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**MEASURES TO ENSURE THE AVAILABILITY AND PREVENT THE ABUSE OF CONTROLLED DRUGS**

# Federal Commission for the Protection against Health Risks

## Executive Directorate for the Regulation of Narcotics, Psychotropic and Chemical Substances

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Measures to ensure the availability and prevent the  
abuse of controlled drugs

Mexico City - April 25, 2018

# Overview

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The importance of having narcotic drugs and psychotropic substances at the disposal of those who require these supplies for medical and scientific purposes is highlighted in international human rights instruments as well as in the resolutions of The Commission on Narcotic Drugs, the World Health Assembly and some regional intergovernmental organizations.

The adequate availability of narcotic drugs for medical and scientific purposes is a principle established in the 1961 Single Convention on Narcotic Drugs, as amended by the Protocol of 1972. Subsequently, it was recognized that psychotropic substances were also indispensable for medical and scientific purposes.

In the 1971 Convention on Psychotropic Substances, the Parties further recognized that the availability of such substances should not be improperly restricted.

# Overview

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The abuse of addictive substances, constitutes a complex phenomenon that has adverse consequences for individual health, for the family cohesiveness and in development and social stability. Although the entire society is currently exposed to drugs, there are groups that are more vulnerable than others that suffer from the negative consequences of their abuse, such as children and young people.

However, the use of the same substances for medical purposes is of great importance to the improvement of the quality of life of the people who genuinely need them.

# Narcotics

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Opioid analgesics, such as morphine, are essential for the treatment of moderate to severe pain caused by different factors such as: surgical interventions, chronic diseases, cancer, among others.

The INCB estimates that 92% of morphine is consumed in countries where only 17% of the world's population lives. At the same time, 75% of the world's population, mainly in low-income countries, has limited or no access to adequate pain-relief treatments.

Reports have indicated that the increased abuse of opioid analgesics worldwide registered since 1991 was driven mainly by North America, Europe, Australia and New Zealand.

# Narcotics

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In Mexico, the low levels of consumption of opioid analgesics are neither due to their insufficient supply, nor to the supply of raw materials used in their production; some of the obstacles that have been identified as barriers to their availability are:

- Lack of training and awareness among health professionals.
- Fear of addiction.
- Limited economic resources, cultural aspects.

By observing the prevalence of health problems requiring palliative care, it is clear that such widespread conditions are seldom accompanied by adequate medical treatment and/or an infrastructure that provides the of palliative care services that are required.

# Narcotic and Psychotropic Substances

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Access to internationally controlled substances may also be improperly restricted for fear of their diversion to illicit channels and for fear of sanctions. The latter may be aggravated when legislation is stigmatizing and unclear, or when health professionals do not have sufficient knowledge.

The regulations required at national level, arising from the provisions of the drug control treaties, could discourage the prescription, dispensation and use of narcotic drugs when they become excessively restrictive without sufficient reason.



## Measures to ensure the availability and to prevent the abuse of controlled drugs

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In an effort to promote the proper use of narcotic and psychotropic substances for medical purposes; and at the same time to avoid the diversion and abuse of these substances, the Agreement through which the General Health Council declared mandatory comprehensive palliative care management schemes was published in the Official Journal of the Federation on December 26, 2014, along with the processes indicated in the Guide on the Comprehensive Management of Care.

*"The Ministry of Health through the Federal Commission for the Protection against Sanitary Risks will announce the general rules for the use of electronic control books for the medicines referred to in article 226, sections I, II and III of the Law General of Health; as well as the general rules for the use of electronic special formulas for the medicines referred to in article 226, fraction I of the General Health Law and that its prescription is made with the generic name and includes prescription options according to presentations .*

*These rules should establish measures to expedite the availability of the aforementioned drugs ".*



## Measures to ensure availability and prevent abuse of controlled drugs

In accordance with the **AGREEMENT**, the COFEPRIS issued the general rules for the electronic processing of permits for the use of special prescription barcodes for medicinal products in part I of article 226 of the General Health Act, and were published in the Official Journal of the Federation on October 14, 2015.



