



DIGIPRIS: Online Regulation

TERMS OF USE.

As part of an administrative modernization effort and with the goal of providing better services to citizens, the Government of Mexico is undertaking transformation initiatives to facilitate citizens' interactions with government institutions, maximizing the benefits of Information Technologies. This allows for greater transparency and access to information, combats corruption and discretionary practices, and ensures the protection of personal data held by this Federal Commission, aligning this transformation with applicable regulations regarding administrative procedures and regulatory improvement.

The DIGIPRIS: Online Regulation service is an online platform designed to facilitate and expedite the process of managing procedures related to health regulations in Mexico. This system allows users to complete procedures from anywhere with internet access, eliminating the need to visit a COFEPRIS office in person. Users can carry out different types of procedures.

Therefore, for the use of this platform, based on articles 4 of the Political Constitution of the United Mexican States; 14, 16, 17 and 39 section XXI of the Organic Law of the Federal Public Administration; 1, 2, 3, , 18, 28, 32, 35, 38, 39 and 69-C of the Federal Law of Administrative Procedure; 3 Section IX, 52, 53, and 54 of the Law General Law on Regulatory Improvement; General Law on Transparency and Access to Information Public; Federal Law on Transparency and Access to Public Information; General Law on the Protection of Personal Data Held by Obligated Entities; Law of Advanced Electronic Signature; Articles 316 and 317 of the Federal Code of Civil Procedure; Articles 1 and 2, subsection C, section X of the Internal Regulations of the Ministry of Health; Regulations of the Federal Commission for Protection against Sanitary Risks; Agreement establishing the provisions that must be observed by the agencies and decentralized bodies of the Federal Public Administration for the receipt of submissions made by users in administrative procedures through electronic means of communication, as well as for notifications, summonses, subpoenas, requirements, requests for information or documents and the final administrative resolutions issued by that same means, published on January 17, 2002 in the Official Gazette of the Federation; Official Standard

Mexican Standard NOM-151-SCFI-2016, Requirements to be observed for the preservation of data messages and digitization of documents, and Agreement by which the Procedures and Services, as well as the formats applied by the Ministry of Health, through the Federal Commission for Protection against Sanitary Risks, registered in the Federal Registry of Procedures and Services of the Federal Commission Regulatory Improvement: The following are made known to users:



GENERAL TERMS AND CONDITIONS OF USE OF THE DIGIPRIS SERVICE:

Online Regulation

This document describes the general terms and conditions applicable to the content, products, and services offered through DIGIPRIS: Online Regulation, hereinafter referred to simply as "terms of use." The Federal Commission for Protection against Sanitary Risks (hereinafter COFEPRIS) owns DIGIPRIS: Online Regulation.

First.— For the purposes of these "Terms of Use," "user" refers to any individual or legal entity that uses DIGIPRIS: Online Regulation, including those authorized to use DIGIPRIS: Online Regulation as editors or viewers; therefore, any actions taken by these individuals will be considered as having been taken on behalf of the owner. The "user" assumes full responsibility for allowing third-party access to DIGIPRIS: Online Regulation, releasing COFEPRIS from any liability for misuse.

Second.- In order to use DIGIPRIS: Online Regulation, the "user" must accept these "terms of use" and have the following:

- TO.** Be of legal age and have the necessary legal capacity to be bound by these "terms of use"
- B.** The current Advanced Electronic Signature (e.firma) certificate of the legal entity or individual in question, issued by the Tax Administration Service
- C.** Federal Taxpayer Registry with active status
- D.** Tax address located in the RFC or in the process of verification by the SAT

Third.- For the use of DIGIPRIS: Online Regulation, to carry out procedures, transmit information and submit electronic or digitized documents, users must use their e.signature, as well as the current and active certificate.

For the purposes of the procedures and services requested in DIGIPRIS, the "user" accepts that the e.signature, with a valid and active certificate, replaces the handwritten signature, guaranteeing the authenticity, veracity, integrity, non-repudiation, and confidentiality of the documentation or information presented. Therefore, the use of the e.signature will produce the same effects that the law grants to documents with a handwritten signature, having the same evidentiary value.



The “user” accepts responsibility for the use and privacy of the e.signature certificate, and for the information and documentation that is provided, modified, known or extracted through the use of the same in the application of the Digital Platform.

Fourth.- In order to carry out the procedures through DIGIPRIS: Online Regulation, users must register within it, among others, the following data: the name, denomination or business name of the natural or legal person; the current RFC, the email address to receive notifications, to which the notices of availability of notification related to their procedure will be sent.

It is the responsibility of the “user” to communicate any modification to their email address registered in DIGIPRIS: Online Regulation, which will take effect on the date and time indicated in the acknowledgment received.

The “user” agrees to provide the data, information, and documentation necessary for proper access to the service and, in accordance with applicable legal provisions, to the respective procedures. Likewise, the user accepts the responsibility of providing their own authentic information in Spanish when requesting procedures and services through DIGIPRIS: Online Regulation, unless otherwise provided by law.

