated in the procedure and provide operational, technical and coordination support to it.
- To make, within the process of resolving the complaints made, the necessary notifications to inform both the complainant and the accused of the admission or not of the complaint filed against them.
- Attend the meetings of the External Decision Panel to provide technical support on the procedure within the framework of the resolution of the complaints made, avoiding any comments on the substantive or factual issues discussed during the process.
- To notify the parties of the decisions adopted by the External Decision Panel and other actions that so require.
- Ensure that the terms and stages established within the process of hearing complaints are complied with.
- To take action, verify the application of the sanctions in accordance with the protocol established for this purpose and keep the ANDI Chamber of Medical Devices and Health Supplies informed.
- Guarantee the custody, conservation, and availability of documentation related to complaints and processes for violations of the Code of Ethics.
- Issue a technical report on the queries submitted to the Ethics Committee.
- Submit a biannual report to the Directorate of the ANDI Chamber of Medical Devices and Health Supplies on its management.

5.1.2.

## Executive Secretariat

It is the administrative and independent body hired by the ANDI Chamber of Medical Devices and Health Supplies to fulfill the functions of a procedural nature derived from the complaints made in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI.

### F. Conflicts of Interest of the Executive Secretariat

The Executive Secretariat shall guarantee an independent and impartial exercise of its function. Consequently, if in a situation of legal impediment or Conflict of Interest that arises after your appointment, you must inform the Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies through the Chamber of Directors and refrain from participating in any procedure that is carried out in relation to the parties or the situation that is the subject of the complaint. The Board of Directors will proceed to appoint an ad-hoc secretary based on the most recent list of eligible candidates presented at the time. The contract signed for this purpose will be per Event and will be valid for the specific case.

5.1.3.

# External Decision Panel

It is the body in charge of deciding in each case, the resolution of the complaints filed in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI, in cases denounced for alleged infractions or non-compliance with its provisions.

## A. Designation

The External Decision Panel shall be made up of at least nine (9) members appointed by the Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies, after evaluation by the Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies, of compliance with the requirements indicated in this Code and the absence of the grounds for inability or recusal indicated therein.

## B. Period

Once selected by the Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies, the members appointed to the External Decision Panel will have a period of four (4) years from the date of their appointment, and may be re-elected and removed at any time.

When any of the members of the Decision Panel resign or retire, the Board of Directors of the ANDI Chamber will provide the replacement(s).

## C. Requirements

To be part of the External Decision Panel, the following requirements must be met:

- Professional with more than ten (10) years of accredited experience in the exercise of their profession.
- Independence and absence of contractual ties of any nature, as well as absence of Conflicts of Interest, with companies and entities belonging to or affiliated with the ANDI Chamber of Medical Devices and Supplies.

5.1.3.

## External Decision Panel

It is the body in charge of deciding in each case, the resolution of the complaints filed in development of the provisions of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies in cases denounced for alleged infractions or non-compliance with its provisions.

the health, its related or related companies, as well as its directors, during the three (3) years before its appointment.

- Accredited knowledge and experience in self-regulation systems, compliance programs, and corporate governance, as well as understanding of the normative and regulatory framework in matters of transparency, ethics, and anti-corruption, at the national level or international reference.
- Knowledge and experience in the health sector or Medical Devices and Health Supplies.
- Absence of a criminal or disciplinary record.

### D. Grounds for Disqualification

Those who are in any of the situations listed below may not be part of the External Decision Panel:

- Be employees, advisors, contractors, counselors, auditors or have any contract or professional relationship with the companies affiliated to the ANDI Chamber of Medical Devices and Health Supplies, their subordinates, affiliates, subsidiaries or related; as well as any belonging to the Business Group to which they are incorporated.
- If it has been, the relationship must have ended at least three (3) years before the date of admission of the complaint made.

5.1.3.

## External Decision Panel

It is the body in charge of deciding in each case, the resolution of the complaints filed in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI, in cases denounced for alleged infractions or non-compliance with its provisions.