The screenshot shows the website interface for the Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS). The main navigation bar includes 'gob.mx', 'Trámites', 'Gobierno', 'Participa', 'Datos', and a search bar. A secondary menu contains 'Blog', 'Trámites', 'Prensa', 'Multimedia', 'Acciones y programas', 'Documentos', 'Contacto', and 'Transparencia'. The breadcrumb trail indicates the current page is 'Acciones y Programas'.

The featured article is titled 'Sistema de recetarios electrónicos para medicamentos de Fracción I'. It includes a text description: 'La plataforma de recetarios electrónicos permite a médicos tramitar sus recetarios especiales para estupefacientes y a farmacias validar las recetas de este tipo para su dispensación.' Below the text is a 'Portal para médicos' section with a brief description of the service. A sidebar on the right displays a sample of the electronic prescription form, which includes fields for patient name, address, medication details, and a QR code. At the bottom of the sidebar, there is a box with the author information: 'Autor: Comisión Federal para la Protección contra Riesgos Sanitarios' and 'Fecha de publicación: 13 de diciembre de 2016'. A dark button at the bottom right of the page reads 'Contesta nuestra encuesta de satisfacción.'

## Measures to ensure availability and prevent abuse of controlled drugs

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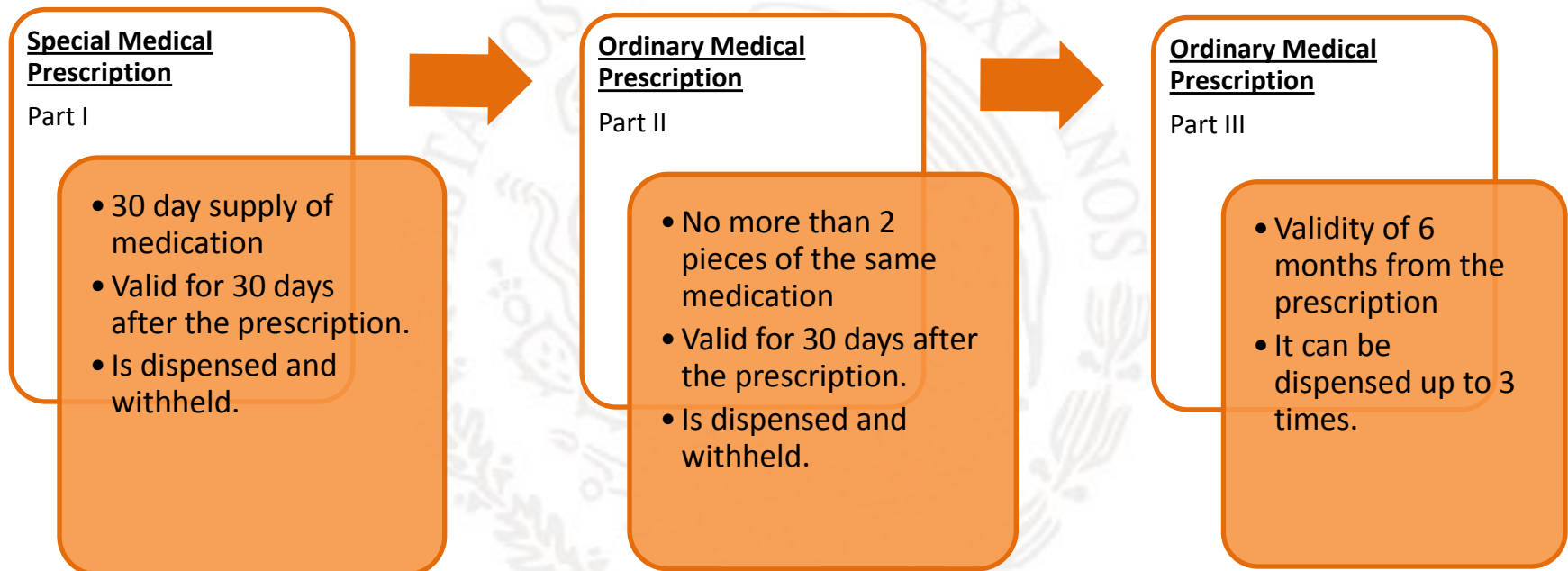
### I. Special formularies for prescription drugs.