The “user” accepts that access to or use of the DIGIPRIS Online Regulation service may be denied if they do not provide any of the data and information required for access to said system.

Fifth. The “user” accepts that the authenticity and veracity of the information and documentation submitted through DIGIPRIS: Online Regulation is their responsibility, and that such information and documentation will be understood to be provided under oath when signed with the e.signature. It is understood that the “user” incurs punishable liability if they provide and/or use false or nonexistent information and documentation, without prejudice to any applicable sanctions and penalties under the corresponding legal provisions.

The “user” accepts that the process initiated through DIGIPRIS: Online Regulation will be resolved with the information and documentation provided in the application or that submitted in compliance with a requirement made by COFEPRIS without allowing modifications to the same.

If the information indicated in the previous paragraph is not provided in the requested terms, it will be considered as not submitted.

COFEPRIS may at any time require the original documents or certified copies of the documentation submitted through DIGIPRIS: Online Regulation by the “user” for verification.



Sixth.-The “user” acknowledges that:

- TO.** The information presented through electronic means is original and authentic.
 - B.** The use of your digital certificate by a person other than the authorized one will be under your sole responsibility, accepting that if this occurs, you will be attributed authorship of the information sent through electronic means.
 - C.** You may be required to resend the information by COFEPRIS when the files sent contain computer viruses or cannot be opened for any reason due to technical problems.
 - D.** You assume any responsibility arising from the misuse of your digital certificate.
- AND.** Mere access to the DIGIPRIS: Online Regulation service does not imply the establishment of any type of relationship between COFEPRIS and the “user”.

Seventh.- The “user” accepts that the procedures are carried out entirely through the Digital Platform, unless the legal provision applicable to the respective procedure requires the presentation of printed documents, with an original signature or the practice of some act or physical inspection, in accordance with the applicable provisions.

The “user” accepts that the administrative acts resulting from the procedures requested on the Digital Platform are signed with the e.signature of the corresponding public servants, except in cases where, according to the applicable legal provisions, it is necessary to issue an administrative act with the handwritten signature of the public servant.

Eighth.- The process will only be considered initiated once the captured information and digitized documentation are signed and sent by the “user”, using their valid e.signature, otherwise it will only remain in the system for 90 calendar days.

Once the process has begun, the “user” will receive a “Proof of Entry of Process” which will be the acknowledgment of receipt of the process by COFEPRIS, through which a process number will be assigned and the date and time of entry will be recorded.

This “proof of application” does not in any way represent an authorization or concession of the procedure requested through DIGIPRIS: Online Regulation; each procedure must be subject to opinion and resolution by the health authority unless the applicable legal provisions provide that it is a notice or procedure of immediate attention through the issuance of a certificate.



Ninth.- The “user” accepts that notifications of all requirements, actions, warnings, resolutions and in general any administrative act derived from the submitted procedure will be carried out through DIGIPRIS: Online Regulation in accordance with the following considerations:

- yo. COFEPRIS, through DIGIPRIS: Online Regulation, will make the resolution of the submitted procedure available to the user. Simultaneously, DIGIPRIS: Online Regulation will send a notification availability notice to the email address provided by the user to receive notifications, stating that an administrative act related to their procedure has been issued and that, for this purpose, they must access DIGIPRIS: Online Regulation within 5 business days from the date the notification availability notice is sent.
- II. The user must access DIGIPRIS: Online Regulation to view the administrative act to be notified. Once the administrative act is opened by the user, DIGIPRIS: Online Regulation will generate the corresponding notification acknowledgment, which will include the date and time of opening. From that moment, the notification will be considered legally served and will take effect on the next business day following the day on which the user opened the document containing the administrative act.
- III. Once five business days have elapsed from the date the notification availability notice was sent by email, without the “user” having opened the administrative act and consequently, the acknowledgment of notification has not been generated; this will be done through an electronic board.
- IV. For notification by electronic notice board, COFEPRIS will publish the administrative act on the electronic notice board available on its website no later than the next business day after the deadline indicated in the previous paragraph has been met, so the notification will be considered to have been made on the day of its publication and will take effect on the next business day

The administrative acts referred to in this consideration will be available for at least thirty days after the date on which they have been published on the electronic notice board; once this period has elapsed they will be archived.

The “user” accepts that it is their obligation and responsibility to permanently consult the notifications derived from the procedures presented through DIGIPRIS: Online Regulation, also considering the notification availability notices that are sent to them; as well as the electronic board established for this purpose.



Eleventh.- COFEPRIS, for the evaluation, opinion and resolution of the procedure, will integrate an electronic file that will include the information and documentation.

Twelfth.- For the purposes of DIGIPRIS, all days of the year will be considered working days, with the exception of Saturdays and Sundays, as well as those that the legal provisions and the Secretarial Agreements of the Agencies indicate as non-working days.

For scheduling purposes, the time used will be that of Central Mexico.

Any procedures or transactions carried out after 6:00 p.m. or on non-working days will be considered to have been carried out on the next working day.

Thirteenth.- For the calculation of deadlines, the date of the acknowledgment of notification, which DIGIPRIS generates and transmits when opening the administrative act in question, or, where applicable, the digital documents generated with respect to the publication on the electronic board of the administrative act in question, will be taken into account.