- Be employees, advisors, stakeholders, counselors, auditors or have any contract or professional relationship with the authorities or regulators of the Medical Devices and Health Supplies sector, in the three (3) years before the date of admission of the complaint made.
- To have been a counterpart or representative of the complainant or the accused, as the case may be, in any judicial or administrative proceeding in the ten (10) years before the date of admission of the complaint made.
- Be involved in any situation that generates a Conflict of Interest with the complainant or defendant, and not express it at the time of appointment as a panelist.

### E. Composition of Decision Chambers

For each instance in the resolution of each complaint formulated, the decision chamber of the instance will be formed, which will be made up as follows:

> Three (3 speakers or members drawn in the manner indicated in the preceding article, after compliance with the requirements indicated in this Code and without being subject to the grounds for disqualification or recusal indicated therein.

5.1.3.

# External Decision Panel

It is the body in charge of deciding in each case, the resolution of the complaints filed in development of the provisions of the Code of Ethics of the Chamber of Medical Devices and Health Supplies of ANDI, in cases denounced for alleged infractions or non-compliance with its provisions.

## F. Functions

The External Decision Panel has the following functions:

- Study the complaint and the response to it and pronounce on the violations of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies.
- Listen to the accused and the complainant during the hearings indicated within the process of resolving the complaints, to practice the necessary evidence, and to decide whether or not there is a violation of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies.
- Issue a reasoned decision based on the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies, through which it qualifies whether the behaviors denounced or investigated represent violations of the Code of Ethics.
- Formulate the corresponding instructions so that the conduct, in case of being a violation of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies, ceases and is not repeated, and establish the corresponding sanctions.
- Communicate the decision to the Executive Secretariat so that it may notify the interested parties, monitor and control the imposition of any applicable sanctions, and deliver a copy of the file and the documents contained therein to the Directorate of the ANDI Chamber of Medical Devices and Health Supplies.

5.1.3.

# External Decision Panel

It is the body in charge of deciding in each case, the resolution of the complaints filed in development of the provisions of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies of ANDI, in cases denounced for alleged infractions or non-compliance with its provisions.

## Duties

The duties of the members of the External Decision Panel are as follows:

- Assist to the sessions of the Panel. In the event of a situation or impediment to the holding of the session, the Executive Secretariat will be informed so that a new date for the Session can be scheduled, which in any case may not exceed ten (10) business days.
- Subscribe the Confidentiality Agreement once it is sworn in as a member and fully complies with it.
- Contribute at all times to the fulfillment of the objectives and proper functioning of the Panel.

## G. Decisions

The decisions of the respective chamber of the External Decision Panel shall preferably be adopted by consensus and in the event that it fails to do so, by an absolute majority of its members.

The Executive Secretariat that accompanies the respective decision-making body of the External Decision Panel has no say in the matter in substantive or factual aspects. It only provides support to the members of the respective board technical aspects of a procedural nature.

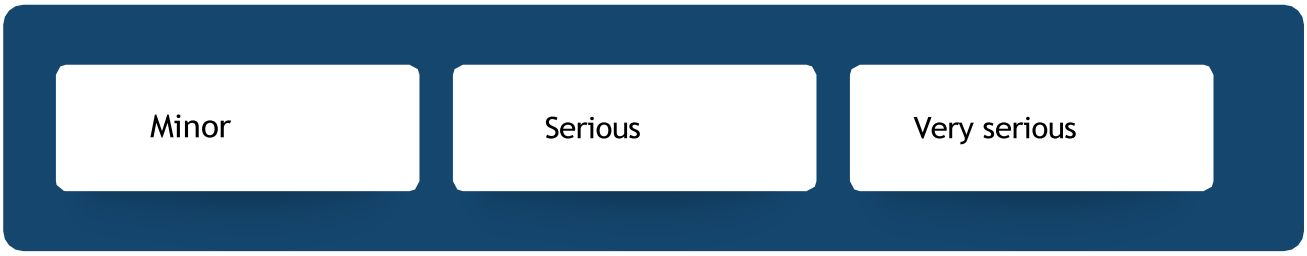
## H. RECORDS

The decisions of the members of the External Decision Panel in the Chamber shall be carried out in the manner indicated in the procedure and shall be signed by the members of the respective Chamber.