- Benefits of drug formularies generated through the electronic portal:
  - a. The doctor does not have to go the offices of COFEPRIS.
  - b. The confidentiality of the physician's identity data is guaranteed by being encrypted in the two-dimensional code.
  - c. The completion of the procedure is in a maximum of 5 days for the first time and one day for the subsequent modality.
  - d. 200 prescriptions are generated in PDF format per procedure (unlike the 50 of the physical procedure).
  - e. The electronic file in PDF format that is delivered to the requesting physician can be printed on any printer.
  - f. The electronic validation of the prescription by means of the alphanumeric reference of the two-dimensional code and the folio number of the prescription allow for validation by the pharmacies before being dispensed.

# Measures to ensure availability and prevent abuse of controlled drugs

## I. Special formularies for prescription drugs.

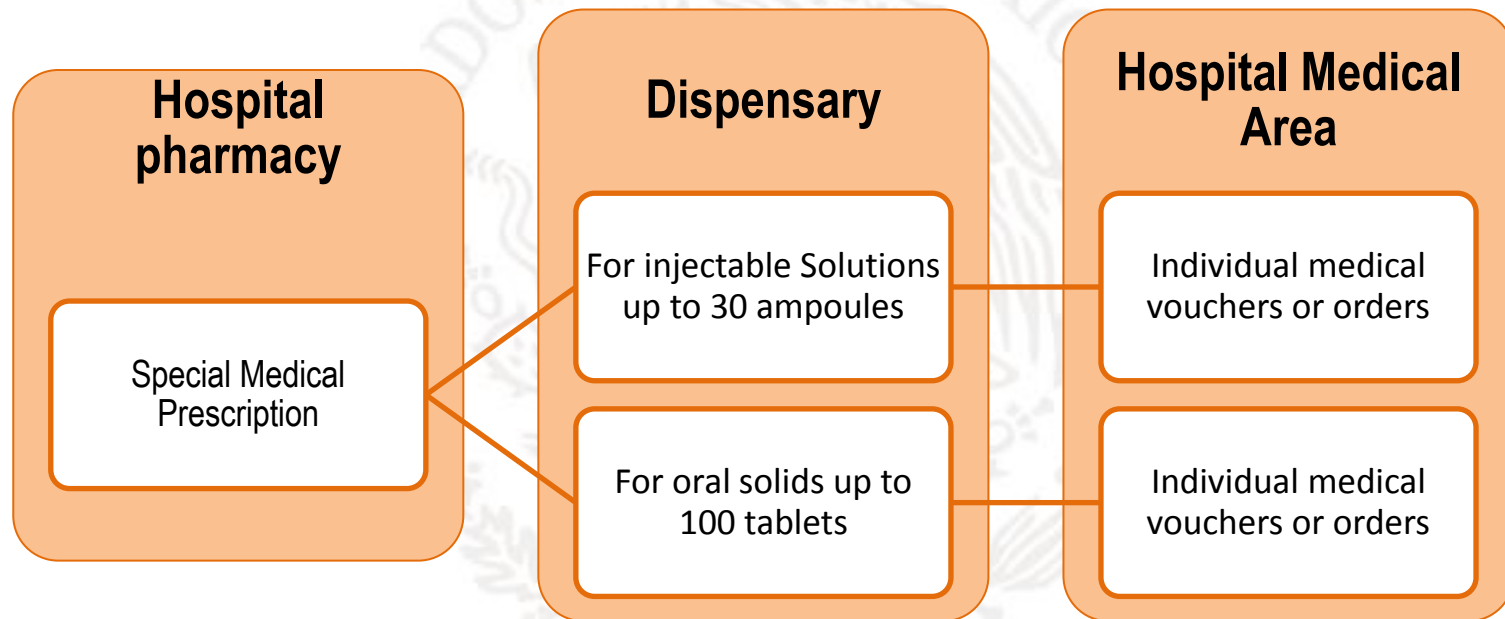
Dispensing special and ordinary medical prescriptions