Fourteenth.- When the supply of information is interrupted due to connection or communication problems attributable to COFEPRIS or inconsistencies in DIGIPRIS: Online Regulation, the deadlines indicated in these terms of use will be interrupted, provided that notice is given through the official means of communication available to the commission.

The "user" must acknowledge and accept that, due to the inherent nature of the services provided through DIGIPRIS, they may be subject to internet or connectivity limitations, as well as other factors external to COFEPRIS. In such cases, the "user" releases COFEPRIS from all liability for any damages that may arise from such events, and the deadlines specified in this document will not be considered suspended.

Fifteenth.- The information and attention provided through the DIGIRPIS service is issued in accordance with legal provisions, therefore it is not binding, does not create, exclude, or establish rights or obligations other than those established in the aforementioned legal provisions.

Access to the DIGIPRIS service by the "user" is a free service without having to provide any consideration in order to enjoy it.

Sixteenth.- The "user" undertakes to use the information, content or services offered through the DIGIPRIS service in a lawful manner without contravening the provisions of these "terms of use", morality or public order and will refrain from carrying out any act that may imply an impact on the rights of third parties, or are contrary to good computer practices and/or the applicable current regulations.



The “user” may not under any circumstances use devices, software, add-ons, malware or any other means intended to interfere with the activities and/or operations of the DIGIPRIS service, likewise the content of the DIGIPRIS service may not be linked or reproduced from websites, platforms, forums, chats, blogs or social networks.

The “user” is responsible for taking the necessary security measures during access to DIGIPRIS to ensure that their information will not be exposed to computer risks such as computer viruses, malicious computer code or other forms of computer threats, which may damage their computer equipment or mobile device or expose information or documentation that may be confidential or reserved.

Seventeenth.- COFEPRIS will carry out the actions that allow it to maintain the proper functioning of the DIGIPRIS service.

The “user” agrees that DIGIPRIS may record and store the information provided for statistical purposes and quality of service provided.

Eighteenth.- In DIGIPRIS, there may be links to internet sites or other pages; however, these links are provided for informational purposes only, so the content or resources of those sites or pages mentioned, or even the processing of personal data that is done in them, will be the exclusive responsibility of the Agency or Entity that in accordance with the Law is responsible for the portal and the corresponding data processing.

Nineteenth.- DIGIPRIS has security measures, policies and programs for information security and personal data protection, based on article 30 of the General Law on the Protection of Personal Data Held by Obligated Entities, with the objective of providing a secure service, protecting personal data and information in compliance with the corresponding legal framework.

Twentieth.- The comprehensive privacy notice of COFEPRIS is available at the following electronic link:

[https://tramiteselectronicos02.cofepris.gob.mx/Frontendnuevoportal/General/Privacy Notice](https://tramiteselectronicos02.cofepris.gob.mx/Frontendnuevoportal/General/Privacy%20Notice) or in the Personal Data Protection section at the access link:

[http://transparencia.cofepris.gob.mx/index.php/es/datos-personales.](http://transparencia.cofepris.gob.mx/index.php/es/datos-personales)

Likewise, COFEPRIS will not be responsible for any failure in security measures when such non-compliance is due to circumstances beyond its control, fortuitous event or force majeure.



Twenty-first.— In cases where it is specified that users may access public information, before reproducing it, they must check if it is protected by copyright and respect those rights in accordance with the regulations concerning copyright and industrial property. Additionally, if they reproduce or process public information contained in DIGIPRIS, they must cite the electronic location and date on which the information was accessed. The “user” must commit to respecting and safeguarding the rights of third parties over the public content accessed through DIGIPRIS, in accordance with applicable law. Therefore, for its use, they must obtain the corresponding authorizations directly from the owners of the personal data, as stipulated in the General Law on the Protection of Personal Data Held by Obligated Entities.

Twenty-second.- The reproduction, distribution, or dissemination of the contents of the DIGIPRIS service for commercial purposes, in any medium and by any means, is expressly prohibited without the authorization of COFEPRIS.

The “user” shall refrain from deleting, altering, or manipulating any element, file, or content of the DIGIPRIS service and shall not for any reason perform acts intended to compromise security.

Twenty-third.- COFEPRIS reserves the right to file any civil or criminal actions it deems necessary for the improper use of the DIGIPRIS service, or for non-compliance with these “terms of use”.

Twenty-fourth.- COFEPRIS reserves the right to modify without prior notice the presentation, content, functionality and configuration that may be contained in the DIGIPRIS service; as well as improve existing features or add new functions or features to the service, implement advances in science and technology and reasonable technical adjustments to the service, guaranteeing its operability and security. In this sense, the “user” recognizes and accepts that COFEPRIS may interrupt any access to the service in question at any time.

Twenty-fifth.- COFEPRIS reserves the right to modify these “terms of use” without prior notice.

Twenty-sixth.- Technical, usage and operation queries arising from the application of DIGIPRIS will be received through the email address: ***sigc@salud.gob.mx***