

2013

Improving Global Opioid Availability for Pain & Palliative Care:

A Guide to a Pilot Evaluation of National Policy



Pain & Policy Studies Group

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Carbone Cancer Center

www.painpolicy.wisc.edu

December 2013

Supported by:

LIVESTRONG

FOUNDATION

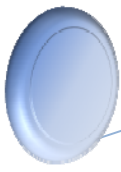


TABLE OF CONTENTS

Executive Summary

Acknowledgment of Support, Citation, Notes to the Reader

Section I: Purpose and Audience

Section II: Policy Research Terms

Section III: Background

Section IV: The Central Principle of *Balance*

Section V: The International Imperative to Evaluate National Policy for *Balance*

Section VI: Improving Patient Pain Care: Other Issues to Consider in Relation to Policy

Section VII: Research Methodology

Section VIII: Research Criteria

Section IX: Results – Country Profiles of National Policies Governing Drug Control and Medical and Pharmacy Practice

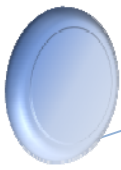
References

Appendix A: Ensuring Medications for Legitimate Purposes Should Not Escalate Diversion

Appendix B: Recommended Readings

Appendix C: Morphine Manifesto

Appendix D: International Authoritative Sources for the Central Principle of *Balance*



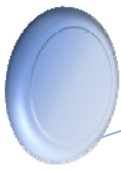
EXECUTIVE SUMMARY

Recently, significant international attention has focused on disparities among countries regarding access to effective treatment for patients with severe or debilitating pain from the disease of cancer, including cancer survivors, as well as for those with other life-threatening diseases in need of palliative care services or end-of-life care. Such treatment disparities can have many causes, but a prevalent factor acknowledged by drug control, regulatory, and health care organizations relates to the inadequate availability of medications indicated for the relief of severe pain – that of opioid analgesics such as morphine. In fact, the World Health Organization (WHO) has designated morphine as an essential medicine for managing pain. At the same time, opioids have an abuse liability and are classified as controlled medicines under the Single Convention on Narcotic Drugs of 1961 (Single Convention), which means that they are subject to governmental control to reduce their trafficking and abuse and to limit their use to medical and scientific purposes. Importantly, Single Convention language has been interpreted by United Nations authorities as obligating governments that are party to the treaty to establish a drug control system that permits medication availability for legitimate uses; attainment of these dual objectives of drug control and medication availability has been referred to as *Balance*.

The drug control requirements of the Single Convention remain critically important due to the deleterious public health consequences that result from the diversion and abuse of controlled substances. Similarly, the availability of controlled medicines is essential to better assure patient access to effective treatment. As a result, these dual objectives are equally essential and one should not be sacrificed for the sake of the other. In fact, sufficient medication availability can only occur within a control system that contains availability provisions and that is not overly burdensome. Research reports have demonstrated, however, that a number of countries' laws fail to recognize medication availability as a drug control objective. This prevalent situation contributes, at least partly, to the current treatment disparities.

It is the Single Convention's framework of *Balance* that guides and serves as the basis for the policy research described in this report. A number of evaluation criteria were developed to determine the extent that a country's legislation and regulations governing drug control and professional healthcare practices also: (1) address medication availability, (2) promote safe and effective pain relief, and (3) avoid requirements or ambiguities that could produce restrictions or impediments to appropriate treatment. Although the viability and applicability of these criteria were originally pilot tested on a small sample of Latin American countries, the results of which serve as the findings for this report, it is anticipated that the evaluation methodology will be generalizable globally. Results from this type of research can be used to inform in-country activities to identify relevant policy language that can be added to law or, conversely, repealed from law.

Of course, it should be recognized that not all people will benefit from opioid treatment. However, there is broad acknowledgement that barriers contained in policy make it more likely that people who could benefit do not have the opportunity to do so because appropriate therapeutic options are not available. We are confident that this criteria-based policy analysis tool can be a useful resource for professionals in countries seeking to improve the availability of controlled opioid medicines for medical purposes – and to do so without compromising the overall capacity of the drug control system; again, *Balanced* national policy relating to legitimate medication availability is the objective of this research. It is our hope that recommendations from this and future national policy evaluations will, cumulatively, serve to enhance patients' access to effective pain relief and palliative care throughout the developing world.



ACKNOWLEDGEMENT OF SUPPORT

This report benefited greatly from the thoughtful comments that the following expert reviewers provided:

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This current policy research, and this resulting *Global Evaluation Guide*, is funded through a cooperative agreement with Livestrong.

CITATION

This report may be quoted or reproduced in whole or in part for educational purposes. The citation for the report is:

Pain & Policy Studies Group. *Improving Global Opioid Availability for Pain & Palliative Care: A Guide to a Pilot Evaluation of National Policy*. University of Wisconsin Carbone Cancer Center. Madison, WI; 2013.

NOTES TO THE READER

This document is one product of the ongoing policy research program of the Pain & Policy Studies Group. Our purpose for making these research results available is to promote education and policy change. We ask that anyone who wishes to use the policy data published herein for the purposes of research seek permission from the PPSG.

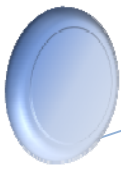
Policies are in constant flux, and the results presented herein pertain to policies adopted through November 1, 2013. Also, the material in this report does not represent legal or medical advice. Individuals who need to know the current policy for legal or advocacy purposes should double-check the current status of any policies in question; PPSG is happy to assist individuals in locating current policies.

This *Global Evaluation Guide* is available on the PPSG website at www.painpolicy.wisc.edu. Comments and suggestions are welcome and may be directed to:

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The Pain & Policy Studies Group

The Pain & Policy Studies Group (PPSG) is a global research program at the University of Wisconsin [Carbone Cancer Center](#) within the [School of Medicine and Public Health](#). The PPSG mission is to improve global pain relief by achieving balanced access to opioids in an effort to enhance the quality of life of people living with cancer and other painful diseases. The PPSG's work, guided by a public health approach, aims to address governmental and regulatory environments governing professional healthcare practice relating to pain management, including barriers to legitimate access of prescription opioid analgesics that are essential for severe pain relief and palliative care. Such efforts are achieved through effective public policy, communications, and outreach efforts. The PPSG is nationally and internationally recognized for its work and leadership to improve availability of opioid pain medicines, having been at the forefront of such efforts since its creation in 1996, since which time it has been the home of a [World Health Organization \(WHO\) Collaborating Center](#).



SECTION I: PURPOSE AND AUDIENCE

PURPOSE

The purpose of this report, entitled “Improving Global Opioid Availability for Pain & Palliative Care: A Guide to a Pilot Evaluation of National Policy” (*Global Evaluation Guide*), is to promote more consistent country policy governing the medical management of pain generally, as well as specifically in palliative care, that allows for the legitimate use of controlled medicines. This report represents a pilot study founded on the conviction that any nation’s governmental and regulatory policies can be examined systematically using valid criteria, as a means to inform activities to better align policy content with established pain management standards and international drug control requirements. For this to transpire, policy language must be evaluated according to structured criteria. International legal, regulatory, and health care authorities have continually called for the examination of countries’ policies, in relation to their impact on pain management and medication availability. When such activity occurs, policy language can be identified that, when implemented into practice, has the potential to either (1) promote safe and effective pain management through legitimate professional practice, or (2) create barriers to safe and effective pain management by imposing severe restrictions or creating practice ambiguities.

This *Global Evaluation Guide* provides a conceptual and methodological framework for identifying policy content that should be examined and addressed, including the identification of language to guide the development of new or revised policies that maintain medication availability and assure that patient care decisions requiring medical expertise are not unjustifiably limited – again, this concept is the foundation of the current pilot study to address international policy.¹ Such policy related to pain management issues can be accomplished and preserved if government authorities, regulatory agency members, and healthcare professionals collaborate and successfully utilize the policy resources that are available. When this is effectively undertaken, a more positive legislative, regulatory, and practice environment can be achieved to treat pain in all patients, including those who are challenged by cancer, HIV/AIDS, polio, sickle-cell anemia, and other painful conditions.

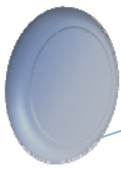
To achieve the goal of policy improvement among countries, this *Global Evaluation Guide*:

(1) describes a broad set of evaluation criteria that was developed to be applied to country’s governmental and regulatory policies to evaluate for the presence or absence of provisions that have the potential to either positively or negatively affect pain management, and provides the legal, regulatory and health care authoritative sources to justify this evaluation and specific criteria, including the World Health Organization, the International Narcotics Control Board, the Commission on Narcotic Drugs, the Economic and Social Council, the United Nations Office on Drugs and Crime, and the World Medical Association,

(2) explains the Central Principle of *Balance* and the sources of authority from which it is derived, as well as the bases of the international call to evaluate for the presence of *Balance* in national policy,

(3) presents the findings from a criteria-based evaluation of national policies that were current and available as of November 1, 2013, which highlights relevant language identified in the evaluated countries that can be used to achieve more improved policies either by their inclusion or removal,

¹ This concept, referred to as and established *Balance* in international drug control treaty, is described in greater detail in [Section IV](#).



SECTION I: PURPOSE AND AUDIENCE

(4) describes authoritative international support for the need for countries to continue efforts to implement a legal and regulatory framework to prevent prescription medication diversion and abuse, while also maintaining medication access for medical and scientific purposes (see [Appendix A](#)), and

(5) provides a bibliography of recommended international readings about the legislative and regulatory issues related to treatment of pain, including with the use of controlled medicines (see [Appendix B](#) for recommended readings).

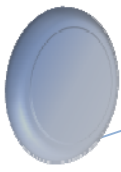
USING POLICY EVALUATION TO INFORM POLICY CHANGE

Results contained in the *Global Evaluation Guide* can be used to learn about the content of national policies that can influence pain management practices in various countries, which can provide an evidence-based foundation to promote changes to achieve policy that promotes safe and effective pain management. This document provides the results from a transparent evaluative framework that can help inform an action plan to remove impediments in, or add positive provisions to, current national policy, or to promote the adoption of new policy. This report is a tool that can be used by government and non-government organizations, as well as policymakers, healthcare professionals, and advocates, to understand the policy in their country that reinforce the legitimacy of pain management or palliative care and those that can hinder patient access to appropriate treatment.

Importantly, none of the provisions that were identified through this evaluation were subjected to a weighting strategy to represent the significance of a particular requirement. Indeed, experience may suggest that some provisions have the potential to influence healthcare practice or patient care to a greater extent than others; however, a valid weighting scheme is not possible due to relevant evidence being generally unavailable for all provisions. As a result, national efforts to improve government and regulatory policy can be informed by the relative importance placed on specific provisions on a country-specific basis.

Once potential impediments have been identified in a country's laws, it is often the case that considerations must be made to determine the most feasible approach to address this situation (Bosnjak, Maurer, Ryan, Leon, & Madiye, 2011; Cleary, Radbruch, Torode, & Cherny, 2013b; Leon et al., 2009). In all cases, policy adoption or improvement must be understood as being only an important step in enhancing effective pain relief – policy must be properly implemented and disseminated to enhance the potential for it to be effective.

Finally, the findings contained in this report should not be interpreted as constituting a “position statement,” but rather represent results from an analysis of current policy content guided by use of evaluation criteria. Although the evaluation methodology used for this project was designed to yield a comprehensive evaluation of applicable policies, it is possible that other relevant policy language exists that ultimately was overlooked due to translational or other issues. In addition, we acknowledge that others may disagree with our interpretation of policy provisions or with our application of the criteria, although this was vetted by our expert reviewers. The PPSG encourages suggestions to improve this work.

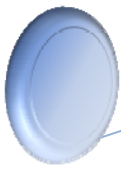


SECTION I: PURPOSE AND AUDIENCE

AUDIENCE

The intended audience for the *Global Evaluation Guide* is individuals or organizations interested in improving policy relevant to pain treatment, palliative care, or end-of-life care, including:

- the National and State Legislatures,
- National or state government or regulatory agencies (e.g., Ministry of Health),
- associations of healthcare professionals,
- multidisciplinary advisory councils, committees and task forces,
- state or regional pain and palliative care associations,
- international health authorities (e.g., World Health Organization),
- international drug control authorities (e.g., United Nations Office on Drugs and Crime),
- international, regional or national cancer, HIV/AIDS, pain, and hospice and palliative care non-governmental organizations, and
- individual practitioners.



SECTION II: POLICY RESEARCH TERMS

Use of Pain Policy Research Terms

Policy Research Terms

Pain policy refers to national policy that relates to pain management, and is generally found in two categories: **Pain-specific** policies directly address pain or palliative care.

Pain-related policies do not directly address pain management but contain provisions that could ultimately affect its treatment, such as laws that address generally the prescribing and dispensing of controlled substances.

Within pain policies are:

Provisions: policy language that was identified as satisfying an evaluation criterion, and include

positive provisions, which are those parts of a policy identified in the evaluation that have the potential to enhance pain management, and

negative provisions, which are those parts of a policy identified in the evaluation that have the potential to impede pain management.

Policy change is the addition or removal of provisions; sufficient policy change in a country will produce a **grade change** for that country.

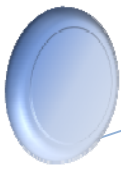
Policy Types

There are several types of policies. For the purpose of this pilot evaluation, focusing on policies from Latin America, the policy types are characterized as follows:

Law (Ley) is a broad term that refers to rules of conduct with binding legal force adopted by a legislative or other government body at the national, state or local levels. **Organic Law (Ley Organica)** is a foundational or fundamental law that establishes the basis for other types of law by regulating the organization, power, and function of government agencies, while **General Law** or **Ordinary Law (Ley General** or **Ley Ordinarias)** typically is less important but nevertheless binding and is subject to the power of the legislature that enacted it.

Regulation (Reglamentos, Normativos, Acuerdo, Decreto, or Resolución) is an official policy issued by an agency of the executive branch of government pursuant to statutory authority. Regulations are found in administrative codes. Regulations have binding legal force and are intended to implement the administrative policies of a statutorily-created agency. For example, regulations issued by licensing boards according to a country's administrative procedures statute govern professional conduct, and establish what conduct is or is not acceptable for those regulated by the agency (such as physicians, pharmacists, and nurses). Regulations of administrative agencies may not exceed the agency's statutory authority.

Guideline (Lineamientos) means an officially adopted policy issued by a government agency to express the agency's attitude about, or position on, a particular matter. Although guidelines do not have binding legal force, they may help those regulated by an agency to better understand the regulating agency's standards of practice. "Guidelines" may also include an officially adopted position statement that appears in a position paper, report, article, letter or agency newsletter.



SECTION III: BACKGROUND

GLOBAL EPIDEMIOLOGIC DISEASE TRENDS

Global health is a dynamic field that must respond to the epidemiologic transition from infectious diseases to non-communicable diseases (NCDs) as leading health threats. NCDs are the leading cause of functional impairment worldwide, and now account for 60% of global deaths, with 80% of those deaths occurring in low- and middle-income countries (LMICs) (World Health Organization, 2011b). Of the NCDs, cancer is a significant and growing problem. Leading international health experts agree that meeting global cancer needs will require new funding sources and a greater targeting of interventions (Soerjomataram et al., 2012).

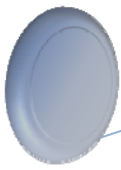
According to the World Health Organization (WHO) (World Health Organization, 2008a; 2011b), cancer accounts for more global deaths than AIDS, tuberculosis, and malaria combined (Jemal et al., 2011). Cancer deaths worldwide have doubled in the past 30 years, are expected to double again by 2020, and are predicted to reach 17 million annually by 2030 (World Health Organization, 2008b). In 2007, over 70% of all cancer deaths occurred in LMICs, and this trend is projected to continue (Kachroo & Etzel, 2009). In fact, the proportion of the total global cancer burden borne by these countries is expected to increase 4-fold, from 15% in 1970 to 60% by 2020 (Kachroo & Etzel, 2009).

The global occurrence of HIV/AIDS also is a critical public health problem. The Joint United Nations Programme on HIV/AIDS (UNAIDS, 2010) reported that, in 2009, 33.3 million people were living with HIV/AIDS, 2.6 million were newly infected, and 1.8 million people died from AIDS. Although HIV/AIDS is considered a communicable disease, those infected often experience AIDS-related cancers and other painful symptoms as the disease progresses (Selwyn, 2005; Woodruff & Cameron, 2010).

UNRELIEVED PAIN IS A GLOBAL PROBLEM

Global health inequalities abound both between and within countries (Friel & Marmot, 2011). In developing countries, people are more likely than those in developed countries to seek treatment late in the disease course, presenting with severe pain or other distressing conditions. Despite evidence that pain and suffering is known to afflict those with advanced cancers (Bruera, 1993; Grond, Zech, Diefenbach, & Bischoff, 1994; Portenoy et al., 1994; Vainio & Auvinen, 1996) and late-stage HIV/AIDS (Lohman, Schleifer, & Amon, 2010; Woodruff & Cameron, 2010), pain is largely underdiagnosed and undertreated in developing countries. In fact, the WHO estimates that, worldwide, 5.5 million terminal cancer patients and 1 million end-stage HIV/AIDS patients are suffering without adequate treatment for moderate to severe pain (World Health Organization, 2012a). Insufficient pain relief has devastating consequences on quality of life and functional status, particularly when the pain is severe or debilitating.

For the majority of individuals living in developing countries, the need for symptom management is great but the chance for cure is slight because diagnostic tools and treatment methods are either non-existent or difficult to obtain. Palliative care, including the critically-important component of pain management, is a model of care focused on relieving symptoms of disease and its treatment and improving the patient and family's quality of life throughout the course of the disease (Center to Advance Palliative Care, 2011; Komurcu et al., 2000; National Hospice and Palliative Care Organization, 1999; World Health Organization, 2002). According to the Worldwide Palliative Care Alliance, at least 100 million people worldwide would benefit from palliative care every year; however, less than 8% of people who need palliative care have access to it (<http://www.thewpca.org/about-hospice-and-palliative-care/the-need/>). With more than 85% of the world's population living in developing countries, but only 6% of palliative care services throughout the world being located in these regions, the opportunity for palliative treatment of pain and other distressing symptoms is grossly inadequate



SECTION III: BACKGROUND

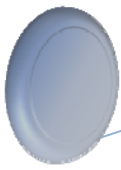
(Webster, Lacey, & Quine, 2007). Additionally, a 2011 study categorized countries according to their level of palliative care development and found that, while a majority (58%) of countries have established one or more palliative care services, a third reported having no identified palliative care activity (Lynch, Clark, & Connor, 2011).

There is a strong international imperative for palliative care, including pain management, to be included in national cancer and HIV/AIDS control efforts. In fact, both the need to address pain and the provision of palliative services in developing countries are complimentary public health objectives. The WHO has emphasized that palliative care be part of any national program aimed at reducing the overall burden of disease – it is, therefore, a government’s public health responsibility to develop a policy and program to address palliative care needs in the country. In their recent report on access to controlled medications, the WHO urged all governments to “ensure that patients have pain relief in accordance with national and international treatment guidelines” (Milani & Scholten, 2011, p. 25). In their 2008 World Cancer Declaration, the Union for International Cancer Control also called for effective pain control measures to be available universally to all cancer patients when needed (Union for International Cancer Control, 2013). These statements reinforce those from other international authorities, including the UN Economic and Social Council (ECOSOC) (United Nations Economic and Social Council, 2005b; 2010), the World Health Assembly (World Health Assembly, 2005), the International Association for the Study of Pain (International Association for the Study of Pain, 2010), and the Council of Europe (Council of Europe, 2003), who recognize access to pain relief as both a public health issue and a universal human right. In September 2011, the UN General Assembly called attention to the growing international epidemic of NCDs (including cancer) by holding a high-level meeting on the Prevention and Control of NCDs. The resulting Political Declaration acknowledges the importance of providing palliative care for people with NCDs, and calls for the use of affordable medicines (including generic formulations) for palliative care (Council of Europe, 2003; United Nations General Assembly, 2011).

OPIOIDS ARE ESSENTIAL MEDICINES FOR TREATING PAIN

Although there are many pharmacological and non-pharmacological modalities to treat pain, potent opioids in the class of morphine, and, in particular, orally-administered morphine, are regarded by international health experts as the gold standard for the treatment of moderate to severe pain (Caraceni et al., 2012; Chiu, Davis, & Burris, 2010; Council of Europe, 2003; Fallon, Cherny, & Hanks, 2010; Inturrisi & Lipman, 2010; Wiffen & McQuay, 2007). Since 1977, morphine has been designated by the WHO as an *essential medicine*, indicating that it should be available at all times and at a price the individual and the community can afford (World Health Organization, 1977). In 2005, at the request of WHO, the International Association for Hospice and Palliative Care (De Lima et al., 2007) recommended a list of essential medicines specifically for palliative care, which included four strong opioids indicated for the treatment of moderate to severe pain: Transdermal fentanyl, methadone, morphine (both immediate- and sustained-release preparations), and oxycodone. This list expanded upon WHO’s list of essential medicines to treat such pain, which previously included only morphine (both immediate- and sustained-release formulations), which has since been updated (World Health Organization, 2013).

The important role of opioids in pain management and palliative care was recently emphasized by the *Opioids in Palliative Care* guidelines from the UK’s National Institute for Health and Clinical Excellence (NICE), as well as the new authority for qualified pharmacists and nurses to independently prescribe opioids to treat pain (National Institute for Health and Clinical Excellence, 2012). The *Lancet* editorial section covered these events under the heading “Pain Control – A Basic Kindness” (The Lancet, 2012). In discussing these events, the editorial briefly outlined the prevalence of undertreated pain, the need for



SECTION III: BACKGROUND

appropriately-trained professionals, reasons for practitioners' reluctance to prescribe, and the need to balance preventing misuse with responsible prescribing (see the [Balancing Control and Availability](#) section below). These factors cumulatively contribute to a clinical practice environment promoting a considered approach for the medical use of opioids for pain and palliative care:

"...there is nothing intrinsically wrong with giving opioid drugs: it is all a question of appropriate use...Prescription drug misuse should be prevented, but the comfort of seriously ill patients cannot be sacrificed for fear of it. Though some patients may be beyond hope of cure, they are not beyond care. Opioid prescription in such cases is not just medical treatment: it is basic human kindness." (p. 2024)

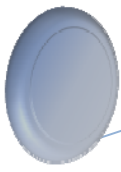
The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol (referred to as the Single Convention) (United Nations, 1972), is the international treaty governing the use of opioid medications. The Single Convention recognizes that these medications are indispensable for the treatment of pain and suffering and asserts that medical access to opioids for legitimate medical and scientific purposes, including relief of pain, is to be assured by governments (Chiu et al., 2010). To accomplish this, the Single Convention provides signatory countries with wide latitude to develop drug control systems based on the needs and resources of a particular country (see [Section IV](#) for a more comprehensive discussion of the Single Convention). By extension, the International Narcotics Control Board (INCB), the international authoritative body responsible for implementing the Single Convention, has repeatedly reiterated the important aim of the Single Convention to maintain medication availability. In fact, the INCB even has recommended that governments assess policies that affect opioid availability and remove impediments (see [Section V](#) for relevant INCB statements).

