



## COFEPRIS: audits of dental care clinics

### *COFEPRIS: las auditorías de establecimientos de atención odontológica*

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The General Health Law, in its article 17 bis, specifies that the Ministry of Health will exercise powers of regulation, control and health promotion through a body called the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), whose functions are to identify and evaluate risks to human health, propose national policies to protect against health risks in health establishments, exercise sanitary control and surveillance, impose sanctions and apply security measures, all the above applied in matters of its competence.<sup>1</sup> COFEPRIS is an administrative authority that acts on the basis of Article 16 of the Constitution, which specifies the following: «The administrative authority may conduct home visits only to verify that sanitary regulations have been complied with and demand the display of the indispensable books and papers to verify that they have complied with tax provisions, subject to the respective laws and the prescribed formalities».<sup>2</sup> Therefore, it is possible that said commission checks the health facilities randomly and without prior notice with the sole purpose of verifying that said establishment is in accordance with the law and the health professional has the obligation to allow this verification to be carried out in an expedited manner. This random inspection carried out by COFEPRIS is what is known by law as an act of nuisance, which is specified in article 266 of the National Code of Criminal Procedures<sup>3</sup> and refers to the preventive restriction of a right, with prior authorization from the competent authority, provided that it is by means of a written order that grounds and motivates the legal cause of the procedure.<sup>4</sup> This means that any competent authority has the autonomy to request the review of a health facility even against the owner's will, in order to verify that everything is in order to provide dental care to the population, and in case of not complying with the minimum necessary regulations, offer observations and conditions that invite the owner to correct the detected errors, adhering to regulations to avoid being penalized for providing health services that could be risky for the population.

#### ATTRIBUTIONS OF COFEPRIS

COFEPRIS is an administrative and decentralized body of the Ministry of Health, with administrative, technical and operational autonomy and which is in charge of exercising the powers in matters of regulation, control and health promotion of health establishments.<sup>5</sup> For the understanding of the present topic it is pertinent to define the concepts of control, regulation, promotion and health risks as specified in article 2 of the Regulations of the Federal Commission for the Protection of Health Risks. Sanitary control is understood as the set of educational, indicative actions, application of safety measures and sanctions exercised by the Ministry of Health based on the provisions of the General Health Law, the COFEPRIS regulations and official Mexican standards. Health promotion refers to actions aimed at promoting the continuous improvement of facilities and services that may be a risk to the health of the population through training schemes of public and private sectors. Sanitary regulation is the provision issued in compliance with applicable laws, tending to regulate processes or activities related to matters of competence of COFEPRIS. All of the above aim to avoid the appearance of health risks and potential adverse events that endanger human health or life.<sup>5</sup>

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### Visits of verification and sanitary promotions

COFEPRIS acts completely through administrative procedures, which may originate automatically or by a complaint from a party. This means that in order to carry out an inspection it can do so randomly or by notification from a dissatisfied patient who was treated and expressed his disagreement before a competent authority. The visits that COFEPRIS performs may be of two types: health promotion and sanitary inspection. The first aims to promote better health practices through counseling and training through good practice guides or brochures to inform the owner of a health facility how to have it in accordance with current legislation. On the other hand, a health verification visit is an inspection of regulatory nature that a competent authority makes to a health establishment to verify compliance with the legal and regulatory requirements of the facilities, services and activities. The inspector must present his/her valid credential, issued by a sanitary authority, with the name and autograph signature of the verifier and of said authority, folio number, date of issue and validity, as well as a list of telephone numbers for complaints and clarifications. The order of verification must be in writing and delivered to the owner of the office, noting on a copy of said office the date, name and signature of the owner of the establishment. The inspector is obliged to disclose the purpose and scope of the visit and the owner of the establishment has the right to designate two witnesses to attest the development of the visit, and in case of not doing so, the inspector will have the freedom to assign them himself, later he will write down all the detected irregularities and the pertinent security measures adhering to current regulations. Once the visit is concluded, the owner of the establishment may express in writing all the allegations that are convenient to him and receive a copy signed by the inspector, the owner and the witnesses.<sup>6</sup>