# 5.2. Infractions and Penalties

## 5.2.1. Infringements

The penalties for violations of the Code shall be of three (3) types:




The External Decision Panel will determine the type and degree of the decision, taking into account the following criteria:

- Degree of intentionality;
- Nature of the infringement;
- Risk to the health of patients and users;
- Impact on the functioning of the health system;
- Impact on health-related professions and/or trades;
- Impact on the image of the Medical Technologies sector;
- Impact on the image of other health-related sectors;
- Recidivism of the offender or offenders in offenses against the Code and,
- Economic benefit related to the infringement.

## 5.2.2. Mitigating and Aggravating Circumstances of the Infringement

### A. Mitigating Factors

- Behavior and degree of collaboration during the procedure.
- Absence of a history of non-compliance with the Code.

### B. Aggravating factors:

- Behavior and degree of collaboration during the
- Degree of intentionality;
- Failure to comply with prior warnings;
- Recidivism;
- Concurrence of infractions;
- Significant benefit or advantage for the associated Company, derived from the infringement.

The accumulation of aggravating factors may change the initial rating from "mild" to "severe" or from "serious" to "very serious".

## 5.2.3. Penalties for Offending Companies

In addition to the power of the External Decision Panel to order the immediate termination of the conduct, in the event that it continues to be executed at the time of the decision, the sanctions will be of two types: moral and material.

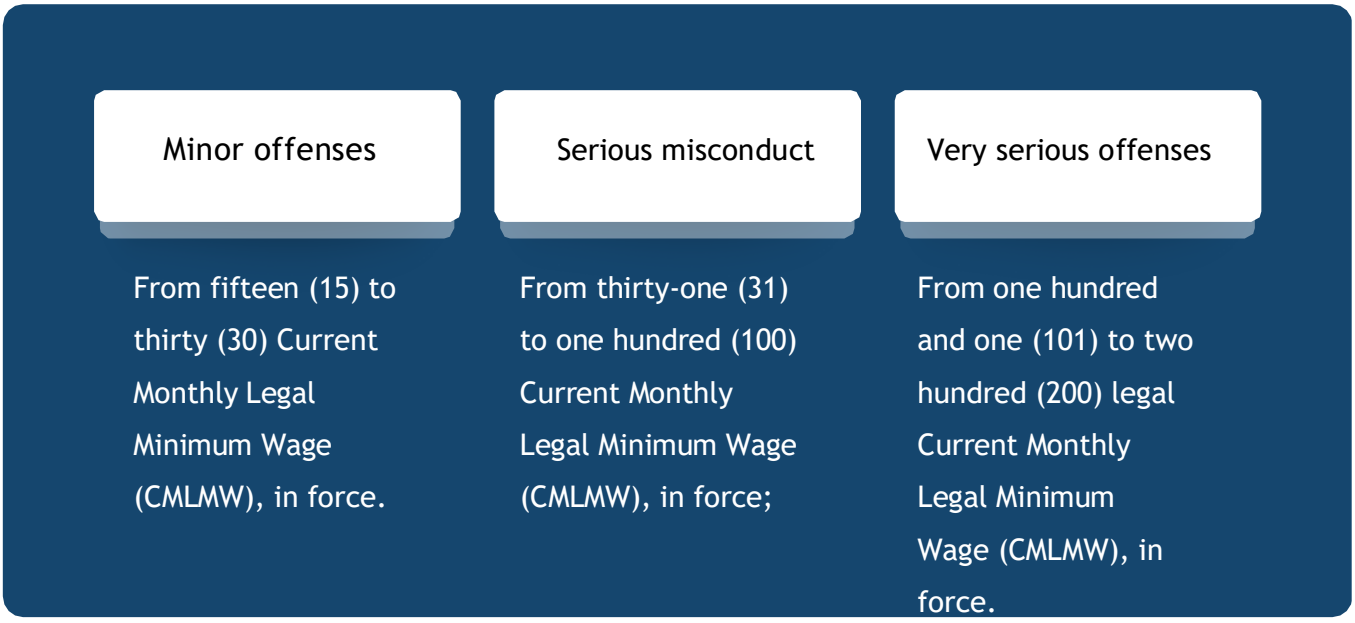
The Moral Sanctions will be the following:

- Admonition written, private or public;
- Publication of the sanction on the website of the ANDI Chamber of Medical Devices and Health Supplies;
- Imposition the obligation to take the necessary measures to adapt the behavior of the infringing company to the standards of the Code;
- Establishment of an external and independent audit by the company that violates the procedures for implementing and complying with the Code;
- Imposition the offending company to demand the reimbursement of the gifts given in breach of the Code, if this is possible;
- Prohibition to belong to the management bodies of the Chamber of Medical Devices and Health Supplies;
- Suspension of membership in the Chamber;
- Expulsion of the Chamber.