## Measures to ensure availability and prevent abuse of controlled drugs

### I. Special formularies for prescription drugs.

Dispensing special prescriptions in the hospital pharmacy for use in multiple patients



# Measures to ensure availability and prevent abuse of controlled drugs

## Authorized Control Books

This page is dedicated to: \_\_\_\_\_

Passes to Folio: \_\_\_\_\_

Folio number: \_\_\_\_\_

| Date of activity | Origin (company name) | Doctor and Address | Professional Certificate | Medical prescription Number and date | Number of invoice of purchase/sale | Set | Quantity Purchased | Quantity Sold | Balance | Observations |
|------------------|-----------------------|--------------------|--------------------------|--------------------------------------|------------------------------------|-----|--------------------|---------------|---------|--------------|
|                  |                       |                    |                          |                                      |                                    |     |                    |               |         |              |

**BALANCE**



**STOCK**



**DID NOT VERIFY GOOD HANDLING AND CONTROL**

## Measures to ensure availability and prevent abuse of controlled drugs

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### II. Health surveillance and verification.

#### a) *Legal documents of the establishment*

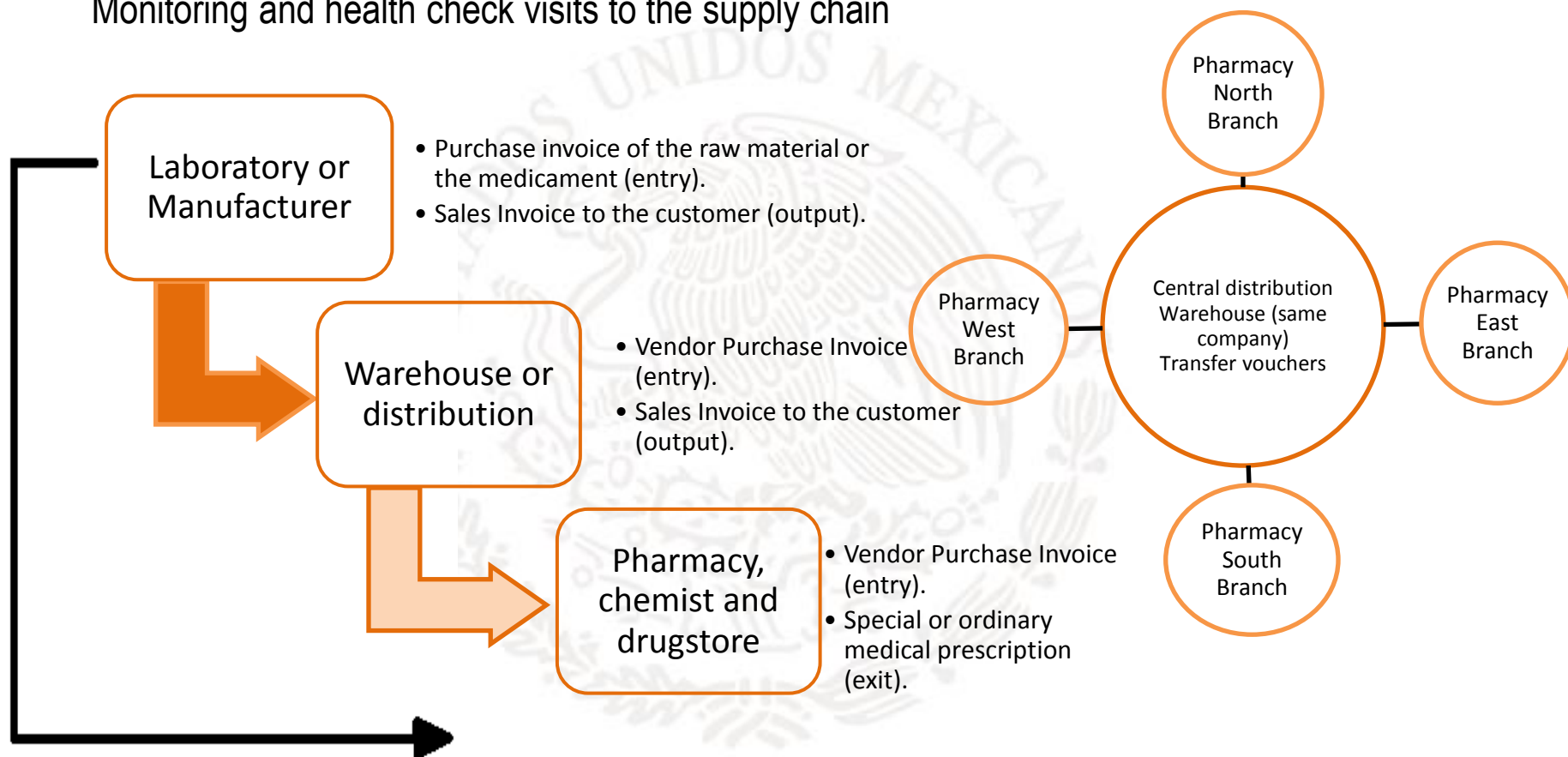
- Healthcare license.
- Declaration of Doctor in Charge
- Authorized Control Books
- Purchase Invoices
- Standard Operating Procedures
- Special and ordinary medical prescriptions