### Regulation of health clinics

Dental clinics must have a specific infrastructure described in detail in NOM-005-SSA3-2010, which establishes the minimum requirements for infrastructure and equipment of facilities for outpatient medical care and COFEPRIS evaluates health facilities with what is specified in this rule. Section 6.1.3 details that the stomatology office must have an area for the dental chair and another for the preparation and sterilization of instruments, there

must necessarily be a free space to circulate easily. In addition, the dental office must have an area for the X-ray device. It is important that the office has enough contacts to provide energy for all the existing devices in it. Said norm also specifies the type of furniture, equipment and instruments of the dental office.<sup>7</sup> Other conditions that are strongly valued during regulatory visits are to have a label that indicates the dentist's attendance schedule and the hours of attention,<sup>8</sup> the title of the dentist,<sup>1,8</sup> complete documentation of the professionals who work in the establishment,<sup>8</sup> fumigation or disinfestation vouchers,<sup>7,9</sup> program for the correct handling of hazardous biological infectious waste (HBIW),<sup>7,10</sup> have the clinical records of patients duly stored allowing them to be available at any time,<sup>5</sup> safeguarding clinical records for at least five years,<sup>1,11</sup> a daily record of patients who come for consultation,<sup>8</sup> a medical prescriptions complying with the specified guidelines,<sup>1,8</sup> functional sinks with soap and disposable towels in the physical examination area,<sup>7</sup> infrastructure that allows the entry of disabled and senior patients,<sup>7</sup> have a waiting room,<sup>7,8</sup> functional toilets and in good conditions,<sup>7,8,12</sup> adequate ventilation and lighting, either by natural or artificial sources,<sup>9</sup> have an extinguisher, evacuation route with signs<sup>13</sup> and bags for municipal waste, HBIW and container for sharp objects,<sup>7</sup> as well as an emergency kit that includes the established medicines.<sup>1,7</sup> In addition, during the visit the clinical files may also be reviewed to verify that it is properly integrated.

**Table I.** Administrative sanctions that a health authority can impose.

Article	Specifications
417	Administrative sanctions may be arrest, warning, fine or partial or total and temporary or definitive closure
418	For the imposition of sanctions, the severity of the penalty, the damage caused to the health of the population and the recidivism of the offender will be taken into account
423	In case of omitting the sanctions imposed, the fine or sanction will be doubled
425	Establishments that do not have a health license, carry out activities that endanger health or violate health regulations will be subject to closure
427	Health authorities have the autonomy to indicate arrest for up to 36 hours to anyone who hinders the actions of the health authority or refuses to comply with the requirements imposed by it

During the health verification visit, it will be noted whether or not there is absolute compliance with the items specified in the record; under no circumstance may there be partial compliance with them.

### Sanctions and security measures

In case of non-compliance with the specifications of the General Health Law and the provisions that emanate from it, there may be administrative sanctions. It is important to clarify that an administrative sanction is not the same as a penalty imposed for the execution of a crime, since the offense is sanctioned by a criminal law,<sup>14</sup> but not by an administrative one. The sanctions and security measures that a health authority can impose are multiple, being described in articles 416 to 437 of the General Health Law<sup>1</sup> and the most important are exemplified in *table 1*.

### CONCLUSION

Dental clinics, when legally considered as health care establishments, must comply with current regulations regarding infrastructure and quality of services. The Federal Commission for the Protection against Sanitary Risks is a health authority capable of carrying out health facility inspections, providing suggestions, opinions and sanctions if required for the sole purpose of reducing the risk to the health of the population. It is essential to have the dental offices in order to prevent the health authorities from closing it because they consider that the dental care provided in it, instead of being beneficial for the patients, is a potential risk to their health.

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