FACTORS CONTRIBUTING TO UNRELIEVED PAIN

Despite widespread acknowledgement of the essential clinical role of opioids for treating moderate to severe pain from cancer and for palliative care, there continues to be a global burden of unrelieved pain. It has been demonstrated that most patients in the developing world do not have access to essential medicines, including opioid pain medicines (International Narcotics Control Board, 2011; Krakauer, Wenk, Buitrago, Jenkins, & Scholten, 2010; Milani & Scholten, 2011; Silbermann, 2011; Vigil, Aday, & De Lima, 2007). At the country and regional levels, there are great disparities in the amount of morphine consumed between high-income countries and LMICs (Gilson, Maurer, Ryan, Rathouz, & Cleary, 2013). The INCB has consistently reported that a small number of high-income countries consume most of the morphine in the world, while the remaining countries, which have over 80% of the world's population, consume a small fraction (International Narcotics Control Board, 2011)

BARRIERS TO OPIOID AVAILABILITY AND ACCESSIBILITY

There are many systemic factors that contribute to the worldwide phenomenon of unrelieved pain. Many of the same factors that have been identified in the US and other high-income countries (Australian Crime Commission, 2011; Cherny, Baselga, De Conno, & Radbruch, 2010) also are prevalent in developing countries. These factors generally relate to the characteristics of the healthcare system, healthcare professionals, and healthcare consumers. The barriers to accessing oral morphine and other potent opioids can be summarized to include the following: (1) lack of knowledge on the part of healthcare professionals, (2) adverse events, (3) concern about dependence syndrome, withdrawal syndrome, and tolerance, (4) poorly-developed health care systems and medication supply, and (5) excessively-strict national or state laws and regulatory policies.



SECTION III: BACKGROUND

Lack of knowledge on the part of healthcare professionals

Incorrect or inadequate knowledge about pain and opioid treatment often underlies beliefs or attitudes that can result in medical and institutional practices that block legitimate medication access. Many health care professionals do not recognize the importance of pain management, or understand how to appropriately assess and relieve pain (Bistre & Strauss, 2012; Harding, Powell, Kiyange, Downing, & Mwangi-Powell, 2010; Human Rights Watch, 2011; International Narcotics Control Board, 1996; 2009b; Zenz, Zenz, Tryba, & Strumpf, 1995). Indeed, professional education programs often do not include training in current pain management practices. As a result, clinicians may either be reluctant to care for patients with pain or lack the confidence to prescribe medications like morphine. In addition, healthcare professionals have reported concerns about legal sanctions when using opioids for medical purposes, which can play a significant role in their reluctance to prescribe (Adams, 2007; American Geriatrics Society Panel on Persistent Pain in Older Persons, 2002; Anderson, Beletsky, Burris, Davis, & Kresina, 2009; Burris & Davis, 2009; Human Rights Watch, 2011; International Narcotics Control Board, 1996; 2009b; National Institutes of Health Consensus Development Program, 2002).

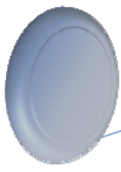
Adverse events

There are many apprehensions about the use of opioids because of the widespread stigma associated with being prescribed these medicines. Patients and families sometimes fear that using opioids to manage pain will result in adverse events. Some associate the use of opioids for pain with the implication that death is imminent. In addition, for those patients who are at the end of life, there often is a belief that opioids will hasten death. Empirical evidence suggests, however, that not only do opioids not hasten death, but that adequate relief from pain can actually improve quality of life and survival (Institute of Medicine Committee on Advancing Pain Research, 2011; Jolly & Cornock, 2003; Meier & Brawley, 2011; Rocque & Cleary, 2013; Temel et al., 2010; Van der Heide et al., 2003).

To be clear, there is a legitimate possibility of adverse events related to opioid therapy, of which prescribers should be aware and which should be monitored and addressed throughout treatment. Adverse events include such common conditions as constipation, sedation, and nausea, as well as the potential for transient cognitive impairment, hyperalgesia, sexual dysfunction, changes in hormone levels, immune system changes, and, in some cases, the development of dependence syndrome and overdose (Caraceni et al., 2012; Chou et al., 2009; Fallon et al., 2010; Hanks, Cherny, & Fallon, 2004; Institute of Medicine Committee on Advancing Pain Research, 2011). Although further evidence is needed to evaluate the extent that many of the more serious risks relate specifically to patients whose medications are taken in prescribed dosage regimens for medical purposes, especially when the patient does not have a history of substance abuse or dependence syndrome, practitioners should be knowledgeable about the clinical potential for these issues. It is, therefore, incumbent on the prescriber to be able to discuss with the patient the benefits and risks of opioid treatment and to periodically assess for particular outcomes once treatment is initiated (World Medical Association, 2011).

Concern about dependence syndrome, tolerance, and side effects

In 1995 and 2007, the INCB conducted surveys of government narcotic regulators to assess the worldwide implementation of international drug control treaties and recommendations concerning the use of opioids for medical purposes. Included in these surveys were questions that related to barriers affecting the supply and availability of narcotic drugs, including opioids. The barrier identified most frequently was concern about opioid-related dependence syndrome (referred to as “addiction” in the reports) (International Narcotics Control Board, 1996; 2008b). Historically, mere exposure to morphine



SECTION III: BACKGROUND

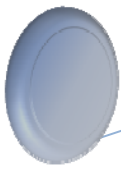
was thought to induce addiction, and evidence of a withdrawal syndrome (a physiological phenomenon expected from extended opioid use) was its principal characteristic (World Health Organization, 1950a; 1952). Early conceptualizations of addiction were developed before pain management and palliative care became a treatment priority. More recent understanding about the biopsychosocial mechanisms of dependence syndrome has led to official recognition that its diagnosis depends on the primary characteristics of compulsive behavior and continued use despite harm, whether or not a withdrawal syndrome or analgesic tolerance is present (American Psychiatric Association, 2013; World Health Organization, 1992; 2006a).

Evidence suggests that dependence syndrome—when defined correctly and applied appropriately—is not an inevitable consequence when opioids are used to relieve pain, especially when a patient does not have an addictive disease, has no history of substance abuse, or is not experiencing psychosocial stressors (Minozzi, Amato, & Davoli, 2012; World Health Organization, 2011a). Nevertheless, misperceptions about dependence syndrome have led some practitioners to avoid prescribing opioids and other controlled medicines, which can limit the availability of sufficient treatment for individuals experiencing severe pain. Continued efforts are needed to not only increase practitioners' awareness of the characteristics of dependence syndrome, but also to utilize methods to competently assess and address its potential manifestation throughout treatment, as a standard procedure in clinical practice (Chou et al., 2009; Kahan, Mailis-Gagnon, Wilson, & Srivastava, 2011; National Institute for Health and Clinical Excellence, 2009; World Health Organization, 2012b).

Poorly-developed health care systems and medication supply

A weak health care infrastructure creates problems in access to basic services and is a typical constraint to obtaining pain relief and palliative care (Vigil et al., 2007). This is found especially, but not only, in developing countries and in countries with remote areas and challenging geography. A related problem is the costs associated with opioids, with comparative analyses demonstrating wide cost variability throughout the world. Studies of developed and developing countries found opioid costs relative to income was significantly higher in developing countries than in developed countries (De Conno, Ripamonti, & Brunelli, 2005; De Lima, Sweeney, Palmer, & Bruera, 2004; Mercadante, 1999; Moyano, Ruiz, Esser, Bruera, & Vainio, 2006). Without the infrastructure to support treatment with opioids, these essential medicines may not be available in the quantities or in regions needed.

On a related issue, developing countries have long lacked the availability of immediate release (IR) oral morphine amid wide availability of sustained release (SR) oral morphine. In many countries, SR oral morphine is being made available in advance of, or even instead of, IR oral morphine (Cherny et al., 2010). In fact, IR morphine is a better choice as a first-line treatment for acute or cancer pain, and is important for initial titration, especially in opioid naïve patients (Fitzgibbon, 2010; National Cancer Institute, 2013). Because SR formulations are more costly, providing these preparations prior to, or in the absence of, IR formulations creates a systematic barrier to adequate pain control. In early 2012, the global pain and palliative care community addressed this situation directly for the first time, with the release of the Morphine Manifesto (<http://palliumindia.org/manifesto/>) (see [Appendix C](#)), calling for affordable availability of IR oral morphine in advance of SR morphine. It is important to consider the context within which analgesic formulations are introduced, rather than considering efficacy alone, in determining best practice for pain management and palliative care.



SECTION III: BACKGROUND

Excessively-strict country laws or regulatory policies

Many of the barriers previously described can be exacerbated, at least in part, by restrictive drug-related public policies. Given that the main responsibility of governments is to protect public health and safety, it is reasonable and necessary for governments to implement national drug control laws and other policies to prevent harm caused by diversion of opioids for non-medical uses. The INCB has recognized, however, that some legislators and administrators have attempted to minimize drug abuse by enacting laws, regulations, and administrative policies that ultimately impede the legitimate availability of opioids for medical purposes (International Narcotics Control Board, 1989; 1999; 2007; 2011). Examples of identified policy barriers include:

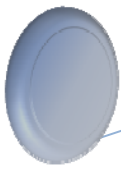
- complex prescription forms and prescription books that must be obtained from the government with considerable difficulty,
- restrictions that limit treatment based on the diagnoses of eligible patients,
- limitations on prescription amount to hours or a few days,
- severe limitations on the number of days that a prescription is valid until dispensed, and
- elaborate licensing requirements for healthcare practitioners or palliative care programs.

In countries in which the medical use of controlled medicines also is governed at the state level, as in India, Mexico, and the United States, some states have enacted laws and regulations that are more restrictive than national laws; this additional level of restriction can further interfere with opioid distribution and patient access to opioid pain medications. Of course, the Single Convention permits countries to adopt stricter control measures than those it offers (Article 39), but also acknowledges that such measures should not create barriers to medication availability for legitimate healthcare practice and patient care (United Nations, 1972).

Unduly strict drug control policies and systems have been widely identified as potential impediments to appropriate pain management internationally (Cherny et al., 2010; Chiu et al., 2010; Human Rights Watch, 2011; International Narcotics Control Board, 2009b; Joranson, Ryan, & Maurer, 2010; Larance et al., 2011a; Larance et al., 2011b; Powell, Kaye, Ddungu, & Mwangi-Powell, 2010; Vigil et al., 2007; World Health Organization, 2011a; World Medical Association, 2011). In fact, in November 2013 the *Annals of Oncology* devoted an entire supplement a series of articles detailing the prevalence of legislative and regulatory impediments to pain-related prescribing globally and in specific regions of the world (Cherny, Cleary, Scholten, Radbruch, & Torode, 2013; Cleary et al., 2013a; Cleary et al., 2013b; Cleary, Radbruch, Torode, & Cherny, 2013a; Cleary et al., 2013b; Cleary et al., 2013c; Cleary et al., 2013d). Such policies and systems were designed largely in response to the potential for abuse and diversion of opioids to illicit markets, and originated when much of the global disease burden was characterized by acute and often infectious conditions. Policy-based restrictions on clinical decision-making, or overly-constraining practice requirements, can lead to serious barriers to access and availability of controlled medicines for those who need them for pain and symptom management.

PUBLIC HEALTH PROBLEM OF PRESCRIPTION OPIOID ABUSE AND DIVERSION

Diversion, as used in the Single Convention, is the unlawful removal of controlled medicines from the government-regulated supply chain (United Nations, 1961). Diversion can lead to increased non-medical use of prescription medicines, morbidity, and mortality, as well as contribute to reduced legitimate availability of essential medicines and ultimately interfering in the relief of pain and suffering. The INCB has repeatedly reported that little if any diversion of controlled medicines occurs from the licit international trade, despite the large number of transactions involved (International Narcotics Control



SECTION III: BACKGROUND

Board, 1996; 2008a; 2009b). Most diversion happens within domestic channels (Larance et al., 2011a; United Nations Office on Drugs and Crime, 2011a). The UNODC reports that, in some regions of the world, diversion of pharmaceutical opioids is a problem (United Nations Office on Drugs and Crime, 2011b). Unfortunately, there continues to be very little empirical data to characterize diversion overall (Larance et al., 2011a), and much more work is needed to document the prevalence and sources of diversion where it occurs throughout the world (Fischer, Bibby, & Bouchard, 2010).

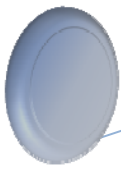
In some high-income countries, there has been a growing recognition in recent years that increases in the availability of prescription opioids indicated for the treatment of severe pain have co-occurred with more prevalent diversion and non-medical use of these medications (Australian Crime Commission, 2011; Fischer et al., 2010; Gilson, Ryan, Joranson, & Dahl, 2004; Novak, Nemeth, & Lawson, 2004; Paulozzi, Budnitz, & Xi, 2006; Peindl, Mannelli, Wu, & Patkar, 2007; Public Safety Canada, 2011; Zacny et al., 2003). However, there is not yet a thorough understanding of the methods in which prescription opioids that are available for medical use are reaching illicit channels, particularly in developing countries (Larance et al., 2011a; Larance et al., 2011b; United Nations Office on Drugs and Crime, 2011b)

It is essential to operationalize and target abuse- and diversion-control measures based on a comprehensive knowledge of the issues. In this way, the potentially numerous diversion sources can be identified, as a means to determine the extent that opioids become available for non-medical use through prescribing and dispensing practices compared to methods that completely eschew the practitioner/patient relationship. Such a thorough approach to the abuse and diversion problem is necessary to prevent drug control efforts that end up using limited resources that have little or no benefit in minimizing abuse or diversion or that can actually obstruct the availability of medications for the people who need them for legitimate medical purposes (United Nations Commission on Narcotic Drugs, 2011; United Nations Economic and Social Council, 2010). [Appendix A](#) provides authoritative international support for the need for governments, when permitting medication access for medical and scientific purposes, to maintain a legal and regulatory framework to prevent prescription medication diversion and abuse.

BALANCING CONTROL AND AVAILABILITY

Nearly every national government, or Party, in the world has formally acceded to the Single Convention. In so doing, each Party has agreed to adopt laws, regulations, and administrative procedures to carry out the aims of the Single Convention. The Single Convention establishes governmental obligations to control the non-medical use of opioids and also to make them available for medical purposes – this context of *Balance* (see [Section IV](#)), which is intended by international treaty, is expected to exist in national drug control laws. Ultimately, the goal of the Single Convention is to create a closed distribution system for medications, including security and recordkeeping requirements. For this to be accomplished, prescribing and dispensing to individuals must be done only for medical purposes (Bewley-Taylor & Jelsma, 2011) by healthcare professionals authorized under national law, using “medical prescriptions.” Distribution outside of the regulated system is prohibited to prevent diversion of controlled drugs from medical to non-medical uses. As a result, Single Convention drug control measures are designed to keep controlled medicines safe within the regulatory supply chain while making them adequately available only by medical prescription:

“...one of the basic principles of international drug control is that reduction in the availability of drugs for non-medical purposes should not affect and limit their therapeutic use.” (Bayer & Ghodse, 1999, p. 12)



SECTION III: BACKGROUND

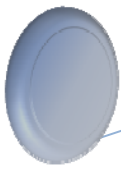
As stated previously, any steps taken to reduce diversion should be designed in such a fashion so as to not interfere with the legitimate flow of controlled medicines through the drug distribution system, which would avoid creating a barrier to appropriate medication availability and, consequently, patient care. Failure to implement the intent of *Balance* between controlling diversion and maintaining adequate drug availability can lead to a lack of recognition about the importance of effective pain relief, as well as the promulgation of overly-restrictive national law to regulate opioid medications. Conversely, policy-makers and advocates interested in improving pain and palliative care should also avoid making opioids available without an effective control system; such an approach also would be unbalanced and could lead to deleterious public health and safety consequences.

As efforts are made to improve the appropriate availability of opioid medications for pain and palliative care, it remains critical to develop or maintain methods to prevent the non-medical use of opioids (see [Appendix A](#)). Many countries have coupled improved opioid access with clinical training of healthcare professionals and students regarding appropriate pain management, as a means to reduce inappropriate use (International Narcotics Control Board, 1996; 2000). Informational sessions also have been provided for health officials and drug regulators when policy changes have occurred, which assists them in upholding proper oversight within different legal requirements (International Narcotics Control Board, 2008b). It is important for countries to promulgate drug control policies that conform to the Single Convention – to support adequate opioid availability, limit these medications to medical and scientific use, and establish effective measures against abuse and diversion. Indeed, countries such as India (Rajagopal, Joranson, & Gilson, 2001), Sierra Leone (Bosnjak et al., 2011), and Uganda (Jagwe & Merriman, 2007) have successfully increased availability of morphine without a concomitant growth in diversion and abuse; such activities require sound security, record-keeping, and prescriptive practices.

POLICY CONTENT CAN HAVE AN IMPACT ON PATIENT CARE

National governmental and regulatory policies can be examined systematically, often using criteria, so that efforts can be directed to better align policy content with established pain management standards and international drug control requirements (Cherny et al., 2013; Chiu et al., 2010). In this way, policy language can be identified that, when implemented in practice, has the potential to either (1) promote safe and effective pain management through legitimate professional practice, or (2) create barriers to safe and effective pain management by imposing undue restrictions or creating practice ambiguities.

A multi-tiered approach, termed a Rapid Policy Assessment and Response (RPAR), was recently developed by Scott Burris and colleagues from the Temple University School of Law (<http://chlpp.org/project/rapid-policy-assessment-and-response>). An RPAR approach not only evaluates whether existing policy creates opportunities or barriers to effective treatment; it also collects additional data such as the overall function of the relevant legal and service delivery systems and feedback from law enforcement members, healthcare professionals, patients and the public to assess whether and how the laws are implemented (Case, Lazzarini, & Burris, 2008). This collaborative, locally-assisted, intervention extends beyond the use of opioids for pain or medication-assisted treatment of dependence syndrome to include the use of controlled medicines for other therapeutic purposes, and even non-drug interventions such as offering sex worker collectives to empower sex workers and reduce HIV in India (see, for example, http://www.temple.edu/lawschool/phrhcs/rpar/about/RPAR%20and%20RAR%20Reports%20and%20Presentations/Parivartan_Sex_Work_Law_on_the_books.pdf). Within an RPAR framework, an action plan and final report are required, which are often used to formalize objectives and strategies and to document outcomes and interpretation of those outcomes.



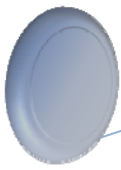
SECTION III: BACKGROUND

As another example, the WHO recently undertook an effort to refine and update its set of guidelines from 2000 (World Health Organization, 2000) that were created to encourage countries to evaluate and modify their drug control and professional practice policies. In 2011, the WHO published a series of 21 guidelines to assist governments in improving their national laws, regulations, and administrative procedures to promote the availability of controlled medicines for pain relief and for a variety of acute and chronic diseases and conditions; the guidelines are entitled “Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines” (*Ensuring Balance*), and have been endorsed by the INCB (World Health Organization, 2011a). The purpose and scope of these guidelines are described as follows:

“The **purpose** of these guidelines is to provide authoritative guidance on policies and legislation with regards to availability, accessibility, affordability and control of medicines made from substances that are controlled under the international drug control conventions. In this document, these medicines will be referred to as ‘controlled medicines.’...The **scope** of these guidelines is ‘all controlled medicines’. These are medicines made from substances controlled internationally under the Single Convention on Narcotic Drugs (further called ‘Single Convention’) and under the Convention on Psychotropic Substances. It also includes medicines made from precursors regulated under the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Furthermore, they could also be other substances controlled under national drug laws and regulations.” (p. 10)

Ensuring Balance promotes the availability of controlled medicines (not solely opioids) for pain relief and for a variety of acute and chronic diseases and conditions. It also applies to the use of opioids (i.e., methadone and buprenorphine) for treatment of dependence syndrome, as well as the use of other controlled medicines for practices such as emergency medicine, obstetrics, and psychiatry. Overall, the guidelines provide a resource for countries to inform legislation and regulations that fulfill their dual obligation concerning these medicines: To prevent their abuse, diversion and trafficking while ensuring availability for medical and scientific purposes. Each of the 21 guidelines is coupled with a conceptual justification that is supported by relevant authoritative or legal citations. The *Ensuring Balance* report even contains a Country Assessment Checklist as a tool for evaluating the extent to which each individual guideline is adhered, which can then be used to identify the specific roles that government officials, regulatory agency members, and health care professionals can play in improving the chain of distribution for controlled medicines. This tool ultimately serves the purpose of helping country members determine whether their national drug control system has the legal and administrative infrastructure required to make medications available for pain relief and other purposes.

Although both the 2000 and 2011 WHO guidelines were designed for use by people in individual countries to assist in policy development, there are examples of recent research projects that evaluate the content of existing policies from multiple countries. A project by the Access to Opioid Mediations in Europe (ATOME) group (<http://www.atome-project.eu/>) involved working with teams from 12 target countries (i.e., Bulgaria, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Serbia, Slovakia, Slovenia, and Turkey) to complete the WHO Country Assessment Checklist as part of their national action plans for improving medication access. Initial analysis of legislation from 11 of the target countries indicate that a number of legal and regulatory barriers exist, primarily affecting the prescribing and dispensing of opioid medications (Radbruch et al., 2012). As an example, stigmatizing language (e.g., “addictive drugs” and “addicts”) appeared often in legislative provisions. Importantly, however, results also demonstrated that barriers to opioid access are not created solely by official legislative requirements. A country team reported that health care professionals remained concerned about investigation, prosecution, or large penalties when prescribing or administering opioids, even though their law acknowledges that controlled medicines are absolutely necessary for medical and



SECTION III: BACKGROUND

pharmaceutical care (Radbruch et al., 2012). In addition, two country teams identified a governmental policy encouraging medical, pharmacy, and nursing schools to offer an education curriculum on the rational use of controlled medicines, although no training courses had yet been developed for these health care professions (Radbruch et al., 2012). The ATOME group promises, in the near future, a more detailed analysis of legislative content from these countries.