**Paragraph**: In the event of suspension of membership, the company's re-entry into the Chamber will only take place, after the period of suspension, if the company expressly undertakes not to carry out the practices prohibited by the Code and to pay all the fees that it would have been required to pay during the period of suspension.

### 5.2.4. Penalties for Offending Companies

Moral sanctions may be accompanied by the following pecuniary sanctions:




### 5.2.5. Destination of the Amount of the Penalties

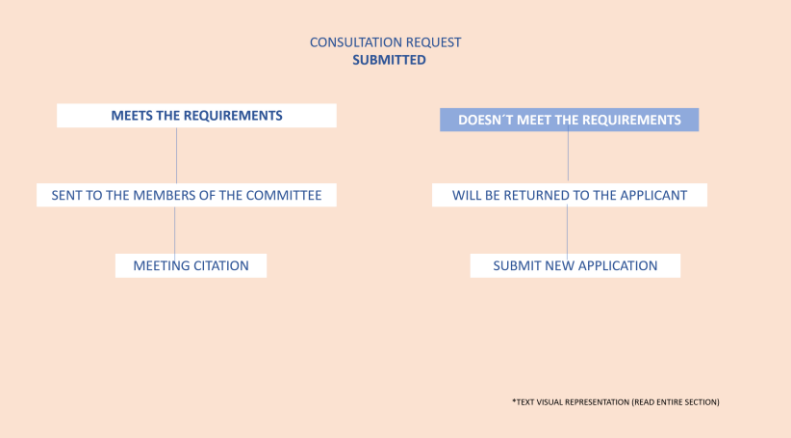
The money collected on the occasion of the pecuniary penalties imposed under the provisions of this Code shall be used in the constitution of a fund to reimburse the reasonable expenses incurred in the processing of complaints and for the payment of the fees of the External Decision Panels and the Executive Secretariat. The remainder will be destined to social responsibility programs of ANDI, the ANDI Chamber of Medical Devices and Health Supplies to charity. The Ethics Committee may set criteria for its destination or establish specific recipients, as it deems appropriate.

## 5.3. Procedures

### 5.3.1. Consultation Procedure

Through the email of the ANDI Chamber of Medical Devices and Health Supplies: lineaeticadm@andi.com.co consultation requests will be received.

Once received, the Executive Directorate of the ANDI Chamber of Medical Devices and Health Supplies, or the official expressly designated by ANDI, will review compliance with the requirement, within two (2) business days, counted from the day following receipt of the same.




If the consultation does not meet the requirement, it will be returned to the applicant, who may submit a new application if he or she deems it necessary.

If the consultation complies with the requirement, it will be forwarded to the members of the Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies and to the Executive Secretariat for the technical report established in paragraph E of article 5.1.2 and will summon them to a meeting to approve it within a maximum term of fifteen (15) business days. a term that may be extended only once for five (5) more days if the circumstances warrant it.
The Ethics Committee of the ANDI Chamber of Medical Devices and Health Supplies will decide the meaning of the response, which will be communicated to the applicant by the Executive Directorate of the Chamber within a maximum term of three (3) business days from the business day following the meeting.

## 5.3.2. Complaints

Complaints will be ordinary and in the public interest.

## 5.3.3. Ordinary Complaints Procedure

Any natural or legal person with a legitimate interest may file a complaint against an associated or adherent Company for an alleged violation of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies, before the ANDI Chamber of Medical Devices and Health Supplies, a means that allows proof of its delivery, preferably via email: lineaeticadm@andi.com.co.