## Measures to ensure availability and prevent abuse of controlled drugs

### II. Health surveillance and verification.

Monitoring and health check visits to the supply chain



## Measures to ensure availability and prevent abuse of controlled drugs

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### III. Health promotion

**UNODC** has carried out a situational diagnosis of the care and availability of controlled substances in hospitals and the COFEPRIS has supported this with health promotion visits and distributing the "**Guide for the sale of controlled drugs in pharmacies**", to inform these establishments about the guidelines and applicable norms .

This guide contains:

- Legal framework
- Self-assessment questionnaire
- Detailed explanation of special prescriptions and validation in the pharmacy portal
- Details of the verifications, security measures and penalties

## Measures to ensure availability and prevent abuse of controlled drugs

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### III. Health promotion

#### Objectives of the Guide :

1. Ensure the **traceability** of the medicines.
2. Accurately identify their **correct dispensation** as well as the legal possession of them.
3. Ensure supply and, at the same time, avoid health risks associated with their abuse or diversion.

## Measures to ensure availability and prevent abuse of controlled drugs

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### IV. Conclusions

With the above-mentioned promotion, regulation and surveillance actions, we are pursuing the following objectives:

- **To ensure the availability and supply** of international controlled substances in compliance with the necessary measures for the provision of medicinal products required for medical care in and outside health institutions, while preserving balance between their availability, accessibility and use.
- **Training and sensitization of** Health professionals, public policy makers and the general population who are reflected in the use of these substances in an appropriate way.
- **To guarantee the traceability** of the medicines precisely identifying their correct dispensation.
- **Avoid health risks** associated with their abuse or diversion.

# Thank you

**Lic. Alberto Miguel Guzmán**

**Executive Director of the Regulation of Narcotics, Psychotropic  
and**

**Chemical Substances**

**[amiguel@cofepris.gob.mx](mailto:amiguel@cofepris.gob.mx)**

**Tel. 50805200 Ext. 1041**

**We are COFEPRIS,  
We are ARN**