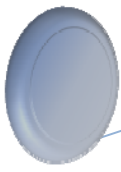
In a more limited context, a PPSG pilot study used a criteria-based evaluation to identify the extent that a sample of 15 countries had established authority in their national laws to implement drug availability provisions from the Single Convention, as recommended by the INCB (Husain, Skemp-Brown, & Maurer, in press). Four policy evaluation criteria were developed to represent drug availability language contained in, or reflecting the intent of, the Single Convention. Results indicated that slightly less than half of the sampled countries had laws acknowledging the intent to carry out the drug control conventions, with notably fewer meeting the standards of the remaining criteria. There were several laws with language that seemed to reflect the intent of the Single Convention, however, but did not explicitly obligate governmental action.

In addition, a PPSG criteria-based evaluation of governmental and regulatory policies in the United States, which has been conducted periodically since 2000, has demonstrated the general prevalence of policy content that is relevant to pain relief (Pain & Policy Studies Group, 2013). As recently as late 2012, evidence showed that most states' laws or regulatory policies acknowledge the need for appropriate pain management, as well as recognize the treatment of pain (including with the use of controlled medicines) as legitimate professional practice, which can provide a supportive therapeutic environment for treating pain. Alternatively, some states' policies contain ambiguous or overly-restrictive requirements that can place undue limits on adequate availability of essential medications like opioids; such language ultimately can impede appropriate pain management. In the United States, there continues to be the need for many states to remove long-outdated provisions from law that create barriers to legitimate practice, some of which have been present for 30 years or more (Pain & Policy Studies Group, 2013). As stated previously, it remains necessary to ensure that all such policies, even those principally designed to control drug diversion activities, should maintain medication availability and assure that patient care decisions are not unjustifiably limited.

This objective of *Balance* in regard to adequate medication availability for legitimate medical purposes is what guides the aforementioned policy evaluation methodologies, as well as the research described in this report. [Section IV](#) provides a comprehensive description of *Balance* as an international policy imperative (with a compendium of international authoritative sources supporting this concept provided in [Appendix D](#)), while [Section VIII](#) enumerates the evaluation criteria, and offers a conceptual justification and identifies the international authoritative sources related to each criterion. It is expected that this policy evaluation document eventually will add to the resources represented by the RPAR, the 2011 WHO Guidelines document, and the ATOME project, to provide countries with a valuable tool to identify policy content relevant to pain management and palliative care.

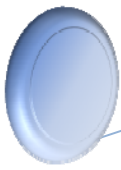
CONCLUSION

Collectively, the findings, statements, and formal documents and resolutions from international authorities (e.g., the WHO, INCB, and the ECOSOC), which will be described more thoroughly in [Section IV](#) and [Section V](#), form an unmistakable and uncontroversial imperative from the highest level of international and national governmental health and regulatory authorities in the world – Government members and health professionals should work together to promote safe and effective pain



SECTION III: BACKGROUND

management, as well as to identify and remove impediments to the adequate availability of opioids for medical purposes. Such multidisciplinary collaboration is emphasized as the basis of not only this report but also the RPAR, the 2011 WHO Guidelines document, and the ATOME project. Positive changes to government and regulatory policy, which is the overall objective of this report, should be acknowledged as one necessary but insufficient mechanism to better achieve safe and effective treatment of pain. Further efforts still are needed to address other barriers related to attitudinal or clinical issues or the degree to which policies are implemented in practice, which include the adequate education of healthcare professionals about proper pain management practices, but which are beyond the scope of this report (unless a requirement for such education is contained in a country's legislation or regulations). Taken together, such improvements have the potential to contribute to a clinical practice and regulatory environment that facilitates, rather than impedes, appropriate pain care and enhanced quality of life.



SECTION IV: THE CENTRAL PRINCIPLE OF BALANCE

Balance is the Central Principle

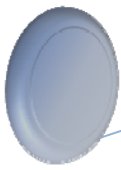
The importance of medication availability, including the use of opioid analgesics for medical and scientific purposes, is inherent in a number of international drug control treaties aimed at preventing drug abuse. The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 protocol (Single Convention²) (United Nations, 1972), is an international treaty to which most governments are parties, and has been interpreted to establish a government obligation to prevent diversion³ and reduce the public health risks of non-medical drug use, all the while maximizing the health value of medicines needed for pain relief and other medical purposes (International Narcotics Control Board, 1989; 2005). Control measures that the Single Convention deem necessary at the international and national level to prevent diversion of Schedule I controlled drugs (a category consisting of opioids such as morphine) include the following:

- Lists Articles concerning control of Schedule I drugs (Article 2(1)),
- Limits uses exclusively to medical and scientific purposes (Article 4(c)),
- Requires governments to estimate requirements only for medical and scientific uses (Articles 12 & 19),
- Report of consumption allows for monitoring (Article 20),
- Manufacture and import must be within estimated amount (Article 21),
- Governments to license manufacturers (Article 29),
- Governments to license trade and distribution (Article 30),
- Medical prescription required; counterfoil prescription an option (Article 30(2)(b)(i)),
- Government to license importer and exporters of opioids (Article 31),
- Possession requires legal authorization (Article 33), and
- All handlers must have adequate qualifications (Article 34) (United Nations, 1961).

It should be noted that the control system is also the availability system – that is, sufficient medication availability can only occur within a control system that is not overly burdensome (Cherny et al., 2010), as will be shown. It is this dual system of control and availability that needs to be extended to patients and their physicians and pharmacies in order to achieve medication access for legitimate medical and scientific purposes.

² In addition, the Convention on Psychotropic Substances of 1971 established a similar imperative for balanced policy concerning psychotropic drug policy but which is not within the purview of this research.

³ Diversion, as used in the Single Convention, is the unlawful removal of controlled medicines from the government-regulated supply chain.



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

The Central Principle of *Balance* is a medico-legal concept underlying the Single Convention, and is stated as follows:

The Central Principle of *Balance* represents a dual imperative of governments to establish a system of controls to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability. Although opioids are controlled medicines, they also are essential and are absolutely necessary for the relief of pain, especially when pain is severe. Opioids, including those in the therapeutic group of morphine, should be accessible to all patients who need them for relief of pain. Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes. These steps include empowering medical practitioners to provide opioids in the course of professional practice, allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and ensuring that a sufficient supply of opioids is available to meet medical demand.

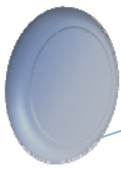
Alternatively, when misused, opioids pose a threat to society. A system of controls, therefore, is necessary to prevent abuse, trafficking, and diversion, but these controls are intended neither to diminish the medical usefulness of opioids, nor to interfere in their legitimate medical uses and patient care. Indeed, governments have been asked to identify and remove impediments to the availability and medical use of opioids.

Convention measures that are obligatory (i.e., those listed above) should be distinguished from more restrictive measures that have the potential to create onerous burdens, which some authoritative sources refer to as impediments or barriers (Chiu et al., 2010; United Nations Commission on Narcotic Drugs, 2011; World Health Organization, 2011a). The Single Convention recognizes that governments are not precluded from enacting controls that are more restrictive if they are deemed necessary to protect public health and safety (United Nations, 1961, Article 39); however, the example provided in the treaty relates to application of Schedule I controls to drugs in other schedules. Regardless of this provision, there is no exemption from the need to ensure adequate availability for medical and scientific purposes.

In addition, it should be determined whether Convention control measures have been adequately designed or implemented before non-Convention measures, which may impede legitimate access and availability, are considered or enforced. Examples of non-Convention drug control measures that are stricter, and which have been identified as regulatory impediments to the medical use of controlled essential medicines, include:

- Undue restriction on duration of prescription supply (Davaasuren et al., 2007),
- Substantial dosage limit (Beubler, Eisenberg, Castro-Lopes, & Rhodin, 2007),
- Extremely short period for prescription validity (Cherny et al., 2010),
- Limits categories of physicians who can prescribe (Stjernswärd et al., 2007),
- Prohibitions from prescribing to patients with certain diagnoses (Mosoiu, Ryan, Joranson, & Garthwaite, 2006; United Nations International Drug Control Programme, 2000),
- Excessive penalties for misprescribing opioids (Philippines Comprehensive Dangerous Drugs Act of 2002, 2002), and
- Special prescription forms that are difficult to obtain or cumbersome to complete (Križanová, 2002).

A report drafted for the 54th session of the United Nations Commission on Narcotic Drugs (United Nations Commission on Narcotic Drugs, 2011) provides additional examples of regulatory impediments, which not only can interfere with legitimate medication availability but also are acknowledged to not



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

significantly improve drug control. Such provisions were generally enacted before pain management for non-acute conditions was considered an accepted part of professional practice. In some countries, regulatory impediments such as those identified above are beginning to be removed or modified in cooperation with Governments (World Health Organization, 2011a).

THE RATIONAL BASIS FOR THE CENTRAL PRINCIPLE OF *BALANCE*

The relevance and credibility of evaluations, as well as the criteria used for those evaluations, provides the foundation for the validity of policy analysis (Patton & Sawicki, 1993; Spicker, 2006). Evaluation criteria should be based on principles, determinations, or recommendations that have been accepted by the highest possible authorities in the field. To this end, the following excerpts⁴ from international legal, regulatory, and health care authorities reinforce the Central Principle of *Balance* (a compendium of these supportive statements is available in [Appendix D](#)).

The Single Convention on Narcotic Drugs of 1961, as amended by the 1972 protocol (Single Convention) (United Nations, 1972), stated that:

“the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made [by governments] to ensure the availability of narcotic drugs for such purposes.” (Preamble)

“The Parties [national governments] shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution... and possession of drugs.” (Article 4(c))

“The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavour to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs.” (Article 9(4))

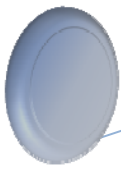
The Single Convention is implemented by the International Narcotics Control Board (INCB). For more than 20 years, the INCB has repeatedly encouraged the availability of adequate amounts of controlled medications:

“One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion.” (International Narcotics Control Board, 1989, ¶1)

“...[the Board], in conjunction with WHO, undertook to identify possible medical needs for opiates which were currently not being met for a variety of reasons. Information was gathered from various sources, including drug regulators, health system managers, medical specialists, pharmacists and specialized units within WHO, to determine how countries are assessing their medical needs for opiates, the extent to which those needs are being met, what impediments have arisen, and what short-, medium- and long-term strategies may be deployed to overcome those impediments.” (International Narcotics Control Board, 1989, ¶15)

“International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotics drugs, but they also recognize that they are indispensable for the relief of pain and

⁴ Text from existing content of policy resources is underlined throughout this policy evaluation report for the purposes of highlighting relevant messages. Such emphases typically do not appear in the resources themselves.



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

suffering...The [INCB], in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use.” (International Narcotics Control Board, 1996, Summary, p. iii)

“The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs.” (International Narcotics Control Board, 1996, ¶1)

“The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes...Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (International Narcotics Control Board, 1996, ¶48)

“The International Narcotics Control Board is the successor to the drug control bodies, the first of which was established by international treaty over 70 years ago. A series of treaties confer on the Board specific responsibilities. The Board endeavors ‘to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes’ [and] ‘to ensure their availability for such purposes...’.” (International Narcotics Control Board, 1997, Forward, p. iii)

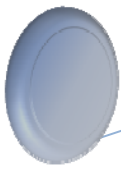
“The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...Adequate availability and limitation were considered by the State parties to the 1961 Convention...as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.” (International Narcotics Control Board, 2000, ¶1)

“If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance.” (International Narcotics Control Board, 2000, ¶38)

“A well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances has to fulfill, inter alia, the following functions: To provide for relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of drugs for the purpose of abuse;” (International Narcotics Control Board, 2000, ¶41(a))

“The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of mankind, as well as of the fact that drug addiction is a worldwide social and economic threat. Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts.” (International Narcotics Control Board, 2005, ¶12)

“Another objective of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical treatment and to promote the rational use of controlled drugs.”



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

(International Narcotics Control Board, 2006, ¶1649)

“The primary objective of the 1961 and 1971 Conventions is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs.” (International Narcotics Control Board, 2009a, ¶120)

“One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances.” (International Narcotics Control Board, 2009a, ¶1770)

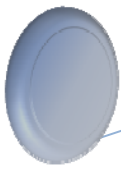
“Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol, and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board.” (International Narcotics Control Board, 2011, ¶1)

“The conventions established a control regime to serve a dual purpose: to ensure the availability of controlled substances for medical and scientific ends while preventing the illicit production of, trafficking in and abuse of such substances. The 1961 Convention, while recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to humankind, affirms that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...The implementation of the international drug control treaties by parties is monitored by the Board, whose responsibilities under article 9 of the 1961 Convention expressly include the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes.” (International Narcotics Control Board, 2011, ¶13)

“The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. However, despite numerous efforts by the Board and the World Health Organization (WHO), as well as non-governmental organizations, their availability in much of the world remains very limited, depriving many patients of essential medicines. The Board continues to monitor the worldwide availability of narcotic drugs and psychotropic substances and has made their availability one of the main topics of its dialogue with Governments on adequate treaty implementation.” (International Narcotics Control Board, 2011, ¶14)

Moreover, the importance of medication availability was stated explicitly in a recent document, published jointly by the INCB and the WHO (2012), to delineate methods to estimate a government’s need for controlled medicines:

“By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the [international drug control] conventions...(¶1)...The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse...(¶2)...WHO also provides guidance to Governments on policies and legislation on the availability, accessibility, affordability and control of medicines made from controlled substances.” (¶4)



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

In 1986, a WHO Expert Committee devised and recommended to all governments a simple, medically- and scientifically-sound, approach to treating cancer pain that depends on the availability of opioids such as codeine and morphine for legitimate medical and scientific purposes (World Health Organization, 1986). The WHO has for many years designated morphine, codeine, and other opioids as “essential drugs:”

“The [Single Convention] also requires the INCB to endeavour to ensure that opioids are available for medical purposes, and to confirm national estimates as quickly as possible...” (World Health Organization, 1996, p. 48)

“those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms...” (World Health Organization, 1998a, p. 2)

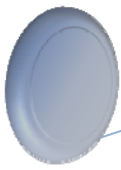
“...access to pain relief and palliative care services is often limited, even in high-resource settings, because of...excessive regulation of opioids (p. 3) [and] urges Member States...to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Control Board.” (World Health Organization, 2004, p. 6)

In 2000, the WHO published guidelines specific to national drug control policies governing opioid medicines (World Health Organization, 2000). However, a decade later the WHO updated (and completely superseded) the 2000 guidelines, with the new guidelines designed to evaluate national policies to ensure availability and accessibility of controlled medicines generally for a variety of medical purposes (World Health Organization, 2011a). Importantly, these revised WHO guidelines continued to be based on the Central Principle of *Balance*, as suggested by the following statement:

“The central principle of ‘balance’ represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meeting those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care.” (p. 11)

In addition, the updated WHO Guidelines (2011a) document explicates the dual obligation embodying the framework of the Central Principle of *Balance*:

“Countries have a dual obligation with regard to these medicines based on a quadruple imperative, which is based on legal, political, public health and moral grounds. They must ensure that these substances are available for medical purposes and they must protect their populations against abuse and dependence. Indeed, here lies the challenge for both public-health and drug-control authorities. WHO promotes policies that simultaneously strive for minimizing substance abuse and maximizing access for rational medical use. The combination that leads to the maximum public health outcome is the optimum between these two elements, and a policy leading to this optimum can be called a ‘balanced policy’.” (p. 11)



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

By 2005, the UN Economic and Social Council (ECOSOC) (2005a) began focusing on the demand for and supply of opioids for medical purposes, including for pain treatment:

“...Recognize[s] that the medical use of narcotic drugs, including opiates, is indispensable for the relief of pain and suffering [and]...the need to balance the global licit supply of opiates against the legitimate demand for opiates used to meet medical and scientific needs is central to the international strategy and policy of drug control.” (p. 1)

Urges all Governments to continue to contribute to maintaining a balance between the illicit supply of and demand for opiate raw materials used for medical and scientific purposes...” (p. 2)

“...Recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics, as advocated by the World Health Organization, especially in developing countries, and calls upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use.” (p. 2)

Even more recently, the ECOSOC (2010) has encouraged activities to assure a balanced approach to controlled medication availability:

“Stressing the importance of promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse,” (p. 1)

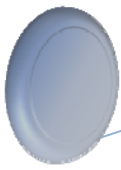
“Affirming that the international drug control conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse,” (p. 1)

“Noting the medical and scientific needs for internationally controlled substances worldwide to be met within a regulatory and legal framework that prevents their diversion and abuse,” (p. 2)

“Also noting with appreciation the efforts of non-governmental organizations and civil society in continuing to highlight the importance of the issue of adequate availability of internationally controlled substances for medical and scientific purposes as set out in the international drug control conventions,” (p. 3)

“Requests the United Nations Office on Drugs and Crime to continue its efforts to ensure the adequate availability of internationally controlled drugs for medical and scientific purposes, cooperating, as appropriate, through the Access to Controlled Medications Programme of the World Health Organization, while continuing its activities to prevent diversion and abuse;” (p. 4)

“Invites Member States to ensure that the International Narcotics Control Board and the United Nations Office on Drugs and Crime are funded adequately, as appropriate, to support their activities to ensure adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes, including the development and implementation of guidelines to assist Governments in estimating their requirements for internationally controlled substances and to address the risk of the diversion and abuse of those substances;” (pp. 5-6)



SECTION IV: THE CENTRAL PRINCIPLE OF *BALANCE*

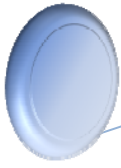
In the last few years, however, a Discussion Paper was issued (United Nations Commission on Narcotic Drugs, 2011), in relation to the 54th session of the Commission on Narcotic Drugs, specific to the adequate availability of medications in conformity to international drug control treaties (i.e., in accordance with the concept of *Balance*):

“The reason that opioids are controlled under the international drug control Conventions is the harm associated with misuse and abuse. As the Commission affirmed in Resolution 53/4, the Conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse. **Both sides of this balance — ensuring availability and preventing diversion and abuse — are concerned with the protection and promotion of health and public safety.** As the World Health Organization (WHO) states, the public health outcome is “at its maximum” when ‘the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use.’” (¶13)

“This recognition of the international drug control Conventions as concerned primarily with health was articulated by the former Executive Director of the United Nations Office on Drugs and Crime (UNODC), in his report to the review of the twentieth special session of the General Assembly, in which he said ‘we must bring public health — *the first principle of drug control* — back to centre stage’ and ‘drug control, and the implementation of the drug Conventions, must proceed with due regard to health and human rights.’” (¶14)

“Opioid analgesics are essential for sufficient pain management, but should never be the only available substance type for the treatment of pain, particularly for the treatment of mild to moderate pain. Both opioid and non-opioid analgesics should be made available for appropriate pain management and their rational use should follow an appropriate clinical assessment, criteria for proportional interventions and pharmacological rules for the integration in a complex therapeutics approach. If appropriately used, opioid medicines are safe and the patients rarely become dependent on opioid analgesia.” (¶23)

“The control provisions of the Conventions are designed 1) to ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and 2) to combat illicit manufacture, trade and distribution. They are designed to serve what the INCB has described as the overall goal of a ‘well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances’ namely ‘to provide relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, to prevent the diversion of drugs for the purpose of abuse.’” (¶32)



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

SOME DRUG CONTROL POLICIES HAVE THE POTENTIAL TO IMPEDE THE USE OF OPIOIDS FOR PAIN RELIEF

Inadequate pain management and palliative care have received both historical and current attention from international and national authorities. Such attention has contributed to the realization that untreated or undertreated pain is due, at least in part, to statutes and regulations that create barriers to the adequate availability and medical use of opioids (Cherny et al., 2013); see [Section III](#), Factors Contributing to Unrelieved Pain. The International Narcotics Control Board (INCB)⁵ has observed that the global medical need for opioids was not being fully met. In fact, the INCB, in cooperation with the WHO in some instances, has determined that there were a variety of reasons for inadequate availability of opiates for pain relief throughout the world, including unduly restrictive drug control policies:

“...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented.” (International Narcotics Control Board, 1989, Summary, p. 1)

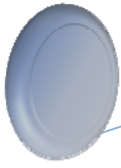
“...legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes.” (International Narcotics Control Board, 1989, ¶42)

“The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession.” (International Narcotics Control Board, 2000, ¶31)

“The Board and WHO reviewed documents and studies on the availability of opioid analgesics at the national level and examined the activities undertaken and planned by various bodies to assist Governments in ensuring the availability of those drugs for medical use. The Board and WHO observed that, although there was no shortage of licitly produced opioid analgesic raw materials worldwide and there had been a substantial increase in the global consumption of opioids in the past two decades, access to opioid analgesics continued to be difficult in some countries. The difficulties in having access to opioid analgesics are due to various interrelated factors, such as inadequate medical education and lack of knowledge and skills in pain management, public attitude, regulatory impediments and economic constraints.” (International Narcotics Control Board, 2008b, ¶210)

“Laws and regulations, and their administration or interpretation, unduly impeded the availability of opiates.” (International Narcotics Control Board, 2011, ¶10)

⁵ The International Narcotics Control Board is an independent treaty-based body affiliated with the United Nations that monitors implementation of the Single Convention on Narcotic Drugs of 1961.