## 5.3.4. Reporting Requirements

If the complaint comes from a legal entity, the Executive Secretariat will only admit complaints signed by its legal representative. In general, the complaints must contain at least the following requirements:

| **NAME** | **FULL NAME** |
|---|---|
| COMPANY NAME OF THE COMPLAINANT | LEGAL REPRESENTATIVE |
| | |
| **ADDRESS** | **E MAIL** |
| YOUR ADDRESS | Mail°youremail.com |
| | |
| **REASON** | **CONTEXT** |
| Or the commercial name of the defendant | A CLEAR, OBJECTIVE STATEMENT OF THE FACTS AND CIRCUMSTANCES GIVING RISE TO THE COMPLAINT. |
| | |
| **ATTACHMENTS** | |
| EVIDENCE OR DOCUMENTS THAT SUPPORT AND REINFORCE THE COMPLAINT<br><br>THE ELEMENTS OR REASONS ON WHICH IT IS BASED TO CONSIDER THAT THE CODE PROVISIONS ARE BEING VIOLATED | |

The companies covered by this Code undertake to act transparently and directly when it comes to reporting violations of the Code.

The complaint must be addressed to the ANDI Chamber of Medical Devices and Health Supplies, through the confidential channels provided for this purpose, which will be channeled to the Executive Secretariat for preliminary review, conciliatory stage, and subsequent steps.

When the complainant is not affiliated with the ANDI Chamber of Medical Devices and Health Supplies, or adherent to the Code, in addition to what is described above, an explanation of his/her motivations for making the complaint must be presented and accompanied in the written statement along with an explicit statement that the complainant acts in his/her own name and not in the interest of a third party.

### 5.3.5. Anonymous Complaints

This procedure admits anonymous complaints through the channels enabled by the ANDI Chamber of Medical Devices and Health Supplies. The anonymity and confidentiality of the complaint will be guaranteed at all times.

In the case of anonymous complaints, the Executive Secretariat shall conduct a preliminary inquiry that will last a maximum of one (1) month to establish whether, reasonably speaking, the facts and evidence provided with the complaint have sufficient merit to activate the dispute resolution mechanism.

When it finds sufficient merit, it will issue a record of the initiation of the process that will be governed by the same rules established for the case of ordinary complaints. In the event that sufficient merit is not found, the Executive Secretariat shall issue a resolution to archive, and the file shall be sent to the Chamber.

If the External Decision Panel finds that this means was used directly or indirectly by a member of the Chamber, it will order that the Board of Directors of the ANDI Chamber of Medical Devices and Health Supplies be informed so that he or she is definitively expelled from the union.

## 5.3.6. Allocation of Expenses for the Processing of the Complaint

If the complaint is admitted, the Executive Secretariat will inform the ANDI Chamber of Medical Devices and Health Supplies within three (3) business days, so that it can proceed to communicate and process with the complainant the payment of the fees generated.

The complainant must make the payment in the amount and form established by the Chamber, within seven (7) business days following receipt of said communication.

As long as such payment is not made, the procedure will not be initiated, and the terms will not run.

If the complainant is an individual who justifiably demonstrates that he or she lacks sufficient resources to pay these expenses, the case will be submitted to the Ethics Committee for consideration to decide whether to apply the exemption established for Public Interest and Anonymous Whistleblowing Events.

**Paragraph:** This provision will not apply in the event of complaints of public interest and anonymous, which will not generate any cost for the complainant.

## 5.3.7. Information to the Complainant on Inadmissibility of the Complaint

When the complaint does not meet the formal requirements indicated, the complainant will have a period of up to five (5) additional business days from the date of the notification to gather the additional information or complement it.

If the complainant does not deposit the budgeted resources within the established term or does not correct the formal requirements, it will be understood that he withdraws the complaint.

## 5.3.8. Notice for the Initiation of the Complaint Process

Once the respective amount has been deposited by the complainant, the ANDI Chamber of Medical Devices and Health Supplies will notify the Executive Secretariat designated for this purpose, so that it may proceed, in the first place, to summon the parties (complainant and defendant) to a prior settlement hearing, to promote a conciliated solution to the facts contained in the complaint as noted below. Only if the conciliated solution is not achieved, the members of the External Decision Panel will be drawn by lot, so that it may coordinate with the intervening parties, communicate, and process, within the terms defined in the procedure, the necessary steps for the study and resolution of the complaint and the application of the corresponding sanctions that may be appropriate.