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

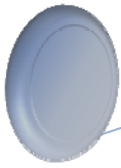
Also, a recent document published jointly by the INCB and the WHO (2012), outlining ways to effectively estimate a country's need for controlled medicines, clearly emphasized the importance of policy influences on medication availability:

“...the effectiveness of the supply management system depends on a well-functioning legal and policy framework that is based on ensuring the availability and rational use of controlled substances for medical purposes. The lack of such a framework can affect the proper functioning of the supply management cycle and create barriers to the rational use of controlled substances. Fundamental changes to the legal and policy framework are necessary to eliminate such barriers.” (¶121)

“Although legal and regulatory measures are necessary to prevent the diversion of controlled substances from the distribution system, they should not be a barrier to the availability of such substances for medical purposes.” (¶136)

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (World Health Organization, 1990a) issued a special report that addressed the obstacles to meeting medical needs for opioids to relieve cancer pain, and concluded that legislative, regulatory, and administrative impediments are present in some countries that contribute to insufficient medical use of prescription opioids. In 2006, the WHO Expert Committee on Drug Dependence identified the negative impact that overly-restrictive drug control policies can have on medical availability (World Health Organization, 2006b):

“During the discussions, factors limiting the availability of drugs for medical use were identified, including barriers inadvertently created by the application of laws and regulations. There are countries where stricter measures are applied than are required by the Conventions. This is permissible, as the requirements of the Conventions are minimum requirements. However, the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines. The appropriate national authorities should carefully consider whether any such measure currently in force could be modified to permit access for patients in need...The Committee requested the WHO Secretariat to suggest including on the proposed agenda of the next Committee meeting, a discussion of the impact of scheduling on the balance between medical availability of controlled substances and the prevention of their abuse.” (pp. 20-21)



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

By 2011, the WHO had published its guidelines to promote the availability and accessibility of controlled medications (World Health Organization, 2011a), updated from similar opioid-related guidelines from 2000 (World Health Organization, 2000). The newest Guidelines document, like the previous version, emphasized the role of government legislation and policies on public health and welfare (World Health Organization, 2011a):

“In many countries, national legislation includes provisions stricter than the international drug control conventions require. This is allowed for by the conventions, as far as it is in the opinion of the government ‘necessary or desirable for the protection of the public health or welfare’. However, in practice, many stricter provisions do not contribute to a better public or individual health. Therefore, it is important to analyze the effects of any stricter rules on the prevention of diversion, abuse and dependence syndrome and on the availability and accessibility of controlled medicines. Rules (and policies) that do not contribute to the protection of public health or welfare should be eliminated or changed. Rules violating any other international obligation, regardless whether originating from the drug conventions or any other treaty, should be guarded against. (p. 27)

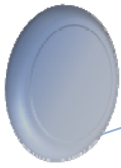
“Such an analysis should be undertaken rule by rule, and cover both legislation and official policy. If a rule provides a barrier for availability and accessibility, but does not contribute to the prevention of abuse, diversion and dependence syndrome, this rule does not contribute to the protection of public health or welfare, and should therefore be either eliminated or changed. In the case where a rule both contributes to prevention and constitutes a barrier for medical use at the same time, alternative ways of providing the same level of prevention without prosing a barrier to rational medical use should be explored. This publication provides a check list that may be used for assessing which rules are overly restrictive and may therefore be in need of correction.” (p. 27)

At the same time as the recent WHO and INCB documents, the UNCND has identified the potential problems associated with legislative and regulatory barriers in narcotics control policies (United Nations Commission on Narcotic Drugs, 2011):

“While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare, efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes “must not adversely affect their availability for such purposes”. A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability.” (¶136)

“Examples of measures that may impede availability and that are not required by the Conventions include: (a) Limitations on the number of days’ supply that may be provided in a single prescription (with too short a period of time allowed); (b) Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low); (c) Excessive limitations on prescription authority, such as only to some categories of medical doctors; (d) Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain, and/or a requirement that multiple copies of the prescription be maintained; (e) Requirements that patients receive special permission or registration to render them eligible to receive opioid prescriptions; (f) Excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids; (g) Arbitrary restrictions on the number of pharmacies permitted to dispense opioid medications; (h) Unreasonable requirements relating to the storage of opioid medications.” (¶137)

“These measures, not required by the Convention, do not significantly improve control, but may interfere significantly with accessibility to and availability of essential medicines.” (¶138)



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

In the last few years, the International Association for the Study of Pain (IASP) issued a “Declaration of Montreal” declaring that access to safe and effective pain management is a fundamental human right (Cousins & Lynch, 2011; International Association for the Study of Pain, 2010). Within this Declaration (International Association for the Study of Pain, 2010), the IASP recognizes the following situation and obligation:

“Most countries have no national policy at all or very inadequate policies regarding the management of pain as a health problem, including an inadequate level of research and education.” (p. 1)

“There are severe restrictions on the availability of opioids and other essential medications, critical to the management of pain.” (p. 1)

“The obligation of governments and all health care institutions, within the scope of the legal limits of their authority and taking into account the health care resources reasonably available, to establish laws, policies, and systems that will help to promote, and will certainly not inhibit, the access of people in pain to fully adequate pain management. Failure to establish such laws, policies, and systems is unethical and a breach of the human rights of people harmed as a result.” (p. 1)

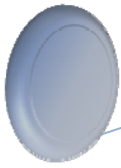
DRUG CONTROL POLICY SHOULD BE EVALUATED

Several international and national authorities have called for studies to identify legal and regulatory impediments to the use of opioids for pain relief. For example, after completing a review of the reasons for inadequate cancer pain relief, the INCB (International Narcotics Control Board, 1989) (in cooperation with the WHO) communicated with governments throughout the world, asking them to attend to potentially-restrictive laws and regulatory policies:

“The use of certain drugs may be directly or indirectly limited by policies or guidelines adopted by Governments or medical associations. The prohibition of the use of a drug to treat one part of the population...or a particular condition may deter use of the drug under any circumstances. The lack of specific guidelines on the use of drugs such as opiates, and on the treatment of certain conditions for which those drugs may be indicated, may contribute to practitioners’ reluctance to use such drugs for legitimate medical purposes...” (¶146)

“In some countries the use of certain drugs is limited by the need for special authorizations or by the conditions under which the drugs may be made available. Policies or regulations may dictate or specify the conditions under which a drug may be used and therefore may affect the way in which health professionals conduct a treatment programme.” (¶147)

“...Governments should examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications.” (¶149(c))



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

The INCB reiterated this recommendation in 1996 (International Narcotics Control Board, 1996):

“The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes. A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licenses, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (¶48)

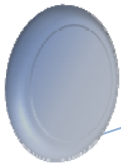
“Governments are invited to consider the following recommendations:...(a) Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments...(f) Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws.” (¶51)

In a report for 1999 (International Narcotics Control Board, 2000), the INCB clarified the responsibility of Governments and the healthcare profession to identify and remove a variety of potential barriers to opioid availability for legitimate medical and scientific purposes:

“The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession.” (¶31)

More recently, the INCB (2009a) emphasized the imperative to evaluate national drug control policy and administration:

“WHO, in consultation with the Board, prepared an assistance programme called Access to Controlled Medications Programme. The programme is designed to address impediments to the rational use of opioid analgesics, focusing on regulatory, attitude and knowledge impediments. The Board encourages UNODC to cooperate with WHO in the implementation of the Access to Controlled Medications Programme, with a view to promoting rational use of opioid analgesics by health-care professionals.” (¶772 - Recommendation 44)



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

In 2011, the INCB again called for governments to improve the legitimate availability of opioid medications by focusing on the need to improve their policies (International Narcotics Control Board, 2011):

“Governments should identify impediments to availability of narcotic drugs and psychotropic substances (policy, regulatory, administrative) and take detailed, step-by-step measures to remove those impediments.” (¶132(b))

“Governments should determine whether their national narcotics laws contain elements of the 1961 Convention as amended by the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws.” (¶132(f))

“Governments should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede the prescribing or dispensing of, or needed medical treatment of patients with, narcotic drugs or psychotropic substances, or their availability and distribution for such purposes, and, should this be the case, make the necessary adjustments.” (¶132(g))

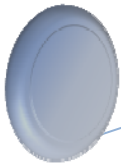
Around the same time that the INCB began calling for greater recognition of the influence of policy barriers, the WHO (1990a) recommended that governments review their administrative practices for opioid control with a view to simplification so as not to impede legitimate use of opioids by patients:

“The following steps are necessary to ensure adequate drug availability:

- review of legislation with a view to permitting the importation, manufacture, prescription, stocking, dispensing, and administration of opioids for medical reasons;
- review of the administrative practices of opioid drug control with a view to their simplification so as not to impede legitimate use of opioids by patients;
- determination of the probable needs of the country, based on estimates of present consumption plus the “best guess” of needs for the likely number of cancer patients to be treated;
- review of legislation and practices that may affect the availability of other drugs.” (p. 41)

The most recent 2011 WHO Guidelines (2011a) document for ensuring medication availability and accessibility called for governments to review its legislation and administrative requirements to determine the extent of barriers to medication availability; such a call is similar to that found in WHO opioid-related Guidelines document from 2000 (World Health Organization, 2000):

“Guideline 9: Governments should examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medicines. They should also ensure that provisions aim at optimizing health outcomes and take corrective action as needed. Decisions which are ordinarily medical in nature should be taken by health professionals.” (p. 27)



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR BALANCE

The UN Commission on Narcotic Drugs (2011) also has called for governments to identify and address regulatory barriers in the narcotics control policies:

“Review and revise national legislation, regulation and policies, in order to ensure that they reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability.” (¶47(b))

Importantly, the same UNCND document also included recommendations for the UN Office on Drugs and Crime (UNODC) regarding the context of countries’ laws or regulations governing the use of opioids for legitimate medical purposes (United Nations Commission on Narcotic Drugs, 2011):

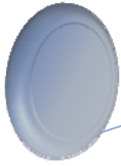
“A central aspect of the work of the UNODC is its normative work assisting States to implement relevant international treaties, including through the development of domestic legislation. UNODC thus has a clear mandate and responsibility to work to assist Member States to implement balanced laws and policies taking into account that different cultures, attitudes, knowledge and experience require individual guidance in such processes.” (¶48)

“UNODC will commence a process of examination of its model laws to ensure that they reflect an appropriate balance between the measures to ensure availability of controlled medications for medical and scientific purposes and the measures to reduce illicit manufacture, illicit trade, and diversion. If required, revisions will be made to remove or modify provisions that create impediments to medical and scientific use and do not advance the objectives of the Conventions.” (¶49)

“UNODC has long worked proactively to assist Member States to implement the diversion and abuse prevention aspect of their obligations under the drug Conventions. This should be, and will remain, an essential element of UNODC’s work, but the Office will also focus equally on all elements necessary to guarantee availability and accessibility with particular attention to avoiding any control measures unintentionally impeding high quality medical treatment.” (¶50)

In addition, the World Medical Association (WMA), which has official relations with the WHO and collaborates with health professional associations, governmental and non-governmental agencies, and regional medical associations to provide guidance to physicians, has promoted the involvement of Governments in reviewing and making changes to relevant legislation and regulations that affect adequate availability and accessibility of controlled medicines (World Medical Association, 2011):

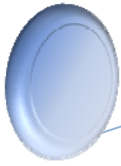
“Lack of education for health professionals in the assessment and treatment of pain and other symptoms, and the unnecessarily restrictive government regulations (including limiting access to opioid pain medications) are two major reasons for [the pain] treatment gap... Countries should review their drug control policies and regulations to ensure that they do not contain provisions that unnecessarily restrict the availability and accessibility of controlled medicines for the treatment of pain. Where unnecessarily or disproportionately restrictive policies exist, they should be revised to ensure the adequate availability of controlled medicines.” (pp. 1-3)



SECTION V: THE INTERNATIONAL IMPERATIVE TO EVALUATE NATIONAL POLICY FOR *BALANCE*

Conclusion

Over the last 25 years, but especially during the last decade, numerous international organizations representing healthcare, regulation, and law enforcement have promoted the necessity of evaluating governmental policy for potentially-restrictive language. Of course, the type and extent of policy barriers vary greatly across nations, so a one-size-fits-all approach to recommending changes is not possible. Efforts must occur within the country to understand current legal provisions and their implications for healthcare practice and patient care. Activities to avoid or repeal undue restrictions or legal ambiguities can create a policy environment free of barriers to medication availability for medical and scientific purposes, including for cancer pain management and palliative care.



SECTION VI: IMPROVING h° @ PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

The criteria-based methodology described in this report was designed to be applied to a country's laws and regulatory policies, to identify language and requirements with the potential to affect availability of controlled medicines and the appropriate treatment of patients with pain. People wanting to improve governmental policy, including healthcare practitioners, regulators, and legislators, can use these evaluation results to help guide their activities while also offering internationally-based authoritative support for specific policy change. However, as explained in the Research Methodology section ([Section VII](#)), an important characteristic of this evaluation is its "black-letter" analysis, which is based solely on explicitly-stated policy language. As a result, the intent or context within which a policy is constructed or enacted typically is not a consideration.

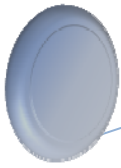
A variety of other potential influences on patient care are not taken into account for the purpose of this evaluation, all of which can have critical implications for patient treatment or can impede successful policy implementation. There remains a need to recognize the important potential significance of these other factors for improving patient pain care, including:

1. Influence of non-legislative actions or clinical practice resources,
2. Influence of unevaluated policies,
3. Policy content should be consistent with its stated intent,
4. Legal or regulatory concerns can undermine actual policy content, and
5. Positive policy change is only the first step to improve pain management.

1. Influence of Non-Legislative Actions or Clinical Practice Resources

There are numerous resources or activities, all of which are unrelated to the content of statutes, regulations, and official regulatory policies that govern drug control as well as medical and pharmacy practice, that are designed to help improve healthcare practice related to pain management. Examples include professional and public awareness campaigns or educational initiatives (unless they are mandated or encouraged by national or state law), the development of institutional standards, and cooperative efforts among healthcare societies or agencies, pain-related organizations (again, unless they are contained in law), and hospice and palliative care groups.

A common non-law resource, at least for the countries evaluated for this report, is available to healthcare practitioners in the form of a Technical Manual designed to relay current legal and regulatory information to improve quality of care for pain and other healthcare services. For example, in Colombia a Technical Manual was constructed for Resolution No. 1043 of 2006 (Minister of Social Protection, 2006). The Manual describes the standards related to a variety of healthcare issues, while also clarifying that changes in pain intensity can interfere with a person's functioning and ability to engage in routine activities; this provision recognizes the impact that untreated or undertreated pain can have on peoples' quality of life. Critically, the Technical Manual is used to convey to a broader audience the new practice standards promulgated by Resolution No. 1043 of 2006, given that fewer professionals may be aware of the content of the actual adopted Resolution. In addition, a non-policy resource was developed by the Mexican *Comisión Federal para la Protección contra Riesgos Sanitarios* in November 2005, entitled "Guidelines for the Management of Narcotic Drugs in Pharmacies of Hospital Units and Clinics for Pain" (*Comisión Federal para la Protección contra Riesgos Sanitarios*, 2005). This clinical guideline outlines, among other things, the various classifications of controlled medicines, the practitioners who can prescribe, and the requirements for obtaining and using the special prescription forms that are required



SECTION VI: IMPROVING PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

for issuing these types of medications. Similarly, recent unofficial rules by Panama's National Medical Services and Benefits agency summarize a number of issues related to the prescribing and dispensing of medications, including controlled substances and opioid pain medications (National Medical Services and Benefits, 2013).

Another example can be found with such regional resources as the guideline from the African Palliative Care Association, entitled "Guidelines for Ensuring Patient Access to, and Safe Management of, Controlled Medicines" (http://www.africanpalliativecare.org/images/stories/pdf/patient_access.pdf). These guidelines cover a number of important regulatory and administrative measures needed to achieve the essential balance between ensuring medication availability and establishing controls over their abuse and diversion, as a means for safely managing patient access to medications that may be necessary for pain relief and palliative care. Such measures include procedures for importation, manufacture, transportation, and wholesale distribution and supply, as well as guidance specific for hospital ward staff and home care teams. Overall, the document provides a resource to policy makers, service providers, and drug regulatory bodies to navigate the supply chain for medicines in Schedules I or II under the Single Convention.

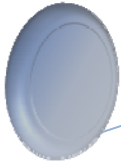
In addition to these issues, it remains essential for Governments to have adequate resources to implement treaty obligations, including when making controlled medicines available for medical and scientific purposes. The INCB has even made statements to this effect:

"The Board is aware that drug control authorities have other tasks besides reporting to the Board. The Board is also aware that the duties of drug regulatory agencies are manifold and include licensing and inspection of manufacturers and traders, issuing export and import authorizations and ensuring the competent national authorities would not be able to report adequately and in a timely manner to the Board. Such internal cooperation may require adequate funding." (International Narcotics Control Board, 2008b, ¶1237)

"The Board calls again upon the Governments concerned to provide adequate resources to ensure the compliance of those authorities with all their control functions, including reporting obligations under the 1961 Convention." (International Narcotics Control Board, 2009a, ¶160)

"Difficulties experienced by some Governments in submitting the required statistical data to the Board have different reasons, including the inadequate resources and inadequate training provided to the authorities responsible for the control of licit activities related to narcotic drugs and psychotropic substances. The Board again calls upon the Governments concerned to allocate adequate resources to their national competent authorities to ensure the compliance of those authorities with all their control functions, including reporting obligations under the conventions." (International Narcotics Control Board, 2009a, ¶1767 – Recommendation 3)

Despite the availability of these non-legislative resources and the recognition of their benefit in communicating complex policy standards, this policy evaluation does not apply to clinical practice or related guidelines and, as a result, these resources were not reviewed.



SECTION VI: IMPROVING PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

2. Influence of Unevaluated Policies

A country frequently can adopt statutes, regulations, or other governmental policies that can have an impact on patient pain care. Such policies can govern the following issues:

- scheduling of controlled medicines,
- prescribing, dispensing, or administering controlled medicines,
- establishing a system to estimate and report medical need for controlled medicines,
- providing financial coverage of therapeutic interventions (i.e., insurance or formulary standards),
- penalties/criminal sanctions for violations of laws,
- instituting taxation systems,
- permitting maintenance therapy (or opioid substitution therapy), and
- movement/transport of controlled medicines.

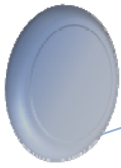
Of particular importance are insurance policies, which may not include opioid analgesics as part of their reimbursement formularies. Due to the expense of some opioid medications, patients may not be able to purchase them fully out of pocket. Pharmacies, in turn, may not stock them because of a lack of demand. As a result, even if evaluated legislation and regulations do not impose significant barriers on prescribing, a lack of medication availability for other reasons may ultimately impede access to appropriate treatment.

However, these and other policies were not evaluated because they fall outside the scope of this policy research methodology (see [Section VII](#)). It nevertheless remains important for empirical investigations into how these policies interact with pain treatment.

3. Policy Content Should be Consistent with Its Stated Intent

As recognized by numerous international authoritative sources, such as the WHO, the INCB, and the UN ECOSOC, national laws can contain requirements or restrictions that create barriers to effective patient care, even when those laws have been designed to improve pain treatment. Such requirements often undermine the law's stated intent used to justify its development, which often is suggested through language from Preamble, Whereas, or Considerations sections. When such a situation exists, it can only be remedied through modification so that the policy content conforms more closely to its explicit intent, or through clarification of its intent.

For example, the Philippine's Comprehensive Dangerous Drug Act of 2002 acknowledges the government's responsibility "to achieve a balance in the national drug control program so that people with legitimate medical needs are not prevented from being treated with adequate amounts of appropriate medications, which include the use of dangerous drugs" (Section 2, English translation) (Philippines Comprehensive Dangerous Drugs Act of 2002, 2002). Despite the obviously stigmatizing term "dangerous drugs," the law does recognize the need to attain and maintain balance. Critically, the policy has the force of law and may have liability for those who fail to comply with the requirements. The law goes on to state that anyone who prescribes dangerous drugs in a dosage that does not conform to standards determined by the "Dangerous Drugs Board" can be imprisoned for 12-20 years (Section 18). An unlawful prescription also can be punishable by life imprisonment or death (Section



SECTION VI: IMPROVING PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

19). Although the legal sanctions imposed by Sections 18 and 19 are grounded in reasonable principles of protecting public health, the extreme penalties indicated have the potential to chill medical practice by making physicians who are not acquainted with the complete context of the law unwilling to prescribe opioid medications as a result of fear of penalties.

Furthermore, the preamble to the Ugandan National Drug Policy and Authority Act (President and National Resistance Council, 1993) recognizes this policy as a:

"...Statute to establish a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means to providing satisfactory health care and safeguarding the appropriate use of Drugs." (Preamble)

Section 30 of the statute further obligates medical practitioners and dentists to keep records of all "persons who are addicted," and that this record is to be supplied to the Minister of Health each year. The record is to include the name of the person with an addictive disease and the drugs to which they are addicted. An additional provision within this Section prohibits those who are addicted to drugs from being prescribed medications unless given specific written Ministerial authorization to do so. This requirement seemingly contradicts the Preamble to the law which establishes a framework for which the entire population of Uganda is to have access to essential drugs.

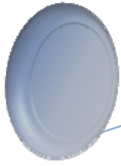
Given the potential legal liability for failing to conform to the requirements of laws such as these, a number of specific provisions contained in the policy can contribute to an inaccurate understanding of, or heightened concern about, the policies. Determining the reasons for practitioners' concerns about any laws, while evaluating whether changes to the laws are warranted (including the types of changes that may be most important), remains essential.

4. Legal or Regulatory Concerns can Undermine Actual Policy Content

In addition to the potential discordance between the intent that guides policy development and the policy that is eventually adopted, the influence of a policy can be affected by prevalent misperceptions about the requirements inherent in that policy. For example, a survey of health care professionals was conducted that evidenced a prevalent issue related to the Bangladesh Narcotic and Psychotropic Substances Act of 1990 (Department of Narcotics Control, 1990). Results demonstrated that respondents' confusion and concerns about the law stemmed more from an inadequate understanding of the legal provisions rather than from a central requirement established through this Act (Department of Narcotics Control, 1990). Such ambiguity could actually create uncertainties in practice that impede appropriate treatment of pain. Specifically, Section 13 of the Act includes this language:

"Restrictions on prescription of narcotics – No physician shall prescribe an A-Class or B-Class narcotic as medicine without written approval of the Director General [of Narcotics in the MoHA]" (emphasis added, English translation) (Department of Narcotics Control, 1990, p. 7).

This provision was interpreted to mean that, each time a physician prescribes an opioid analgesic, he or she would need to obtain a letter from the Director General within the national Ministry of Home



SECTION VI: IMPROVING PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

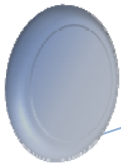
Affairs. However, when palliative care experts raised this concern with government officials, they were informed that there was a Decree issued later that same year, in 1990, clarifying this requirement to mean that a single letter issued by the Director General would meet the requirement, thereby obviating the need for a separate approval for each prescription (Government of Bangladesh, Department of Cancer Control, 1990). Palliative care experts were not aware of this Decree and its effect on the interpretation of the language in the 1990 Act.

Inaccuracies and misconceptions surrounding the breadth and mandates of this Act have the potential to facilitate prescribers' concerns about legal sanctions because of a failure to conform to this standard. In fact, practitioners' concerns about criminal sanctions or regulatory discipline, resulting from misinterpretations about any policy requirement or exaggerated perceptions of legal liability, can hinder appropriate prescribing to an equal extent as actual policy barriers; the consequence on practice can be the same – avoiding prescribing altogether rather than taking the risk of failing to comply with statutory or regulatory obligations. Clearly, rectifying a situation like the one that arose around the Bangladesh Act is more a matter of enhancing prescribers' awareness of the Decree clarifying the interpretation of the original language, as well as promoting the positive intent of the Act, rather than repealing or replacing the Act.

A similar circumstance was created through the implementation of new Opioid Prescribing Regulations for patients with cancer or HIV/AIDS, which were issued in February 2008 by the Vietnam Ministry of Health (MoH) (Ministry of Health, 2008). Before the changes in 2008, an official diagnosis of cancer or AIDS was required to receive a prescription for an opioid. Only a central or provincial hospital, however, could officially diagnose cancer or AIDS. As a result, in some cases patients living in rural and remote mountainous areas, many of whom were already in the late stages of cancer or HIV/AIDS, were required to travel very long distances to obtain an opioid prescription. The new regulations included many positive changes, such as:

- increasing the maximum number of days for which opioids could be prescribed from 7 to 30 days,
- lifting the limit on prescribing for only 5 days,
- lessening the burden on cancer and HIV/AIDS patients to receive prescriptions if the dose is above 30 mg, and
- expanding the prescription of opioids to patients without a diagnosis of cancer or HIV/AIDS.

Following the 2008 changes, a patient from a rural area who does not have an official diagnosis of cancer or AIDS, but who nevertheless requires an opioid, can receive an emergency prescription for 7 days from a local physician or physician assistant; the emergency prescription can be renewed every 7 days. Furthermore, in October 2009, the Vietnam MoH issued a clarification of the 2008 regulations regarding opioid therapy for cancer and HIV/AIDS patients in the home. The MoH statement explained that patients are not required to leave their homes to receive a prescription. Instead, a physician assistant from the community health clinic can confirm the patient's pain severity and the fact that the patient is still alive, which then allows a family member to procure the opioid from the closest pharmacy that has it in stock. Despite these positive policy changes, as well as the implementation efforts to make healthcare workers aware of them, fear of prescribing opioids persists in rural areas throughout the country. Many physicians who have received training in palliative care and now understand how to prescribe opioids, and are also knowledgeable about the changes in the regulations, are either afraid to



SECTION VI: IMPROVING PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

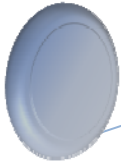
prescribe or have supervisors who prohibit prescribing. This is true especially for physicians who practice in HIV/AIDS outpatient clinics and for physicians who treat patients with past or current illicit heroin use. Furthermore, a number of physicians, health managers, pharmacists, and nurses remain unaware of the revised Opioid Prescribing Regulations, particularly those in rural areas. Thus, they do not recognize that the MoH is encouraging clinicians to treat pain and that many governmental barriers to opioid prescribing have been abrogated.

As these examples suggest, any policy considered to be confusing, excessive, or time-burdensome can have the unintended consequence of hampering legitimate practitioners and preventing patients from receiving needed treatment. Again, it is possible that such concerns will diminish as the policy content and implications become more understood, and as efforts are offered to solicit practitioner feedback to prompt further policy evaluation and revision. Until these situations are remedied, however, there is the potential to adversely impact patients with legitimate medical needs.

5. Positive Policy Change is Only the First Step to Improve Pain Management

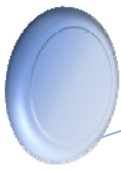
To be clear, advancements in national policy are necessary but, by themselves, are not likely to achieve a positive professional practice and regulatory environment that contributes to a healthcare system able to provide safe and effective pain relief. Policy change usually should be viewed similarly as any other single approach designed to improve the multifaceted issue of treating pain – it can be adequately addressed only through a multifaceted process. In addition, effective communication and implementation strategies are essential for maximizing the effect of a new or modified policy, and the clinical benefit of even the most positive policy will be undermined by deficient or ineffectual efforts to put the policy into practice. Accurate awareness of new policy content and requirements, especially those relating to the context of patient care, is compulsory so that those governed by these requirements remain compliant with, and thoroughly conform to, legal standards. To achieve this important objective, newly-adopted or modified policies should be disseminated widely and conveyed repeatedly to healthcare workers and, when relevant, to the public. National law that promotes safe and effective pain management must be broadly recognized as doing so, to help ensure beneficial consequences for patient care.

An example of implementing policy changes occurred in Romania in the mid-2000s, following the passage of a new law governing opioid prescribing in 2005 and the corresponding regulations in 2006 (Mosoiu, Mungiu, Gigore, & Landon, 2007). The process of enacting the policies began with a meeting in 2006 of all the major stakeholders to discuss how the new law and regulations would be successfully implemented. The meeting, entitled “Implementing a Modern and Balanced Opioid Legislation in Romania,” was attended by approximately 40 people, including the vice chair of the Parliament Commission for Health (Mosoiu et al., 2007). The meeting provided an opportunity to educate all parties (including law enforcement) about opioids for treating pain, how to interpret the new law, and how the regulations could change to conform to the new law. Additionally, a MoH Palliative Care Commission recognized that it would be necessary to develop a curriculum to educate health care practitioners about how to prescribe opioid analgesics to patients in pain, including a description of the new law and regulations and their intended impact on practice and patient care. As a result, a new Curriculum Planning Committee developed a training program for physicians and pharmacists that consisted of 20 hours of classroom teaching on two consecutive weekends and six hours of clinical practice in each participant’s own setting. The courses, which include interactive case studies, are



SECTION VI: IMPROVING PATIENT CARE: OTHER ISSUES TO CONSIDER IN RELATION TO POLICY

endorsed by the MoH and are nationally accredited for continuing medical education by the College of Physicians and Pharmacists. Similarly, in 2004 the Ugandan government passed an amendment to the National Drug Policy and Authority Statute that greatly expanded the number of health care professionals able to prescribe morphine by granting such prescribing authority to specially trained palliative care nurses and clinical officers (President and National Resistance Council, 1993). As a result, a certificate training program for palliative care specialists (called the *Clinical Palliative Care Course*) was initiated (Jagwe & Merriman, 2007). The specialist course is a nine month program for nurses and clinical officers, and the course curriculum has been approved by the Nursing and Allied Professionals' Councils of Uganda. As of 2007, 53 professionals had graduated from the course with the authority to prescribe morphine and are now working in hospice, palliative care teams in hospitals, and for the MoH in various regions of the country (Jagwe & Merriman, 2007). This action allowed Ugandans living in rural areas to have more reliable access to pain relief in their homes.



SECTION VII: RESEARCH METHODOLOGY

OVERVIEW

This *Global Evaluation Guide* presents the results of a systematic, criteria-based, evaluation of policies affecting pain management that have been adopted by the governments of a small sample of Latin American countries (although the criteria were conceptualized to be applied to policies in any country). The PPSG evaluated national drug control legislation and regulations, as well as legislation and regulations governing medical and pharmacy practice. We also can evaluate other governmental policies where present and available, such as official policy statements and guidelines regarding issues affecting pain management. As a result, policies influencing the treatment of pain, palliative care, and end-of-life care, including the prescribing and dispensing of controlled opioid medications, comprise the population studied for this research.

The following policies were collected and analyzed for the purpose of this research:

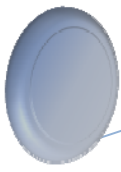
National laws – including legislation and regulatory laws related to controlled medicines and medical and pharmacy practice, such as:

- Decrees (Presidential Decrees)
- Government Accords
- Laws
- “Official Norms”
- Regulations
- Resolutions
- Rules

Also included are other governmental policies where present, such as medical regulatory agency guidelines and official policy statements, as well as any other policies identified that contained language directly mentioning the treatment of pain, such as:

- Policies authorizing or requiring healthcare facilities to assess or treat pain, including as part of palliative care or end-of-life care services,
- Provisions encouraging or requiring medical school education or continuing medical education related to pain management or palliative care,
- Provisions establishing pain councils or task forces as governmental vehicles designed to improve pain management, palliative care, or the medical use of controlled medicines (evaluation is based on the objectives stated in policy, and not on the procedures or results of the commission’s work), and
- Provisions authorizing or requiring regulatory agencies to create and implement rules or guidelines specifically relating to pain management, and communicating these policies to licensees.

Specifically, the types of policies examined for this report would include those affecting the treatment of diseases, both short-term and chronic, that typically are associated with pain as a symptom, such as cancer and HIV/AIDS. In this context, pain related to cancer could include not only pain resulting from the active disease but also pain manifesting from treatment or occurring after treatment or during survivorship. Other diseases that are often accompanied by pain include sickle-cell anemia, polio, emphysema, lupus, typhoid, tuberculosis, and congestive heart failure.



SECTION VII: RESEARCH METHODOLOGY

The evaluation of provisions that relate to the medical use of controlled substances focuses only on those relevant to opioid medications indicated for analgesia that are controlled under Schedule I of the amended Single Convention on Narcotic Drugs (e.g., fentanyl, morphine, and oxycodone). Such attention on this class of prescriptions is appropriate because these are the only controlled medications approved and essential for treating moderate to severe pain (World Health Organization, 1996; 2012b).

Importantly, this document describes a methodology that can be applied to the content of a country's drug control policies as they relate primarily to the controlled *availability* and *medical use* of opioids. The purpose of this guide, therefore, is to evaluate governmental policies affecting availability, but does not extend to the content of policies relevant to drug trafficking and abuse prevention. Of course, the presence and adequacy of *controls* to prevent diversion and abuse of controlled substances remain valid and important topics for policy evaluation, and ones that are undertaken periodically by other entities. In this regard, the Single Convention requires that medication availability be limited to medical and scientific purposes (United Nations, 1961, Article 4(c)), and national governments that have difficulty accomplishing this can be considered unbalanced in relation to effective drug control to prevent abuse and diversion. [Appendix A](#) illustrates further international support for the need for countries to continue efforts to implement a legal and regulatory framework to prevent prescription medication diversion and abuse, while also maintaining medication access for medical and scientific purposes.

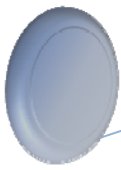
DATA COLLECTION

National policies⁶ that were identified, evaluated, and found relevant are listed on the cover pages of each Country Profile ([Section IX](#)). An electronic legal database (Lexis, from "Lexis-Nexis Research Software") initially was used to identify and obtain relevant national statutes and regulations where possible. Within the pilot sample of countries selected for this evaluation, Mexico was the only country for which at least some health care laws were obtainable through Lexis, though they were not relevant to this policy research.

The website for each Ministry of Health (MoH) also was accessed periodically to determine whether it contained official legislation, regulations, or policy statements that had been adopted and are current. If the policies were available electronically, through MoH websites or other Internet-based sources, they were downloaded.

Governmental legislation or regulations not available through MoH websites or via the Internet were collected directly from a variety of in-country contacts (see [Acknowledgement of Support](#) section for the principal contacts) using already-established networks with members of the national government or healthcare regulatory agencies. These personal contacts were initiated with health care professionals who are knowledgeable about the policy trends in their country.

⁶ Although many countries are comprised of states, provinces, districts, municipalities, etc., which can have policies that further govern drug control or healthcare practice, these policies were not evaluated for the purpose of this report. Also, we did not focus the evaluation on a number of other national policies that could affect pain management, but which fall outside the scope of our evaluation (see [Section VI, Item 2](#)). Civil or administrative case law, language from legislative notes, or clinical practice guidelines or national essential medicines lists promulgated by national agencies were not evaluated. Finally, we did not evaluate potential non-policy barriers such as requirements that are not written in any law, but which can nevertheless establish impediments imposed by historical precedents. Examples of such potential barriers include: Requiring physicians to attach to the prescription a document that includes complete medical history and a detailed description of the diagnosis and exams; requiring the prescription must be signed by the director and legal representative of the hospital, who also check the medical history; and having the pharmacy require that prescribers return empty ampoules in order to obtain new requested ampoules for in-hospital use.



SECTION VII: RESEARCH METHODOLOGY

This methodology was designed to maximize the thoroughness of the data-collection. Even given this procedure, however, it is possible that relevant policies or provisions within those policies were not identified. This is especially true when national policies were adopted after November 1, 2013, once the data-collection phase of this project had ended, or where that policy's title did not suggest pertinent content and, therefore, was not chosen to be evaluated.

POLICY TRANSLATION

Initial translations from Spanish to English for all collected policies, if required, were conducted using Google Translate® so that the entire policies could be cursorily reviewed to identify potentially relevant sections or content. Content identified as possibly related to pain, palliative care, or end-of-life care, from every collected policy, then was subject to a formal translation (using Spanish translation services provided by the Geo Group Corporation to the University of Wisconsin). This official translation underwent a final confirmatory evaluation and a subsequent review by an in-country expert. Results from this extended and iterative process are meant to constitute the approved and accurate translation used for this study.

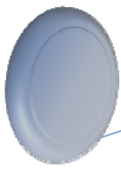
POLICY EVALUATION

All relevant policies that were in force and available as of November 1, 2013, were examined for this evaluation. A Central Principle, termed *Balance*, has been identified and operationalized as the conceptual framework for this evaluation (see [Section IV](#)), from which a total of 20 evaluation criteria were developed and defined (see [Section VIII](#)). Two of the 20 criteria ([Criterion B.8](#) and [Criterion C.7](#)) were created to acknowledge the presence of provisions that have the potential to affect pain management but do not relate to the content of any specific criterion. [Section IV](#) lists citations from the international authoritative sources that support the Central Principle, while [Section V](#) reinforces the imperative to evaluate pain policy.

After the data collection phase, four policy analysts at the PPSG separately applied the criteria to evaluate all the policies that were identified. Provisions were judged to satisfy the criteria only on the basis of explicitly-stated language (“black letter policy”), not by their implication or intent. For example the overall intent of a policy may be to provide an infrastructure for palliative care services within a country but, if the policy language did not include specific statements relevant to the criteria, the policy was not presented in this report. Provisions that met any of the criteria were identified by consensus among the policy analysts. These initial evaluation findings then underwent a final confirmatory review by an in-country expert.

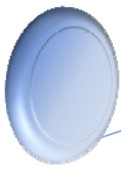
These provisions are compiled and presented in the Country Profiles section (see [Section IX](#)). If a policy contained repetitive language, so that the same criterion could have been satisfied multiple times, we identified only one provision that met that criterion; that is, we did not identify repeated mentions of the same prescription requirement in a particular statute or regulation. As a result, when findings from this evaluation are used to revise a policy, the entire policy must be examined to identify all potential occurrences of the same provision that should be changed; however, we did indicate the presence of the same criterion in other, separate, policies in which similar provisions were identified. Conversely, to be clear, [Criterion B.8](#) and [Criterion C.7](#) can be applied more than once to the same policy if they represent different concepts or standards.

The Country Profiles (see [Section IX](#)) contain all relevant provisions extracted from each identified policy. Highlighting and underlining is used to draw attention to the specific language. A “comment” box



SECTION VII: RESEARCH METHODOLOGY

identifies the criterion that was satisfied by a particular provision, using a positive (+) or negative (-) sign and shading to indicate whether the provision has the potential to enhance (+) or impede (-) the appropriate provision of pain management. It should be noted that the effect of the provisions on pain treatment practice, or palliative care or end-of-life care services, may vary according to how the provisions are perceived, implemented, or enforced, and is a matter for further study (see [Section VI](#)). The Country Profiles in this report are meant to constitute the approved and accurate policy evaluation results for this study.



SECTION VIII: RESEARCH CRITERIA

The criteria used to evaluate the policies are based on requirements contained in the Single Convention, as well as on the Central Principle of *Balance* inherent in the Convention, and are presented in the following two sections:

- (1) criteria that identify positive provisions that may enhance safe and effective pain management, and
- (2) criteria that identify negative provisions that may impede safe and effective pain management.

For the purpose of this evaluation, balanced policy governing medication availability recognizes the legitimacy of pain management practice, including the prescribing and dispensing of controlled substances, and is operationalized by having policy with a number of positive provisions and few, if any, negative provisions.

Each criterion is elaborated with relevant justifications and recommendations from international and, in a few cases when necessary, United States expert bodies.

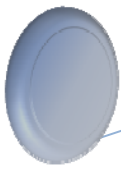
Section 1 – Positive Provisions: Criteria that identify provisions that may *enhance* safe and effective pain management

A Criteria related to the Single Convention

- A.1 Acknowledges the intent to carry out drug control Conventions
- A.2 Designates administrative responsibility to implement the Conventions in the country
- A.3 Acknowledges the Government's responsibility to ensure availability of narcotic drugs for medical and scientific purposes
- A.4 Recognizes the medical use of controlled substances as indispensable for the relief of pain and suffering, including being necessary for the public health
- A.5 Represents the principle of *Balance*

B Criteria related to the Central Principle of Balance

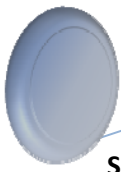
- B.1 Patients have a right to pain management
- B.2 Pain management is recognized as part of general healthcare practice
- B.3 Medical use of opioids is recognized as legitimate professional practice
- B.4 Pain management is encouraged
 - Category A: Ensures treatment of certain patient populations
 - Category B: Promotes training of healthcare professionals
 - Category C: Promotes patient or public awareness
- B.5 Practitioners' concerns about sanctions are addressed
- B.6 Legitimacy of prescribing is not based solely on amount of medication prescribed
- B.7 Withdrawal syndrome or analgesic tolerance are not confused with *dependence syndrome* (i.e., "addiction")
- B.8 Other provisions that may enhance pain management
 - Category A: Issues related to healthcare professionals
 - Category B: Issues related to patients
 - Category C: Other regulatory or policy issues



SECTION VIII: RESEARCH CRITERIA

Section 2 – Negative Provisions: Criteria that identify provisions that may *impede* safe and effective pain management

- C *Criteria related to the Central Principle of Balance*
- C.1 Opioids are relegated as only a treatment of last resort
- C.2 Withdrawal syndrome or analgesic tolerance are confused with *dependence syndrome* (i.e., “addiction”)
- C.3 Restrictions that could limit medical decision-making
 - Category A: Restrictions based on patient characteristics
 - Category B: Mandated consultation for all patients
 - Category C: Restrictions regarding quantity prescribed or dispensed
- C.4 Length of prescription validity is restricted
- C.5 Practitioners are subject to undue prescribing requirements
 - Category A: Requirement to use special prescription forms
 - Category B: Requirement to report certain patients
 - Category C: Requirement of a separate license/registration
 - Category D: Requirement of an additional prescription authorization
- C.6 Provisions that are ambiguous
 - Category A: Arbitrary standards for legitimate prescribing
 - Category B: Unclear intent leading to possible misinterpretation
 - Category C: Conflicting or inconsistent policies or provisions
 - Category D: Unclear definitions of dependence syndrome
- C.7 Other provisions that may impede pain management
 - Category A: Issues related to healthcare professionals
 - Category B: Issues related to patients
 - Category C: Other regulatory or policy issues



SECTION VIII: RESEARCH CRITERIA

Section 1 – Positive Provisions: Criteria to Identify Provisions That May *Enhance* Pain Management

CRITERIA A: CRITERIA RELATED TO THE SINGLE CONVENTION

The following five policy assessment criteria are based on the plain language of the Single Convention. The criteria were developed to reflect balanced drug availability language contained in, or representing the intent of, the Single Convention.

All criteria, as well as the authoritative sources justifying each criterion, are listed below.