## 5.3.9. Notification of Complaint and Prior Settlement

Within two (2) business days following the notification to the Executive Secretariat of the disposition of the remedies, the latter shall notify the associated or adherent Company(s) of the complaint filed against them, sending a copy thereof together with the evidence supporting it, and summoning both the complainant and the defendant to a prior settlement hearing to bring the parties closer together and invite them to reconcile their differences, before starting the other stages of the process.

Such a hearing must be held within a period of no more than three (3) business days following the date of the summons and may only be extended for an additional period of two (2) business days.

If a settlement is reached, the dispute will be considered resolved, and a record will be drawn up signed by the parties (complainant and defendant) and by the Executive Secretariat, indicating the commitments and agreements obtained. A copy of this will be sent to the ANDI Chamber of Medical Devices and Health Supplies, accompanied by the complaint and its annexes.

If a settlement is not achieved, a record will be drawn up signed by the parties (complainant and defendant) and by the Executive Secretariat, indicating that the settlement failed, indicating to the defendant that he or she has a term of eight (8) business days from the day following the closing of the settlement to answer or complete the complaint filed and to gather the relevant evidence. A copy of this will be sent to the ANDI Chamber of Medical Devices and Health Supplies.

All communications will be made by a means that allows for a record of their deliveries.

## 5.3.10. Response to the Complaint

The company(s) denounced will have eight (8) business days from the business day following the closing of the failed settlement. This period may be extended for up to another eight (8) working days at the request of the defendant by means of a reasoned letter.

The Executive Secretariat shall forward the response and accompanying documents to the External Decision Panel within two (2) business days following the date of acceptance by all its members.

## 5.3.11. Formation of the External Decision Panel

Within two (2) business days following the closing of the failed settlement, the Executive Secretariat will proceed to the respective selection process of the three (3) members of the External Decision Panel, by lottery, in the presence of a member of the ANDI Chamber of Medical Devices and Health Supplies.

A record of this appointment will be drawn up, signed by the delegate of the ANDI Chamber of Medical Devices and Health Supplies and by the Executive Secretariat.

Within two (2) business days following the date of the draw, the Executive Secretariat shall communicate by means that allow a record of its delivery to each of the elected members of the External Decision Panel

The elected members must respond to their acceptance within three (3) working days following the date of communication, by a means that allows proof of their delivery.

If any of the members is unable to accept or is unable to do so, the Executive Secretariat will proceed to carry out a new draw under the terms mentioned herein.

## 5.3.12. Resolution on the Complaint

The External Decision Panel shall take a period of time to study the complaint and the response, which may not exceed ten (10) business days, counted from the business day following the expiration of the deadline for the complainant to respond to the complaint.

At the expiration of this term, the Executive Secretariat will convene a meeting within the following three (3) working days for the External Decision Panel to hear the accused and the complainant, take the necessary evidence, and, if possible, decide whether or not there is a violation of the Code.

If a decision is not possible at the meeting, the External Decision Panel will have a maximum of ten (10) business days, counted from such meeting, to make a decision.

If the case is complex, this period may be extended for up to five (5) additional business days.

## 5.3.13. Content and Effects of the Decision

The External Decision Panel shall issue a reasoned decision based on this Code of Ethics. If the decision qualifies the conduct(s) under investigation as an infraction(s), it will formulate the corresponding instructions so that the conduct(s) cease and are not repeated, and will establish the corresponding sanction.

## 5.3.14. Notification of the Decision

Within three (3) business days following the making of the Decision, the Executive Secretariat shall notify the investigated party and the complainant, with a copy to the ANDI Chamber of Medical Devices and Health Supplies the decision of the External Decision Panel.

If the sanction consists of a private reprimand, the complainant will be notified of the decision, warning him of his duty of confidentiality regarding the process and the decision.

If the decision of the External Decision Panel establishes that there was a violation of the Code of Ethics of the ANDI Medical Devices Chamber, the Executive Secretariat will proceed to enforce the sanction imposed.

If the second instance is activated, the sanction will be suspended until the case is finally resolved. The Executive Secretariat will be in charge of monitoring and verifying compliance with the decisions of the External Decision Panel, and once the process is completed, it will send the proceedings to the ANDI Chamber of Medical Devices and Health Supplies.