CRITERION A.1: ACKNOWLEDGES THE INTENT TO CARRY OUT DRUG CONTROL CONVENTIONS

The Single Convention clearly requires that language in national laws establishes the government and regulatory framework to implement the provisions concerning drug control (United Nations, 1972):

“The Parties shall take such legislative and administrative measures as may be necessary: (a) to give effect to and carry out the provisions of this Convention within their own territories...” (Article 4(a))

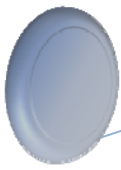
In addition, the International Narcotics Control Board (INCB), the organizational body charged with monitoring treaty implementation, reiterated the Single Convention language regarding this objective (International Narcotics Control Board, 1996):

“A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licenses, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (¶148)

CRITERION A.2: DESIGNATES ADMINISTRATIVE RESPONSIBILITY TO IMPLEMENT THE CONVENTIONS IN THE COUNTRY

Administrative authority to implement the Conventions within a country usually is conferred upon a body that is referred to as the National Competent Authority (NCA). The NCA typically is responsible, inter alia, for managing the government’s obligations under the Single Convention, including submission of estimates of the amounts of narcotic drugs that will be required to satisfy medical and scientific needs in the country. Additional responsibilities include setting maximum manufacturing allotments, administering scheduling of substances, and authorizing exports and imports. Such responsibility is designated in the Single Convention (United Nations, 1972) as:

“The Parties shall maintain a special administration for the purpose of applying the provisions of this Convention.” (Article 17)



SECTION VIII: RESEARCH CRITERIA

As with Criterion A.1, the INCB historically has recognized Governments' obligation to establish administrative responsibility for implementing the Single Convention:

"A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licenses, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes." (International Narcotics Control Board, 1996, ¶48)

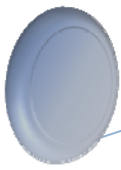
"Governments are invited to consider the following recommendations:...Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol...to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws." (International Narcotics Control Board, 1996, ¶51(f))

"Pursuant to article 17 of the Single Convention, Parties shall maintain a special administration for the purpose of applying the provisions of the Convention. Such an administration must coordinate the work of the various ministries and Government offices relating to the implementation of the treaty provisions, in the fields of health, social welfare, justice, law enforcement, etc. This may include, among other things, the competent national authorities empowered to issue certificates and authorizations for the import and export of narcotic drugs, the authorities that control domestic production/manufacture of narcotic drugs, state enterprises that produce/manufacture narcotic drugs, the institutions dealing with prevention and treatment of drug abuse, and the law enforcement authorities charged with preventive and repressive action against illicit traffic in narcotic drugs." (International Narcotics Control Board, 2005, ¶25)

"It should be noted that a special administration does not necessarily mean a single authority, although a single authority may be designated as the interlocutor, on behalf of the Government, with the international drug control organs, such as the Ministry of Foreign Affairs. A special administration may simply consist of a mechanism of coordinated and effective cooperation between the different authorities and institutions involved in implementing the Single Convention." (International Narcotics Control Board, 2005, ¶26)

"The most important provisions of article 31 are those that require a license regime for the authorization of export and import of substances under the control of the Convention, also defining the manner in which such a regime shall function. Each country must have a competent authority empowered to issue export/import authorizations for narcotic drugs, and the name and address of that authority must be communicated to the Secretary-General (c/o the Executive Director of UNODC)." (International Narcotics Control Board, 2005, ¶42)

"Difficulties experienced by some Governments in submitting the required statistical data to the Board have different reasons, including the inadequate resources and inadequate training provided to the authorities responsible for the control of licit activities related to narcotic drugs and psychotropic substances. The Board again calls upon the Governments concerned to allocate adequate resources to their national competent authorities to ensure the compliance of those authorities with all their control functions, including reporting obligations under the conventions." (International Narcotics Control Board, 2009a, ¶765, Recommendation 3)



SECTION VIII: RESEARCH CRITERIA

A recent document published jointly by the INCB and the WHO (2012), outlining ways to effectively estimate a country's need for controlled medicines, provided emphasis about the importance of medication availability that is achieved through a coordination of responsibilities:

"The competent national authorities are responsible for the following:

- (a) Developing a method to accurately determine the legitimate requirements for controlled substances for medical purposes in their countries;
- (b) Calculating the estimates and assessments for controlled substances to be furnished to INCB;
- (c) Informing operators (manufacturers, distributors, dispensers, administrators and healthcare providers) about their legal obligation to provide information for preparing the estimates and assessments of controlled substances and providing training to allow them to do so;
- (d) Organizing the collection of relevant data from operators and other sources;
- (e) Coordinating with other Governmental bodies involved in drug supply management and public health, notably the Ministry of Health in cases where the competent national authority is not part of that ministry, to ensure that conditions are met for the accurate quantification of requirements for controlled substances." (§11)

CRITERION A.3: ACKNOWLEDGES THE GOVERNMENT'S RESPONSIBILITY TO ENSURE AVAILABILITY OF NARCOTIC DRUGS FOR MEDICAL AND SCIENTIFIC PURPOSES

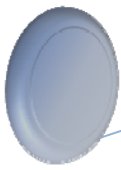
According to the Central Principle of *Balance*, the purpose of controlled medicines policies is to prevent the abuse of drugs (including prescription opioids) and also to recognize their important contribution to public health. Drug control policies establish the system for prescribing and dispensing prescription medications that are approved for human use and, therefore, should not conflict with their use for legitimate medical purposes; this dual purpose of drug control policy should continue to be recognized in a country's policy language. Legislative language establishing government responsibility for adequate drug availability can provide justification for healthcare professionals who are attempting to convince members of government agencies of the need to increase medical access to medications. Such an approach can be especially beneficial when a government member believes that pain medicines should be subject to overly-strict control.

In 1972, this drug availability obligation of parties was strengthened in the Single Convention (United Nations, 1972) by the following language:

"The Parties, Concerned with the health and welfare of mankind, Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,...Hereby agree as follows:..." (Preamble)

Historical statements from the INCB have repeatedly referenced Governments' responsibility to ensure adequate medication availability:

"The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs." (International Narcotics Control Board, 1996, ¶1)



SECTION VIII: RESEARCH CRITERIA

“The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes...Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (International Narcotics Control Board, 1996, ¶48)

“The provisions of the 1961 Convention, intended to limit the availability of narcotic drugs to medical and scientific purposes, were supplemented by the [1972 Protocol] obligation of parties to ensure the availability of those drugs for such purposes.” (Bayer & Ghodse, 1999, p. 12)

“The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. Guided by a similar principle, States recognized in the Convention on Psychotropic Substances of 1971 that the availability of psychotropic substances for medical and scientific purposes should not be unduly restricted. Adequate availability and limitation were considered by the State parties to the 1961 Convention and the 1971 Convention as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.” (International Narcotics Control Board, 2000, ¶11)

“The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of mankind, as well as of the fact that drug addiction is a worldwide social and economic threat. Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts.” (International Narcotics Control Board, 2005, ¶12)

“For years, the Board has called on Governments to fulfill that treaty obligation [ensuring the availability of narcotic drugs used for medical purposes] and make the availability of drugs a priority public health issue. Nevertheless, large discrepancies in the consumption of those medicines remain.” (International Narcotics Control Board, 2009a, Foreword by Dr. Hamid Ghodse, page iii)

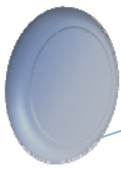
“Governments must ensure the provision of narcotic drugs and of psychotropic substances for medical and scientific purposes.” (International Narcotics Control Board, 2009a, ¶17)

“The primary objective of the 1961 and 1971 Conventions is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs.” (International Narcotics Control Board, 2009a, ¶20)

“The Board again urges all Governments concerned to identify the impediments in their countries to adequate use of opioid analgesics for the treatment of pain and to take steps to improve the availability of those narcotic drugs for medical purposes, in accordance with the pertinent recommendations of WHO.” (International Narcotics Control Board, 2009a, ¶102)

“One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances.” (International Narcotics Control Board, 2009a, ¶770)

“In its annual report, the Board has consistently addressed the issue of making opiates available for medical needs, urging Governments to critically examine their methods of assessing domestic medical needs for opiates and to take the steps necessary to remove impediments to the adequate availability of those drugs”



SECTION VIII: RESEARCH CRITERIA

for medical and scientific purposes..." (International Narcotics Control Board, 2009b, ¶62)

"Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol, and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board." (International Narcotics Control Board, 2011, ¶1)

"The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. However, despite numerous efforts by the Board and the World Health Organization (WHO), as well as non-governmental organizations, their availability in much of the world remains very limited, depriving many patients of essential medicines. The Board continues to monitor the worldwide availability of narcotic drugs and psychotropic substances and has made their availability one of the main topics of its dialogue with Governments on adequate treaty implementation." (International Narcotics Control Board, 2011, ¶4)

As early as 1996, a Special Report from INCB made a specific recommendation that national policies should include this Governmental responsibility (International Narcotics Control Board, 1996):

"Governments are invited to consider the following recommendations:...Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that...adequate provision must be made to ensure the availability of narcotic drugs for such purposes..." (¶51(f))

A jointly-published report by the INCB and the WHO (2012), outlining ways to effectively estimate a country's need for controlled medicines, also clearly emphasized the importance of medication availability:

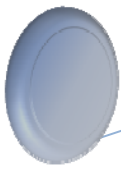
"By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the [international drug control] conventions. (¶1)...The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse. (¶2)...WHO also provides guidance to Governments on policies and legislation on the availability, accessibility, affordability and control of medicines made from controlled substances." (¶4)

Recently, the United Nations Economic and Social Council (ECOSOC) (2010) called on all Governments to evaluate their policies as a means to improve legitimate medication availability:

"...update policies and legislative frameworks, as appropriate, to ensure adequate availability of internationally controlled substances, [balanced with preventing] the diversion and abuse of those substances, in line with the provisions of the international drug control treaties." (¶10)

In addition, the World Medical Association (WMA) (2011) emphasized a similar approach that Governments should take to attain adequate availability and accessibility of controlled medicines:

"Governments must ensure the adequate availability of controlled medicines, including opioids, for the relief of pain and suffering...International and national drug control policies should balance the need for adequate availability and accessibility of controlled medicines like morphine and other opioids for the relief of pain and suffering with efforts to prevent the misuse of these controlled substances." (p. 2)



SECTION VIII: RESEARCH CRITERIA

This statement was further reinforced when President-Elect of the WMA, Dr. Cecil Wilson, while speaking at a WMA side meeting, acknowledged the prevalent lack of access to pain relief worldwide (World Medical Association, 2012):

“...Governments must ensure the adequate availability of controlled medicines, and governmental drug control agencies’...the appropriate use of morphine, new analgesics, and other measures could relieve pain and other distressing symptoms in a majority of cases. Health authorities must make necessary medications accessible and available to physicians and their patients.”

Importantly, the critical nature of Governments’ ensuring adequate availability and accessibility of controlled medicines is directly highlighted as a specific guideline in the WHO’s updated Guidelines resource (2011a):

“Guideline 2: Governments should comply with their international legal obligations to ensure adequate availability and accessibility of controlled medicines for all medical and scientific purposes through national legislation and drug control policies...International human rights treaties and other instruments provide a further source of guidance related to the availability and accessibility of controlled medicines...Advocates argue that international human rights principles require that governments must provide essential medicines – which include controlled medicines – as part of their minimum core obligations under the right to health. In addition, other advocates have linked access to controlled medicines to the human rights obligation of governments to take measures to protect people under their jurisdiction from inhuman and degrading treatment.” (pp. 20-21)

CRITERION A.4: RECOGNIZES THE MEDICAL USE OF CONTROLLED SUBSTANCES AS INDISPENSABLE FOR THE RELIEF OF PAIN AND SUFFERING, INCLUDING BEING NECESSARY FOR THE PUBLIC HEALTH

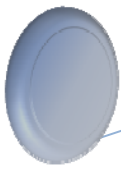
A Government’s responsibility to assure adequate availability and accessibility of controlled medicines is further supported by national policies acknowledging the Single Convention’s assertion about the indispensability of these medicines for public health in general and for pain and suffering in particular:

“The Parties, Concerned with the health and welfare of mankind; Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...Hereby agree as follows:...” (United Nations, 1972, Preamble)

“One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion.” (International Narcotics Control Board, 1989, ¶11)

“According to WHO projections, two thirds of the estimated 15 million new cancer cases per year will occur in developing countries by the year 2015. Some 70-80 per cent of cancer patients suffer severe pain, whether acute or chronic, in the late stages of the disease. There is broad consensus today that, for the treatment of severe pain related to cancer, opioids, above all morphine, are indispensable due to their affordability and analgesic efficacy.” (International Narcotics Control Board, 2000, ¶19)

“Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol,



SECTION VIII: RESEARCH CRITERIA

and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board.” (International Narcotics Control Board, 2011, ¶1)

The following INCB statement specifically addresses the need for national policies to recognize that controlled substances are indispensable (International Narcotics Control Board, 1996):

“Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws.” (¶51(f))

In addition, in 2008, Manfred Nowak and Anand Grover, in their capacities as UN Special Rapporteur, addressed this important topic as a fundamental human right (Nowak & Grover, 2008):

“The failure to ensure access to controlled medicines for the relief of pain and suffering threatens fundamental rights to health and to protection against cruel inhuman and degrading treatment. International human rights law requires that governments must provide essential medicines – which include, among others, opioid analgesics – as part of their minimum core obligations under the right to health.” (p. 2)

Nowak & Grover’s human rights position was further illustrated in the 2011 WHO Guidelines document (2011a):

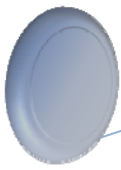
“Moreover, in 2008, the United Nations’ Special Rapporteur on the prevention of torture and cruel, inhuman, or degrading treatment or punishment, and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, jointly wrote a letter to the CND on human rights aspects of drug control, in which they requested that ‘national drug control laws recognize the indispensable nature of narcotic and psychotropic drugs for the relief of pain and suffering, and guarantee adequate availability of those medicines for legitimate medical uses, including opioid analgesics and opioids for substance dependence programmes’.” (p. 11)

The indispensability of controlled medicines, including opioid analgesics, also is reinforced in the narrative of the 2011 WHO Guidelines report (2011a), as well as being represented by a specific guideline:

“Drug control should not be approached as an objective in itself, but as a tool to optimize public health.”
“One focus should be the prevention of abuse and dependence; the other to avoid collateral harm. The outcomes should be judged both by the harms from abuse it prevents *and the harm it causes through, for example, lack of access.* (p. 12)

For all of these patients, pain relief should be part of their overall treatment. Oral opioids are key components for the treatment of moderate to severe pain and several are regarded as essential medicines. Paracetamol (acetaminophen), acetylsalicylic acid, non-steroidal anti-inflammatory medicines (NSAIDs) when used alone and weak acting opioids (tramadol, codeine) are usually not effective in the case of moderate to severe pain. NSAIDs can have serious side-effects and should be used with caution on a chronic basis. Despite a century of pharmaceutical chemistry, suitable alternatives to strong opioids for treatment of moderate to severe pain have yet to be found. (p. 14)

“Guideline1: National drug control policies should recognize that controlled medicines are absolutely



SECTION VIII: RESEARCH CRITERIA

necessary for medical and scientific purposes. It can be considered as a condition sine-qua-non for enabling and facilitating availability and accessibility of controlled medicines, that national policies are explicit about their objectives. National policies should recognize the necessity of controlled medicines and ensure they put in place policy statements to ensure implementation of the policies. Such statements would include those on improving access to all in need. Moreover, countries may want to establish this in their law, either as an objective or an obligation for the government. This would mirror the imperative stated in the international drug control treaties to make narcotic drugs and psychotropic substances available for medical use.” (p. 20)

CRITERION A.5: REPRESENTS THE PRINCIPLE OF *BALANCE*

Importantly, as suggested for [Criterion A.3](#), countries can establish a policy with the clear intent to prevent the abuse or diversion of controlled medicines while, at the same time, ensuring their availability for legitimate medical and scientific purposes. This approach directly reflects the Central Principle of *Balance*:

“...one of the basic principles of international drug control is that reduction in the availability of drugs for non-medical purposes should not affect and limit their therapeutic use. (Bayer & Ghodse, 1999, p. 12)

[Section IV](#) contains the conceptualization of *Balance*, as well as the numerous authoritative sources supporting its importance as a foundation for drug control laws (also synopsized in [Appendix D](#)).

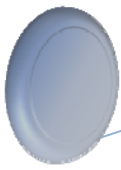
Another critical feature of this concept would be the explicit designation of responsibility for National Competent Authorities to ensure balance when meeting their obligation to implement the UN Conventions, which would include enhancing the availability and accessibility of controlled medicines. In fact, a recent document published jointly by the INCB and the WHO (2012), outlining ways to effectively estimate a country’s need for controlled medicines, repeatedly focused on the importance of estimation methods to ensure medication availability:

“The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse. An essential component of this regime is a system under which Governments are requested to estimate the quantities of controlled substances required for legitimate purposes and to limit the use of and trade in such substances to within those estimates. If applied correctly, this system should not hinder but rather promote access to appropriate amounts of controlled substances and should prevent their excessive use. The accurate estimation of requirements for controlled substances is an essential step in ensuring their adequate supply for medical and scientific purposes. On the one hand, underestimation of requirements can contribute to many problems in the use of controlled substances in the health-care system, notably shortages, inappropriate prescribing, distortion of demand and lack of cost-effectiveness; on the other hand, overestimation can lead to surpluses, wastage and increased risk of diversion of controlled substances.” (¶1)

“Estimates and assessments should be based on legitimate medical and scientific requirements. The process of calculating these estimates and assessments:

(a) Allows the competent authorities to obtain accurate and realistic information about the quantities of controlled substances actually required for medical and scientific purposes;

(b) Provides information that is essential for authorities to ensure that sufficient quantities of controlled



SECTION VIII: RESEARCH CRITERIA

substances are available in the health-care system;

(c) Informs authorities about the levels required for legitimate use so that they are able to limit their supply of controlled substances and take appropriate measures to prevent the diversion of those substances for illicit use.” (¶18)

Such a concept was further exemplified in the recent WHO Guidelines document (2011a) through the proposition of a specific guideline:

“Guideline 3: Governments should designate a National Authority for ensuring adequate availability and accessibility of controlled medicines in health care...Such an authority could be part of the National Competent Authority or a separate office, whatsoever is the most appropriate in the national situation.” (p. 22)

Designating administrative responsibilities that explicitly include ensuring adequate availability and accessibility of controlled medications remains critical. Such language expands the administrative authority beyond the singular issues of the illicit movement of controlled substances and other illicit activities and, as a result, makes both control and availability similar priorities within an overall obligation to implement the Conventions.

CRITERIA B: CRITERIA RELATED TO THE CENTRAL PRINCIPLE OF *BALANCE*

The following criteria individually reinforce the Single Convention’s commitment to the availability of controlled medicines for legitimate medical purposes, while representing their indispensability for the relief of pain and suffering. The presence of this type of positive language is critical to creating an environment that promotes safe and effective pain management, which is a message that is highlighted in *Managing Drug Supply* (a WHO collaborative publication) (Management Sciences for Health & World Health Organization, 1997):

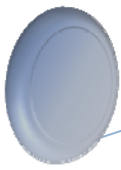
“The approach to pharmaceutical regulation should not be purely repressive: rules creating a positive situation tend to be more effective than those that merely prevent harm from being done.” (p. 91)

All criteria, as well as the authoritative sources justifying each criterion, are listed below.

CRITERION B.1: PATIENTS HAVE A RIGHT TO PAIN MANAGEMENT

A number of international authorities, including the UN Economic and Social Council (ECOSOC) (2005b; 2010), the World Health Assembly (2005), the International Association for the Study of Pain (2010), and the Council of Europe (2003), have recognized access to pain relief or palliative care as a serious public health issue or as an important humanitarian responsibility.

As a specific example, In 2011, the World Medical Association’s General Assembly drafted a “Resolution on the Access to Adequate Pain Treatment (World Health Assembly, 2005), including the following principle:



SECTION VIII: RESEARCH CRITERIA

“The right to access to pain treatment for all people without discrimination, as laid down in professional standards and guidelines and in international law, should be respected and effectively implemented... Under the right to health, people facing pain have a right to appropriate pain management, including effective medications such as morphine. Denial of pain treatment violates the right to health and may be medical unethical.” (p. 2)

Perhaps the most through acknowledgement of pain management as a fundamental human right comes from the International Association for the Study of Pain (2010):

“...recognizing the intrinsic dignity of all persons and that withholding of pain treatment is profoundly wrong, leading to unnecessary suffering which is harmful; we declare that the following human rights must be recognized throughout the world:

Article 1. The right of all people to have access to pain management without discrimination.

Article 2. The right of people in pain to acknowledgement of their pain and to be informed about how it can be assessed and managed.

Article 3. The right of all people with pain to have access to appropriate assessment and treatment of the pain by adequately trained health care professionals.” (p. 1)

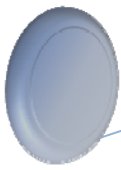
The relevance of this concept also was reflected in the WHO’s 2011 *Ensuring Balance* Guidelines document (2011a), which promotes treatment equality and non-discrimination of healthcare services:

“Guideline 8: Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rational medical use and the prevention of diversion, abuse, and dependence syndrome. Non-discrimination is a fundamental principle that runs throughout the entire body of international human rights law...When developing policies and establishing treatment services, governments should not only guard against deliberate discrimination, but also ensure that the policies do not unintentionally lead to discrimination against vulnerable groups. A number of groups, including women, children, the elderly, people in lower income classes, ethnic minorities, prisoners, people living with HIV, sex workers, men who have sex with men, and injecting drug users, are particularly vulnerable and may require a special effort to ensure realistic access to controlled medicines. When designing policies, it should be ensured that such policies and resultant services allow for equal access and availability for these groups and are both gender sensitive and culturally appropriate.” (p. 26)

CRITERION B.2: PAIN MANAGEMENT IS RECOGNIZED AS PART OF GENERAL HEALTH CARE PRACTICE

The Single Convention recognizes that the relief of pain and suffering, including but not limited to the medical use of controlled medicines, is within the scope of science and professional health care practice (United Nations, 1972). As such, pain management is considered a fundamental part of health care practice for policy that promotes safe and effective use of controlled medicines while, at the same time, mitigating their non-medical use:

“Physicians and other health care professionals have an ethical duty to offer proper clinical assessments to patients with pain and to offer appropriate treatment, which may require prescribing medications – including opioid analgesics – as medically indicated.” (World Medical Association, 2011, p. 2)



SECTION VIII: RESEARCH CRITERIA

The WHO has recommended that the health professions and all governments adopt an approach for the management of cancer pain that includes the use of opioid analgesics (World Health Organization, 1986; 2002), and has classified some opioid analgesics as Essential Drugs (World Health Organization, 1998a). For example, the most recent WHO Guidelines document (2011a) recognizes that:

“Pain is prevalent in almost all medical specialties, including in general practice, palliative care, oncology, internal medicine, haematology and surgery. Patients who are affected include people who have cancer, HIV, sickle-cell disease, or those who have had surgery or accidents...For all of these patients, pain relief should be part of their overall treatment. Oral opioids are key components for the treatment of moderate to severe pain and several are regarded as essential medicines.” (pp.13-14)

“It should be recognized that controlled medicines when used rationally for medical purposes are safe medicines.” (p.15)

CRITERION B.3: MEDICAL USE OF OPIOIDS IS RECOGNIZED AS LEGITIMATE PROFESSIONAL PRACTICE

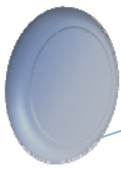
The Single Convention (United Nations, 1972), the INCB (1996), and the WHO (1986; 1990a; 1996) conceptualize legitimate professional practice with controlled substances as including the medical use of opioids for pain management. Since the inception of its Three-Step Analgesic Ladder (World Health Organization, 1986), the WHO has recommended that the health professions and all governments adopt an approach for the management of cancer pain that includes the use of opioid analgesics and, as a means to this end, has classified a number of opioid analgesics as Essential Drugs (World Health Organization, 1998a). Given this authoritative recognition, a licensed practitioner’s use of opioids for pain management is considered within the boundaries of professional practice and, as such, a legitimate medical purpose as long as certain basic requirements are met:

“International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotic drugs, but they also recognize that they are indispensable for the relief of pain and suffering. Narcotic drugs, including opiates, have a variety of medical uses. They are used as an anaesthetic or analgesic, and to treat diarrhea, cough or narcotic addiction, as well as for veterinary, dental and laboratory purposes. The International Narcotics Control Board, in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use.” (International Narcotics Control Board, 1996, Summary, p. iii)

“The majority of substances controlled under the international drug control treaties, notably narcotic drugs and psychotropic substances, have a variety of medical uses. Opioid analgesics, such as codeine and morphine, and antiepileptics, such as lorazepam and phenobarbital, are considered as essential medicines by the World Health Organization.” (World Health Organization, 2011a, p.1)

“It should be recognized that controlled medicines when used rationally for medical purposes are safe medicines.” (World Health Organization, 2011a, p. 15)

“Physicians and other health care professionals have an ethical duty to offer proper clinical assessments to patients with pain and to offer appropriate treatment, which may require prescribing medications – including opioid analgesics – as medically indicated.” (World Medical Association, 2011, p. 2)



SECTION VIII: RESEARCH CRITERIA

Critical to this conceptualization is that the laws or regulatory policies that govern the use of medications that have an abuse liability, as a general rule, also prohibit uses of these medications for other than legitimate medical purposes. The tendency for laws to be prohibitive heightens the importance for them also to explicitly recognize that the legitimate use of opioids is part of professional practice.

CRITERION B.4: PAIN MANAGEMENT IS ENCOURAGED

Laws and regulatory policies governing professional practice or the use of controlled medications also can contain language that offers clear encouragement for proper pain management. Statements such as “this policy is intended to promote better treatment for patients who experience pain” can provide a policy mechanism for healthcare practitioners to appropriately assess and treat pain. It also is likely that such language can promote the appropriate referral of patients, whose pain is unable to be managed, to clinicians who have different therapeutic expertise. It is important to consider, however, that language of positive intent can be linked to requirements and restrictions that actually create barriers, and ultimately exacerbate practitioner wariness, for providing effective pain relief (see [Section VI, Item 3](#)) – these policy determinations must be made on a case-by-case basis.

A number of international bodies have promoted the provision of safe and effective pain treatment, including the INCB and the WHO. In fact, the INCB’s 1999 *Annual Report* (2000) clarified this point within the context of the Single Conventions:

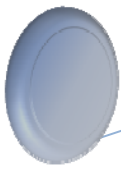
“Adequate availability and limitation were considered by the States parties to the 1961 Convention and the 1971 Convention as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those conventions. In adopting such aims, Governments were motivated by two complementary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.” (¶1)

The INCB (2011) more recently highlighted the importance of encouraging pain care, when discussing how countries have successfully implemented programs to improve pain management:

“...key factors in the successful implementation of [a programme that provides home-based palliative care] include the commitment of the Government to making relief from pain a health-care priority and the education of health-care professionals about the use of opioids and palliative care.” (¶101)

As stated previously, the recent update of the WHO Guidelines document (2011a) reiterates this point:

“Pain is prevalent in almost all medical specialties, including in general practice, palliative care, oncology, internal medicine, haematology and surgery. Patients who are affected include people who have cancer, HIV, sickle-cell disease, or those who have had surgery or accidents. Cancer patients may need pain relief at every stage of the disease. More than two thirds of patients with advanced cancer and about half of all patients with advanced HIV/AIDS will experience moderate to severe pain. In obstetrics, women may need pain relief during labour, surgery and post-surgery. For all of these patients, pain relief should be part of their overall treatment...” (pp. 13-14)



SECTION VIII: RESEARCH CRITERIA

Three categories of specific policy provisions have the potential, if implemented, to enhance pain management:

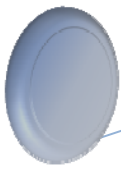
Category A: Ensures treatment of certain patient populations. In the absence of specific legal provisions that clearly allow all patient groups to have equal access to pain treatment or palliative care services, it can be beneficial to encourage appropriate treatment for clinical conditions. Advancing pain management for particular groups of patients at risk for treatment disparities, especially when access to appropriate care is broadly granted to relevant patient groups and not universally withheld from others, can help alleviate the pain burden within certain diseases or conditions. For the WHO (2011a), at least, the justification for this approach lies in the concept of non-discrimination:

“Guideline 8: Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rational medical use and the prevention of diversion, abuse, and dependence syndrome. Non-discrimination is a fundamental principle that runs throughout the entire body of international human rights law...When developing policies and establishing treatment services, governments should not only guard against deliberate discrimination, but also ensure that the policies do not unintentionally lead to discrimination against vulnerable groups. A number of groups, including women, children, the elderly, people in lower income classes, ethnic minorities, prisoners, people living with HIV, sex workers, men who have sex with men, and injecting drug users, are particularly vulnerable and may require a special effort to ensure realistic access to controlled medicines. When designing policies, it should be ensured that such policies and resultant services allow for equal access and availability for these groups and are both gender sensitive and culturally appropriate.” (p. 26)

Category B: Promotes training of healthcare professionals. This category identifies language within a country’s laws that provides institutional training to practitioners regarding pain management or palliative care, or that requires professional schools that prepare healthcare practitioners who prescribe or dispense medicines (e.g., medical, pharmacy, and nursing schools) to provide curricula regarding the medical use of controlled medicines, including pain management and the use of opioids.

“Guideline 13: Governments should promote that medical, pharmaceutical and nursing schools teach the knowledge and skills for the treatment of pain, substance use disorders in the context of medical use of controlled medicines, and other health conditions that need treatment with controlled medicines. In all countries, including those where the use of controlled medicines is not yet common, it is important that all healthcare schools teach their use. Although controlled medicines and in particular strong opioids can be applied safely, basic knowledge is essential and an opportunity to practice their application under supervision of an experienced peer is important. In its 2006 annual report, the INCB encouraged all Governments to ensure that “the rational use of narcotic drugs and psychotropic substances for medical purposes and the risks associated with drug abuse are included ... in university curricula.” (WHO, 2011a, p. 31)

“Guideline 14: In countries where controlled medicines become available and accessible for the first time, governments should organize education initiatives for healthcare professionals to ensure their rational use. It is important while introducing policies on accessibility and availability of controlled medicines to provide the relevant healthcare staff with knowledge and skills for using these medicines appropriately; training courses should therefore be provided throughout the country. This also applies to some degree when a new substance becomes available or a new indication is approved.” (World



SECTION VIII: RESEARCH CRITERIA

Health Organization, 2011a, p. 31)

“Instruction on pain management, including clinical training lectures and practical cases, should be included in mandatory curricula and continuing education for physicians and other health professionals.” (World Medical Association, 2011, p. 2)

“WHO advocates 12 core interventions to promote more rational use of medicines. These interventions include the establishment of a multidisciplinary national body to coordinate policies on the use of medicines, the use of clinical guidelines, the inclusion of treatments of choice in national essential medicines lists, the inclusion of problem-based pharmacotherapy training in undergraduate curricula, continuing in-service medical education, public education about medicines, appropriate and enforced regulation, and sufficient Government expenditure to ensure the availability of medicines and trained staff. All these key interventions are also relevant for controlled substances.” (International Narcotics Control Board & World Health Organization, 2012, ¶40)

The rational use of controlled substances depends heavily on the training of health-care professionals and raising the awareness of patients. Prescribers (a group that may include physicians, veterinarians, dentists, nurses and midwives, depending on the country) should be educated and appropriately trained to prescribe and administer controlled substances. Pharmacists should be trained in the rational dispensing of controlled substances.” (International Narcotics Control Board & World Health Organization, 2012, ¶41)

When the INCB conducted its first survey of governments regarding pain medication availability for medical purposes (International Narcotics Control Board, 1996), training deficiencies were identified as a significant impediment:

“Insufficient education of health-care professionals and restrictive narcotic laws and regulations tied for second (59 per cent each).” (¶14)

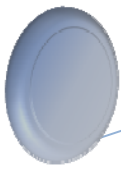
“Fifty-two percent of the governments said that they had sponsored, supported or endorsed educational programmes in their countries or areas to improve the medical use of opiates. In most cases, the programmes were sponsored by the governments that had issued policies or guidelines.” (¶15)

In 2011, the UNCND (2011) recognized the potential consequences of healthcare practitioners not having sufficient training or expenses regarding pain management issues:

“In many countries, health-care professionals are insufficiently trained in the recognition and management of pain. Many do not know how to ask patients about pain or how to understand patients’ descriptions of pain, do not appreciate the need to ease pain, and underestimate the extent to which pain can be relieved through treatment that includes the use of opioid analgesics.” (¶40)

“Many are overly concerned about the side effects of opioid treatment and hold exaggerated fears of the potential for the development of dependence or of depression of the central nervous system.” (¶41)

“These attitude and knowledge impediments are often the result of medical schools and other healthcare related programs inadequately teaching pain management and also not including pain management in continuing health affiliated professional education programmes. These shortcomings can commonly result in health professionals not treating a patient’s pain or using ineffective medicines that are not suitable for the treatment of moderate to severe pain.” (¶42)



SECTION VIII: RESEARCH CRITERIA

Category C: Promotes patient or public awareness. In addition to the need for providing healthcare practitioners with a better understanding of pertinent pain issues, patients and members of the general public can benefit from a greater knowledge of information related to pain and its treatment. Currently, people often are reluctant to report their pain experiences because of a variety of concerns, attitudes, and misperceptions. An appropriately-informed public can help to overcome existing social or interpersonal stigma relating to pain treatment and the medical use of opioid analgesics. To achieve this objective, governmental policies can be designed to authorize mechanisms to provide pain-related education:

“Moreover, general policies should be developed that address the rational use of controlled medicines. Such policies could include an information campaign, or campaigns to address myths and stereotypes about opioids. Patients and their families should be informed about the treatment of pain and treatment of dependence. Involving the patient and the patient’s family will lead to a better understanding and ‘ownership’ of the issue.” (World Health Organization, 2011a, p.25)

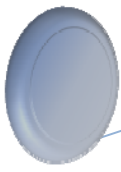
“The rational use of controlled substances depends heavily on the training of health-care professionals and raising awareness of patients...Educating patients also contributes to rational use by dispelling misconceptions about the abuse potential of controlled substances, as well as about problems associated with non-medical use.” (International Narcotics Control Board & World Health Organization, 2012, ¶41)

CRITERION B.5: PRACTITIONERS’ CONCERNS ABOUT SANCTIONS ARE ADDRESSED

This criterion is exemplified by provisions that recognize the need for health care professionals to have reassurance while striving to adhere to the requirements and measures contained in their country’s policies, as a means to provide effective patient care while reducing the potential for non-medical use of controlled medicines. The importance of this criterion is based on a long-recognized phenomenon – that many health care professionals hold a concern that their prescribing practice for pain may be construed to be in violation of drug control or professional practice laws, especially as a result of unintended errors (Cherny et al., 2013).⁷ Practitioners often have reported reluctance to use opioids because of the stress, expense, and potential consequences of being sanctioned by government or regulatory agencies, as well as by law enforcement. Such concerns can have a profound effect on practitioners’ willingness to consider controlled medications a viable treatment option and, in turn, can create a barrier to their adequate availability or use for patient pain relief. Legislative and regulatory policies can contain language that helps create an environment that abates health care professionals’ concerns about investigation, prosecution, or unwarranted punishment for minor or unintended infringements of policy requirements (see [Section VI, Item 3](#) for examples of this issue).

In support of this criterion, the INCB has long observed that the clinical need for opioids is not being fully met; in cooperation with the WHO in 1989, the INCB originally studied the reasons for inadequate availability of opioids for pain relief in the world. It was determined that there were a number of

⁷ Of course, diversion and abuse of prescription opioids can and do occur, and the safety issues need to be considered throughout treatment and clinical measures should be taken to mitigate these occurrences (Fischer et al., 2010). [Appendix A](#) illustrates further support for the need for countries to continue efforts to implement a legal and regulatory framework to prevent prescription medication diversion and abuse, while also maintaining medication access for medical and scientific purposes.



SECTION VIII: RESEARCH CRITERIA

reasons for inadequate availability (International Narcotics Control Board, 1989), and the following observation was proffered:

“the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented.” (p. 1)

The INCB (1989) further suggested that:

“While sanctions are necessary to deal with persons who transgress the law, they should not, as such, constitute an impediment to the prescription or dispensation of opiates in accordance with existing regulations. The vast majority of health professionals exercise their activity within the law and should be able to do so without unnecessary fear of sanctions for unintended violations. Occasions may still arise when a health professional could nevertheless be exposed to legal action for technical violations of the law. This possibility may tend to inhibit the prescribing or dispensing of opiates.” (§43)

A 1995 INCB survey (International Narcotics Control Board, 1996) about impediments to opioid availability also found that: “...reluctance to prescribe or stock opiates owing to concerns about legal sanctions ranked third (47%)” (p. 4). As a result of this finding, the INCB (1996) requested that all governments in the world:

“determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment...[and]... communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and...provide an opportunity to discuss mutual concerns.” (§51(f) & (g))

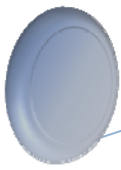
However, there had not been notable improvement by the time of a subsequent survey of governments evaluating the extent of impediments to opioid availability (International Narcotics Control Board, 2009b). When asked about “reluctance to prescribe or stock opiates because of concerns about legal sanctions,” the item was ranked second in terms of relevance (International Narcotics Control Board, 2009b, p. 16).

As early as 1990, the WHO, specifically the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (World Health Organization, 1990a), recognized that:

“Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licenses being suspended or revoked by the governing authority in cases where large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved.” (p. 39)

To address this issue in a systematic manner, the WHO issued a Guidelines document in 2000 (World Health Organization, 2000) that was designed to improve national policies and processes related to the appropriate use of controlled medicines, which also included a checklist containing the following question:

“Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids?” (p. 25)



SECTION VIII: RESEARCH CRITERIA

Concern about adverse regulatory or legal actions in response to the medical use of opioids was further highlighted, more than a decade later, in the WHO's updated Guidelines document for ensuring the global availability and accessibility of controlled medicines (World Health Organization, 2011a):

"Some countries maintain severe punitive provisions for errors or problems in the prescribing and dispensing of controlled medicines that deter healthcare workers from legitimated prescribing and dispensing of these medicines. The INCB has stated: 'Health professionals ... should be able to ... [provide opiates] without unnecessary fear of sanctions for unintended violations [including] ... legal action for technical violations of the law ... [that] may tend to inhibit prescribing or dispensing of opiates.' Unintentional errors that do not result in diversion of controlled medicines or serious health consequences should not be subject to criminal penalties." (p. 28)

Again, the Guidelines checklist contained a question related to addressing practitioner concern (World Health Organization, 2011a):

"Can health professionals be free from fear of investigation, prosecution and disproportionate punishment for minor or unintentional breach of drug control rules?" (p. 56)

Finally, according to a recent report from the Commission on Narcotic Drugs (2011), a prominent regulatory impediment that should be addressed when warranted is health care practitioners' concerns about potentially punitive legal requirements:

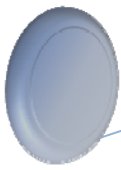
"Examples of measures that may impede availability and that are not required by the Conventions include:...excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids." (¶37(f))

CRITERION B.6: LEGITIMACY OF PRESCRIBING IS NOT BASED SOLELY ON AMOUNT OF MEDICATION PRESCRIBED

Laws or regulatory policies maintaining that duration or amount of drug therapy will be used as the singular basis by which to judge the appropriateness of prescribing contradict the Central Principle of *Balance* – such a standard does not conform to current medical and scientific consensus. As such, implementation of this standard can inadvertently contribute to a restrictive regulatory environment for pain management. Consequently, it seems important for a country's policies to have a clear statement promoting the notion that the amount or duration of medication prescribed, by itself, does not necessarily represent the legitimacy of the prescription.

For this criterion, principal confirmation currently comes from two authoritative sources from the United States: (1) the Federation of State Medical Boards, and (2) the Drug Enforcement Administration. The Federation of State Medical Boards (FSMB) is the national organization representing all 70 medical and osteopathic boards of the U.S. and its territories, which are the state medical regulatory bodies that license and discipline physicians. The FSMB originally recognized the importance of this standard in 1998 (Federation of State Medical Boards of the United States Inc., 1998) and 2004 (Federation of State Medical Boards of the United States Inc., 2004), and then reiterated its support for this concept more recently (Federation of State Medical Boards of the United States Inc., 2013):

"The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered." (p.8)



SECTION VIII: RESEARCH CRITERIA

The most recent version of the *Pharmacist Manual* (Drug Enforcement Administration, 2010) published by the Drug Enforcement Administration (DEA), which is the U.S. national competent authority, also contains a statement in support of a broader approach to determining prescribing legitimacy, which is a verbatim repetition of language from previous DEA publications:

“The quantity of drugs prescribed and frequency of prescriptions filled are not lone indications of fraud or improper prescribing, especially if a patient is being treated with opioids for pain management.” (p. 66)

Although the authoritative support underlying this criterion presently derives from U.S. sources, the RPAR initiative from the Temple University School of Law recognizes that it is valuable to ascertain the prevalence with which other countries have acknowledged the significance of this clarification. In fact, the RPAR (Case et al., 2008) was designed for international application, and includes the following evaluative criterion:

“4.0 Licensing and discipline of medical and allied health professionals (may be part of medical practice acts)

.
. .

4.2 Are licensing and disciplinary bodies authorized to review “legitimacy” of health care professionals’ prescription or administration of opiates?

4.2.1 Is the amount prescribed alone used to determine legitimacy?

4.2.1.1 Number of prescriptions written by a practitioner?

4.2.1.2 Number of patients on specific drugs?

4.2.1.3 Size of the dosage for individual patients?” (pp. 63-64)

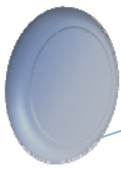
A justification for this criterion also is implied through the WHO *Ensuring Balance* Guidelines document (2011a), which argues for prescription amount or treatment duration being a function of healthcare decision-making based on the particular clinical situation:

“Guideline 10: Appropriately trained and qualified physicians, and, if applicable, nurses and other health professionals, at all levels of health care should be allowed to prescribe and administer controlled medicines, based on their general professional license, current medical knowledge and good practice without any further license requirements.

.
. .

When balancing drug *control* legislation and policies, it is wise to leave *medical* decisions up to those who are knowledgeable on medical issues. Therefore, the amount of medicine prescribed, the appropriate formulation and the duration of treatment should be the practitioner’s decision, based on individual patient needs and on sound scientific medical guidance (e.g. national or WHO treatment guidelines).” (pp. 29-30)

As a result, this evaluation will identify any country that has adopted policy language to delineate that the quantity of medication or the duration of treatment is not sufficient by itself to judge the legitimacy of a practitioner’s opioid prescriptions for a pain patient.



SECTION VIII: RESEARCH CRITERIA

CRITERION B.7: WITHDRAWAL SYNDROME OR ANALGESIC TOLERANCE ARE NOT CONFUSED WITH *DEPENDENCE SYNDROME* (I.E., “ADDICTION”)

When the INCB surveyed members of government narcotic control agencies to identify impediments to improving availability and use of opioids, the most frequently-identified issue was concerns about “addiction” (which was the term used in the survey) (International Narcotics Control Board, 1996; 2009b). Addiction-related terminology includes the current WHO concept of “dependence syndrome,” (World Health Organization, 1998b) which is also an ICD-10 diagnostic classification (World Health Organization, 1992). When such terminology is used in law, but remains undefined or is defined inaccurately, it has the potential to be mis-applied to people who are using opioids for legitimate medical purposes and, because of this, have developed common physiological responses like withdrawal syndrome or analgesics tolerance. Policies are considered unbalanced when they contain terminology (e.g., “habituation,” “addiction,” “psychological dependence,” “drug dependence”) that is inconsistent with current medical and scientific knowledge. No modern model drug control law defines addiction-related terms that can then be used to classify people as an “addict” or a “habitué.” However, if such terminology appears in a country’s current drug control or professional practice policy, they should either be removed or be defined according to the prevailing medical standard for defining the concept of “dependence syndrome” (World Health Organization, 2000; 2011a).

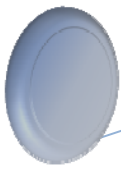
Importantly, the WHO has demonstrated an evolution of conceptualizations of “drug addiction,” as it was originally termed and defined. “Drug addiction” was initially considered the direct and largely inevitable effect of specific substances:

“Drug addiction...is a state of periodic or chronic intoxication, detrimental to the individual and to society, produced by the repeated consumption of a drug.

Characteristics include: (1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means; (2) a tendency to increase the dose; and (3) a psychic (psychological) and sometimes a physical dependence on the effects of the drug.” (World Health Organization, 1950b, pp. 6-7)

“There are some drugs, notably morphine and pharmacologically morphine-like substances, whose specific pharmacological action, under individual conditions of time and dose, will always produce compulsive craving, dependence, and addiction in any individual. Addiction will develop sooner in those individuals whose psychological make-up leads them to seek and find escape in the pharmacological action of drugs. Sooner or later there must come a time when the use of the drug cannot be interrupted without significant disturbance, always psychic (psychological) and sometimes physical. With these drugs pharmacological action is paramount, psychological make-up adjuvant. Such drugs cause individual and sociological damage and must be rigidly controlled.” (World Health Organization, 1952, p. 10)

“a state of periodic or chronic intoxication produced by the repeated consumption of a drug (natural or synthetic). Its characteristics include: (1) an overpowering desire or need (compulsion) to continue taking the drug and to obtain it by any means; (2) a tendency to increase the dose; (3) a psychic (psychologic) and generally a physical dependence on the effects of the drug; (4) detrimental effect on the individual and on society.” (World Health Organization, 1957, pp. 9–10)



SECTION VIII: RESEARCH CRITERIA

In 1964, the WHO replaced the term “addiction” with the term “drug dependence” to reduce stigma. Under this new conceptualization, “drug dependence” was comprised both of a psychic component (psychological dependence) *and* a physical component (an abstinence syndrome) (World Health Organization, 1964). The WHO clarified, however, that the more general term of “drug dependence” did not indicate degree of risk to public health.

In a few more years, in 1969, “drug dependence” was defined centrally as compulsive use despite harm, with neither physical dependence nor tolerance sufficient to define “drug dependence” (or “addiction”) (World Health Organization, 1969):

“Drug dependence. A state, psychic and sometimes also physical, resulting from the interaction between a living organism and a drug, characterized by behavioral and other responses that always include a compulsion to take the drug on a continuous or periodic basis in order to experience its psychic effects, and sometimes to avoid the discomfort of its absence. Tolerance may or may not be present.” (p. 6)

This conceptualization has remained relatively consistent to the present time, with the 1993 definition of “drug dependence” representing a biopsychosocial construct (World Health Organization, 1993):

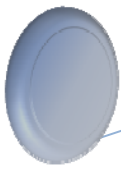
“A cluster of physiological, behavioral and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behavior.” (p. 5)

Although in 1998 the WHO replaced the term “drug dependence” with “dependence syndrome” (World Health Organization, 1998b), there was no substantive reinterpretation of the 1993 definition; this nomenclature is current as of today.

Over the last two decades, the WHO has attempted to distinguish addiction from pain management with opioids, clarifying for healthcare practitioners, policy –makers, and drug control regulators that patients using opioids would not be considered “drug dependent” merely because they develop withdrawal symptoms after cessation of the medication (World Health Organization, 1990a; 1996).