## 5.3.15. Second Instance

The decisions of the External Decision Panel may be appealed to a second instance.

To this end, the interested party must notify the Executive Secretariat in writing within five (5) working days following notification of the decision of the External Decision Panel of its decision to appeal to the second instance.

The interested party may submit new evidence to the External Decision Panel that was not available at the time of the response to the complaint.

If the intention to appeal is not expressed, the decision of the External Decision Panel will be final.

## 5.3.16. Composition of the Decision Chamber of the Decision Panel for the second instance

Once the written notification of the decision to appeal has been received, the Executive Secretariat shall proceed to the appointment of the three (3) members who will make up the decision chamber in the second instance, by drawing lots, which shall be carried out within the following five (5) working days, after notification by the Chamber of the corresponding fees.  by the complainant, according to the procedure established for the first instance.

The External Decision Panel will initiate the process within the following five (5) business days.

Thereafter, the appellant will have a maximum period of ten (10) business days to receive evidence or additional elements or new or complementary arguments that the appellant wishes to present, including the possibility of a hearing that the Decision Panel deems necessary.

Once this phase is closed, it will have a maximum period of five (5) business days to issue its decision. No appeal may be lodged against its decisions.

## 5.3.17. Application of the Sanction

Once the decision of the External Decision Panel indicates that a violation of the Code has been presented, the Executive Secretariat will proceed to enforce the sanction imposed. Likewise, it will request the denounced company to provide a written detail within the following ten (10) business days on the actions taken to comply with the decision.

At a minimum, the affected company will be asked for a Statement of Compliance, in which it will confirm that the activity in violation of the Code of Ethics of the ANDI Chamber of Medical Devices and Health Supplies will cease immediately and that it will take all possible measures to avoid a similar violation in the future.

The Declaration of Compliance must be signed or authorized by the company's legal representative.

## 5.3.18. Reimbursement of Expenses to the Complainant

When the result of the investigation of the complaint is the application of a sanction for the denounced company, the latter must pay it and additionally cover the expenses incurred by the complainant to file the complaint within the same ten (10) business days following the final decision.

The value of the reimbursement of the complainant's expenses shall be that credited by the Executive Secretariat in accordance with the payments that the complainant has made based on the provisions of this Code.

**Paragraph**: If the External Decision Panel finds that the complaint filed was manifestly unfounded, it may sanction the complainant by ordering the reimbursement of the expenses incurred by the accused for the purposes of his defense, having as a limit the amount paid for the activation of the complaint mechanism.

## 5.3.19. Dispute Settlement Mechanism Statistics and Archive

The ANDI Chamber of Medical Devices and Health Supplies will take note and keep the records of what was done with the decisions that were made. Based on the foregoing, it may require the Executive Secretariat to prepare statistical reports on the operation of the operating procedure contemplated in this chapter.

## 5.3.20. Public Interest Complaints Procedure

In complaints of public interest, the following special rules will be taken into account:

- They may only be filed by Patients affected by the alleged infringement, patient associations, and public entities of any kind¸
- In addition to the requirements indicated in point 5.3.4, the complainant must demonstrate a legitimate and direct interest in proceeding.
- The processing of the complaint is not conditional on the payment of the expenses indicated in the articles.

  5.3.6. and 5.3.18. of this Code. For all purposes, the fees of the members of the External Decision Panel will be considered as a Donation;
- The Executive Secretariat shall proceed to appoint all the members of the External Decision Panel of first and second instance, if applicable.
- If the External Decision Panel finds that this means was used indirectly by a member of the Chamber, it will order that the ANDI Board of Directors of the Chamber of Medical Devices and Health Supplies be informed so that he or she is definitively expelled from the union.

In all other matters, the ordinary procedure of the Code shall be followed.

**Paragraph**: In the case of anonymous complaints, the provisions of paragraph 5.3.5 of this Code.

# References


- Code of Ethics, Mexican Association of Innovative Medical Device Industries (AMID), 2019.
- Code of Conduct, Brazilian Association of the Health Technology Industry (ABIMED), 2022.
- AdvaMed Code of Ethics, Advanced Medical Technology Association (AdvaMed), 2022.
- Code of Ethics on Interactions with Healthcare Professionals, European Coordinating Committee for the Radiology, Electromedicine and Health Technologies Sector (COCIR), 2019.
- Code of Ethics and Transparency, Chamber of the Pharmaceutical Industry, National Association of Businessmen of Colombia-ANDI-2016.
- Code of Good Practices of the Pharmaceutical Industry, National Business Association of the Pharmaceutical Industry (FARMAINDUSTRIA), 2023.
- Code of Good Practice, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), 2021.
- Code of Ethical Business Practice, MedTech Europe, 2022.
- Code of Ethics, Association of Pharmaceutical Research and Development Laboratories (AFIDRO), 2022.
- Law 84 of 1873, Congress of the Republic, Civil Code.
- Law 155 of 1959, Congress of the Republic, "By which some provisions on restrictive commercial practices are issued".
- Law 23 of 1981, Congress of the Republic, "By which rules are issued in matters of medical ethics".
- Law 23 of 1982, Congress of the Republic, "On Copyright".
- Law 599 of 2000, Congress of the Republic, Penal Code.
- Law 1164 of 2007, Congress of the Republic, "By which provisions are issued in the field of Human Talent in Health".
- Law 1474 of 2011, Congress of the Republic, "By which rules are issued aimed at strengthening the mechanisms for the prevention, investigation and punishment of acts of corruption and the effectiveness of the control of public management".
- Law 1438 of 2011, Congress of the Republic, "By means of which the General System of Social Security in Health is reformed and other provisions are issued".
- Law 1480 of 2011, Congress of the Republic, "By means of which the Consumer Statute is issued and other provisions are issued".
- Law 1581 of 2012, Congress of the Republic, "By which general provisions for the protection of personal data are issued".

- Law 1712 of 2014, Congress of the Republic, "By means of which the Law of Transparency and the Right of Access to National Public Information is created and other provisions are issued".
- Law 1751 of 2015, Congress of the Republic, "By means of which the fundamental right to health is regulated and other provisions are issued".
- Law 1778 of 2016, Congress of the Republic, "By which rules are issued on the liability of legal persons for acts of transnational corruption and other provisions are issued in the fight against corruption".
- Law 2195 of 2022, Congress of the Republic, "By means of which measures are adopted in matters of transparency, prevention and fight against corruption and other provisions are issued".
- Decision 486 of 2000, Andean Community of Nations, "Common Regime on Industrial Property".
- Decree 4725 of 2005, Presidency of the Republic, "By which the regime of sanitary registrations, marketing permits and sanitary surveillance of medical devices for human use is regulated".
- Decree 1663 of 1994, Presidency of the Republic, "which regulates paragraph 2 of Article 67 and Article 74 of Decree-Law 1298 of 1994", competition law for the health sector.
- Decree 780 of 2016, Ministry of Health and Social Protection, "By means of which the Single Regulatory Decree of the Health and Social Protection Sector is issued".
- Decree 218 of 2019, Ministry of the Interior, "By which international donations of products for human use for social and humanitarian purposes are regulated and other provisions are issued".
- Decree 1122 of 2024, Presidency of the Republic, "By which Article 73 of Law 1474 of 2011 is regulated, modified by Article 31 of Law 2195 of 2022, in relation to the Transparency and Public Ethics Programs".
- Resolution 1995 of 1999, Ministry of Health and Social Protection, "Establishing standards for the management of medical records".
- Resolution 839 of 2017, Ministry of Health and Social Protection, "By which Resolution 1995 of 1999 is modified and other provisions are issued".
- Resolution 2881 of 2018, Ministry of Health and Social Protection, "By which the Registry of Value Transfers between stakeholders in the health sector and the pharmaceutical and health technology industry is created".
- External Circular No. 9 of 2016, National Superintendence of Health, "By which instructions are issued regarding the Money Laundering and Terrorist Financing Risk Management System (MLTFRM)".

- External Circular 202117000000005-5 of 2021, National Superintendence of Health, "General instructions regarding the Subsystem for the Management of the Risk of Corruption, Opacity and Fraud (SICOF), and modifications to external circulars 018 of 2015, 009 of 2016, 007 of 2017 and 003 of 2018".
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