The WHO Expert Committee on Drug Dependence (2003) has stressed the importance, however, of maintaining an appropriate relationship when considering the occurrence of withdrawal or tolerance within the context of dependence syndrome:

“The International Classification of Diseases (ICD) is the most widespread tool used in health epidemiology. While it is correct to say that *withdrawal* and *tolerance* are neither required nor sufficient for a positive diagnosis of *dependence syndrome*, excessive emphasis on this aspect can lead to the misconception that *withdrawal* is unrelated to *dependence*.” (p. 19)



SECTION VIII: RESEARCH CRITERIA

Recently, the WHO reinforced the importance of national law having clear and up-to-date addiction-related terminology (World Health Organization, 2011a):

“Guideline 10: Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse. (p. 28)

Drug control legislation and policy have sometimes contributed to stigmatization of controlled medicines because of the use of inappropriate terminology. Confusion and discrimination relating to terminology can deter doctors from prescribing controlled medicines when it is legitimate to do so; it can also confuse authorities who wish to discriminate between legitimate and illegitimate use. Countries should therefore take steps to review policies to ensure the consistent use of medical terms and remove stigmatizing terminology from their legislation. These guidelines specifically recommend the use of non-stigmatizing terminology. (pp. 28-29)

“... The WHO definition of “dependence syndrome” requires the presence of at least three out of six symptoms, including a strong desire or a sense of compulsion to take the drug and also the neglecting of interests and daily activities because of devotion to the use of psychoactive substances. It is clear that a patient requiring increasing doses of an opioid for pain relief because of pharmacological tolerance due to prolonged treatment does not normally fall into this category. Neither does a patient who develops withdrawal syndrome. (p. 29)

Patients should be referred to in a respectful way; WHO does not therefore recommend the use of “addict” for a patient living with dependence syndrome, as the term is considered to be stigmatizing.” (p. 29)

A Discussion Paper also was issued relating to the Commission on Narcotic Drugs (2011), which clarified the distinctions between physiological symptomology and the characteristics that define dependence syndrome:

“The issue of opioid dependence related to the treatment of pain remains controversial. On the one side, the fear of opioid dependence is discouraging public opinion and also health care personnel in respect to the use of opioid analgesics. On the other side, the evidence concerning dependence in patients affected by pain should be expanded. All persons exposed continuously to opioids develop tolerance and withdrawal, two important, but by themselves not sufficient characteristics to diagnose dependence. Dependence is understood as a bio-psycho-social condition which clusters physiological, behavioural, and cognitive phenomena and their related vulnerability factors. In most cases, patients treated with opioid analgesics for pain do not present the vulnerability characteristics that contribute to inducing a condition of dependence, although they develop tolerance and withdrawal symptoms.” (¶26)



SECTION VIII: RESEARCH CRITERIA

CRITERION B.8: OTHER PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

This analysis also has the potential to identify policy language that can improve the provision of pain management or palliative care, but for which no specific criterion currently exists. Three categories of policy provisions were conceptualized to denote additional language that, if implemented, could enhance pain management:

Category A: Issues related to healthcare professionals. This criterion category could relate, for example, to policy language that, in addition to allowing physicians to prescribe, authorizes other healthcare workers with appropriate training to prescribe controlled medicines. This expansion of prescribing privileges to a broader array of appropriately trained practitioners can enhance a country's ability to manage pain for a greater number of patients. This is particularly important for a country that has a shortage of physicians or has many patients living in rural areas in which physicians do not practice (Jack & Merriman, 2008; Jagwe & Merriman, 2007; Kumar & Palmed, 2007; World Health Organization, 2011a):

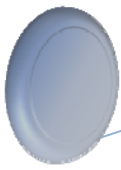
"In some countries, other healthcare workers, such as nurses, can specialize in a specific area and are then allowed to prescribe within the area of their specialization as well. Nurse prescribing can be useful for mitigating pain in a number of circumstances; for example, during a shortage of physicians or to improve the quality of care." (World Health Organization, 2011a, pp. 29-30)

"The scope of practice of the [Advanced Practice Registered Nurse – APRN] is unique in the nursing profession. The APRN practices as an independent primary care provider in a majority of states, with nearly all states conferring controlled substances prescribing authority upon APRNs, in conjunction with the DEA. In the role of primary care provider or licensed independent provider, the APRN is held to a high standard of education and practice in patient care. In providing treatment for pain, the APRN is charged with the responsibility to diagnose the causes of pain, intervene with a variety of therapies, and evaluate the effectiveness of pain treatment being prescribed. The APRN is responsible for appropriate, accurate and complete documentation of assessment, treatment plan, informed consent and ongoing review of efficacy." (National Council of State Boards of Nursing, 2008, p. 132)

Category B: Issues related to patients. An example of a policy that is relevant to this category would require continuity of treatment when patients require different medical services, as suggested by the 2011 WHO Guidelines report (2011a):

"It is essential that government policies ensure that patients are able to continue their treatment with controlled medicines when they are hospitalized in health facilities that normally do not use such medicines." (p.25)

Category C: Other regulatory or policy issues. This category would be fulfilled in instances where healthcare policy defines pain management or palliative care as a subspecialty in medicine. Another relevant example in this category relates to a legal provision that creates an exemption to a restrictive policy requirement.



SECTION VIII: RESEARCH CRITERIA

In addition, the UNCND (2011) has identified the potential problems associated with legislative and regulatory barriers in narcotics control policies:

“While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare, efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes “must not adversely affect their availability for such purposes”. A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability.” (¶136)

“Examples of measures that may impede availability and that are not required by the Conventions include: (a) Limitations on the number of days’ supply that may be provided in a single prescription (with too short a period of time allowed); (b) Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low); (c) Excessive limitations on prescription authority, such as only to some categories of medical doctors; (d) Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain, and/or a requirement that multiple copies of the prescription be maintained; (e) Requirements that patients receive special permission or registration to render them eligible to receive opioid prescriptions; (f) Excessive penalties and prosecutions for unintentional mis-prescription or mishandling of opioids; (g) Arbitrary restrictions on the number of pharmacies permitted to dispense opioid medications; (h) Unreasonable requirements relating to the storage of opioid medications.” (¶137)

“These measures, not required by the Convention, do not significantly improve control, but may interfere significantly with accessibility to and availability of essential medicines.” (¶138)

To address these issues, country laws can be adopted that identify specific policy requirements that could create barriers to appropriate treatment of pain. This criterion would apply to those laws that explicitly recognize that the codification of undue prescribing or other treatment limitations could impede patient access to effective pain care.



SECTION VIII: RESEARCH CRITERIA

Section 2 – Negative Provisions: Criteria to Identify Provisions That May *Impede* Pain Management

CRITERIA C: CRITERIA RELATED TO THE CENTRAL PRINCIPLE OF *BALANCE*

The potential deleterious impact of overly restrictive or ambiguous laws or regulatory policies, especially on the care of patients with severe or debilitating pain, has longed been recognized as a reality. As far back as 1989, at least, the INCB raised this specific possibility when discussing impediments associated with legislation and administration of the controlled substances distribution system (International Narcotics Control Board, 1989):

“...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented.” (Summary, p. 1)

“In enacting such domestic legislation, as well as carrying out its provisions, either the legislator or the official entrusted with implementing the legislation may lose sight of or encounter difficulties in ensuring the need for balance between availability of opiates and prevention of their abuse. In this connection, it should be recalled that prevention of availability of many opiates for licit use does not necessarily guarantee the prevention of the abuse of illicitly procured opiates. Thus, an overly restrictive approach to the licit availability of opiates may, in the end, merely result in depriving a majority of the population of access to opiate medication for licit purposes.” (¶40)

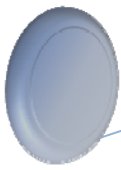
“...legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightening concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations that have the practical effect of reducing availability for licit purposes.” (¶42)

“Governments should examine the extent to which their health-care systems and laws and regulations permit the use of opiates for medical purposes, identify possible impediments to such use and develop plans of action to facilitate the supply and availability of opiates for all appropriate indications;” (¶49(c))

Around the same time, the WHO referenced an INCB/WHO joint working document that identified a number of obstacles to the availability of morphine, including legal and regulatory content, and then repeated this message in its second edition of *Cancer Pain Relief*:

“Legislative, regulatory, and administrative impediments that exist in various countries and that lead to underutilization of opioids.” (World Health Organization, 1990b, p. 31)

“There are many reasons why cancer pain is not adequately treated at present, including...legal restrictions on the use and availability of opioid analgesics.” (World Health Organization, 1996, p. 42)



SECTION VIII: RESEARCH CRITERIA

By the mid-to-late-1990s, the INCB was reiterating this message based on results from a 1995 survey of government members, when asked about their perceptions of impediments to opioid availability in their country:

“Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments;” (International Narcotics Control Board, 1996, ¶151(a))

“The most frequently mentioned causes of inadequate opioid availability are restrictive regulations, cumbersome administrative procedures, concerns about diversion and the consequences of inadvertent errors, concerns about iatrogenic addiction, and inadequate or insufficient training of health personnel. The removal of these impediments should be first of all the responsibility of the concerned Governments and that of the medical profession.” (International Narcotics Control Board, 2000, ¶131)

The INCB (2008b) acknowledged that this situation has, unfortunately, remained largely unchanged after a decade:

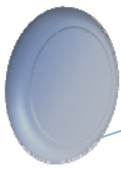
“The [INCB] and WHO reviewed documents and studies on the availability of opioid analgesics at the national level and examined the activities undertaken and planned by various bodies to assist Governments in ensuring the availability of those drugs for medical use. The [INCB] and WHO observed that, although there was no shortage of licitly produced opioid analgesic raw materials worldwide and there had been a substantial increase in the global consumption of opioids in the past two decades, access to opioid analgesics continued to be difficult in some countries. The difficulties in having access to opioid analgesics are due to various interrelated factors, such as inadequate medical education and lack of knowledge and skills in pain management, public attitude, regulatory impediments and economic constraints.” (¶210)

A recent Discussion Paper emanating from the UN Commission on Narcotic Drugs’ 54th session further called for the identification and removal of legal and regulatory barriers to the safe and effective therapeutic use of controlled medications (United Nations Commission on Narcotic Drugs, 2011):

“While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare, efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes ‘must not adversely affect their availability for such purposes’. A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability.” (¶136)

“These measures, not required by the Convention, do not significantly improve control, but may interfere significantly with accessibility to and availability of essential medicines.” (¶138)

“Review and revise national legislation, regulation and policies, in order to ensure that they reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability;” (¶147(b))



SECTION VIII: RESEARCH CRITERIA

The WHO also drew attention to this general issue in the recent update of its Guidelines document for assuring availability and access of controlled medicines (World Health Organization, 2011a):

“...the drug control conventions that established the dual obligation of ensuring adequate availability of controlled medications and of preventing their misuse have existed for almost 50 years. Yet the obligation to prevent abuse of controlled substances has received far more attention than the obligation to ensure their adequate availability for medical and scientific purposes, and this has resulted in countries adopting laws and regulations that consistently and severely impede accessibility of controlled medicines. (p. 16)

Further, the updated WHO Guidelines document (2011a), importantly, devoted a single guideline to addressing restrictive policy language:

“Guideline 9: Governments should examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medicines. They should also ensure that provisions aim at optimizing health outcomes and take corrective action as needed. Decisions which are ordinarily medical in nature should be taken by health professionals...Such an analysis should be undertaken rule by rule, and cover both legislation and official policy. If a rule provides a barrier for availability and accessibility, but does not contribute to the prevention of abuse, diversion and dependence syndrome, this rule does not contribute to the protection of public health or welfare, and should therefore be either eliminated or changed. In the case where a rule both contributes to prevention and constitutes a barrier for medical use at the same time, alternative ways of providing the same level of prevention without posing a barrier to rational medical use should be explored.” (p. 27)

Legislative and regulatory language meeting these criteria would conflict with current medical and scientific understanding and are unnecessarily more restrictive than international drug control policy.

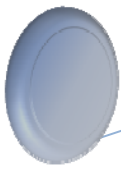
All criteria, as well as the authoritative sources justifying each criterion, are listed below.

CRITERION C.1: OPIOIDS ARE RELEGATED AS ONLY A TREATMENT OF LAST RESORT

As demonstrated in the previous section, policies congruent with the Central Principle of *Balance* acknowledge the need to maintain the availability of medications for legitimate medical purposes, including the appropriate use of opioid analgesics as part of legitimate medical practice (which can include their use for pain relief). Government and regulatory policies, however, can ultimately impose requirements that discourage the appropriate medical use of opioids to treat pain, even when the policy was designed to encourage proper pain management.

Almost 30 years ago, the WHO introduced a three-step analgesic ladder for recommending the therapeutic use of various pharmacologic agents (both non-opioid and opioid) for the treatment of cancer pain, which depended on the severity of the pain (World Health Organization, 1986); the ladder was promoted again in 1996 (World Health Organization, 1996). Use of potent opioids now is supported as a first-line modality when a patient’s pain has been assessed as severe and when such treatment benefits outweigh the risks (Caraceni et al., 2012; Fallon et al., 2010; Kahan et al., 2011). Of course, non-pharmacologic and non-opioid modalities are valuable treatment options, and their use should be encouraged when warranted, but decisions to utilize a particular therapy, including when to use opioids, should be based on the needs for the specific clinical situation and not governmental mandate.

A misperception continues, however, that the WHO analgesic ladder stipulates that treatment requires a progressive path up the individual steps – this clinically translates into initial treatment utilizing the



SECTION VIII: RESEARCH CRITERIA

weakest medications, even with patients suffering from severe pain, which will likely be ineffective, and create the potential to prolong patients' pain, suffering, and diminished functioning (Meldrum, 2005; Silbermann, 2011). Policy language that requires certain opioids to be used only after non-opioid or other opioid medications may result from, and can ultimately perpetuate, this misunderstanding. In the context of policy, it means compulsory practitioner commitment to inflexible legal restrictions on treatment decision-making and the potential disregard of patients' clinical needs.

The RPAR initiative from the Temple University School of Law recognizes that it is valuable to ascertain the prevalence with which other countries have codified the medical use of opioids as a treatment of last resort regardless of a patient's clinical needs. In fact, the RPAR (Case et al., 2008) was designed for international application, and includes the following evaluative criterion:

"2.0 Legal provisions related to pain management and treatment of opiate addiction

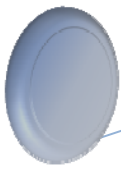
2.0 Using opiates in medical practice Include provisions related to physicians, nurses, and other allied health professionals who prescribe opiates (see below for questions specific to pharmacists and others who may dispense opiates)

.
. .

2.1.4 Does the law describe opioids as a treatment of last resort?" (pp. 58-59)

CRITERION C.2: WITHDRAWAL SYNDROME OR ANALGESIC TOLERANCE ARE CONFUSED WITH *DEPENDENCE SYNDROME* (I.E., "ADDICTION")

This criterion is the converse of [Criterion B.7](#), and recognizes that the incorrect use of terminology related to dependence syndrome remains in some national policies and has the potential to be misapplied to people who are taking opioids therapeutically for pain management. When this occurs, dependence syndrome (or related classifications) could be established solely by the presence of physiological symptomology such as a withdrawal syndrome. Outdated policy terminology, when implemented in practice, can stigmatize people who suffer from pain and restrict treatment options and decisions, leading to inadequate pain management. For example, some governmental laws or regulatory policies require that people who are labeled as "addicts" be reported to a government agency or be included in a central registry (see [Criterion C.5.B](#)). If physiological symptomology, such as the potential for the development of a withdrawal syndrome, is sufficient to fulfill the criteria for "addiction," people using opioids on a long-term basis to manage their pain could be reported even if they do not exhibit compulsive drug use despite harm.



SECTION VIII: RESEARCH CRITERIA

The implications of outdated terminology on patient care, as well as the need to avoid, remove, or modify such language, were directly and thoroughly addressed in the updated WHO Guidelines document (2011a):

“Guideline 10: Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse...Drug control legislation and policy have sometimes contributed to stigmatization of controlled medicines because of the use of inappropriate terminology. Confusion and discrimination relating to terminology can deter doctors from prescribing controlled medicines when it is legitimate to do so; it can also confuse authorities who wish to discriminate between legitimate and illegitimate use. Countries should therefore take steps to review policies to ensure the consistent use of medical terms and remove stigmatizing terminology from their legislation. These guidelines specifically recommend the use of non-stigmatizing terminology...A further confusion relates to the definition of ‘dependence’ and ‘dependence syndrome’...The WHO definition of ‘dependence syndrome’ requires the presence of at least three out of six symptoms, including a strong desire or a sense of compulsion to take the drug and also the neglecting of interests and daily activities because of devotion to the use of psychoactive substances. It is clear that a patient requiring increasing doses of an opioid for pain relief because of pharmacological tolerance due to prolonged treatment does not normally fall into this category. Neither does a patient who develops withdrawal syndrome.” (p. 29)

CRITERION C.3: RESTRICTIONS THAT COULD LIMIT MEDICAL DECISION-MAKING

For balanced national governmental laws and regulatory policies governing the use of pain medications for legitimate medical purposes, healthcare practitioners with training or experience are allowed the flexibility to make clinical treatment decisions, rather than being constrained by overly-restrictive governmental requirements (World Health Organization, 2011a). According to this standard, determining clinical issues, such as the eligibility of patients to receive opioids, the choice of medication, and the dose and duration of prescribing, represents a therapeutic decision-making process based on treatment needs of the patient. Legislators or regulators that establish inflexible barriers can hamper satisfactory patient care.

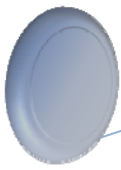
Numerous international organizations have recognized this situation as a potential barrier since the 1980s, such as:

International Narcotics Control Board

“...the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates. The problem may also arise as a result of the manner in which drug control laws and regulations are interpreted or implemented.” (International Narcotics Control Board, 1989, p. 1)

“In some countries the use of certain drugs is limited by the need for special authorizations or by the conditions under which the drugs may be made available. Policies or regulations may dictate or specify the conditions under which a drug may be used and therefore may affect the way in which health professionals conduct a treatment program.” (International Narcotics Control Board, 1989, ¶47).

“Laws and regulations, and their administration or interpretation, unduly impeded the availability of opiates.” (International Narcotics Control Board, 2011, ¶10)



SECTION VIII: RESEARCH CRITERIA

World Health Organization

“Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation.” (World Health Organization, 1996, p. 58).

“In many countries, national legislation includes provisions stricter than the international drug control conventions require. This is allowed for by the conventions, as far as it is in the opinion of the government ‘necessary or desirable for the protection of the public health or welfare’. However, in practice, many stricter provisions do not contribute to a better public or individual health. Therefore, it is important to analyze the effects of any stricter rules on the prevention of diversion, abuse and dependence syndrome and on the availability and accessibility of controlled medicines. Rules (and policies) that do not contribute to the protection of public health or welfare should be eliminated or changed. Rules violating any other international obligation, regardless whether originating from the drug conventions or any other treaty, should be guarded against.” (World Health Organization, 2011a, p. 27)

United Nations Commission on Narcotic Drugs

“While States are not precluded from adopting measures that are more restrictive than those required by the Conventions if they deem them necessary or desirable to protect public health or welfare, efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes “must not adversely affect their availability for such purposes”. A recent survey conducted by the INCB found that laws and regulations that were unduly restrictive or burdensome were commonly perceived as a significant limitation on availability.” (United Nations Commission on Narcotic Drugs, 2011), ¶136)

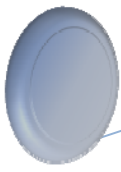
International Association for the Study of Pain

“Most countries have no national policy at all or very inadequate policies regarding the management of pain as a health problem, including an inadequate level of research and education...There are severe restrictions on the availability of opioids and other essential medications, critical to the management of pain.” (International Association for the Study of Pain, 2010, p. 1)

Three categories of policy provisions have the potential to restrict medical decisions and impede patient care:

Category A: Restrictions based on patient characteristics. National laws and other policies can limit healthcare practitioners from prescribing controlled substances to certain patient populations. For example, this criterion would apply to laws that permit opioid prescribing only for patients with advanced cancer or in the terminally-ill stage of disease, to the exclusion of other medical conditions or disease states.

In addition, drug control or prescribing laws can impose restrictions on treating those who “habitually use” controlled medicines, although “habitual” is an outdated term that the WHO made obsolete more than 40 years ago and may be defined primarily by the potential for exhibiting a withdrawal syndrome. In the case of laws that completely restrict prescribing to patients with pain who also have a dependence syndrome, regardless of the type or severity of the pain, implementation of such laws can create significant treatment disparities. Barriers to appropriate treatment, even if such patients will require extra care, monitoring, and consultation with or referral to experts with relevant training to ensure that prescribed medications are being used therapeutically, will interfere with the management of those who



SECTION VIII: RESEARCH CRITERIA

also have severe pain from cancer or HIV/AIDS and who may require an opioid to relieve their pain (World Health Organization, 2011a).

Such policy language would not only fail to broadly grant access to treatment to relevant patient groups, but also serve to withhold needed treatment from others. The WHO (2011a) recognized the benefit of reducing the occurrence of language that could produce treatment disparities when it appears in a country's legislation or regulatory policies:

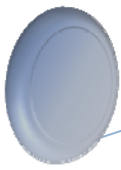
"Guideline 8: Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rational medical use and the prevention of diversion, abuse, and dependence syndrome. Non-discrimination is a fundamental principle that runs throughout the entire body of international human rights law. When developing policies and establishing treatment services, governments should not only guard against deliberate discrimination, but also ensure that the policies do not unintentionally lead to discrimination against vulnerable groups. A number of groups, including women, children, the elderly, people in lower income classes, ethnic minorities, prisoners, people living with HIV, sex workers, men who have sex with men, and injecting drug users, are particularly vulnerable and may require a special effort to ensure realistic access to controlled medicines. When designing policies, it should be ensured that such policies and resultant services allow for equal access and availability for these groups and are both gender sensitive and culturally appropriate. Patients who have a history of substances abuse have as much right to be treated for their pain as anybody else, and regulations should not limit their access to essential medicines. It is a medical decision to consider the advantages and disadvantages of different treatment options. The fact that someone has or had opioid dependence syndrome is not a reason to withhold adequate pain management from that person."

(p. 26)

It is important to differentiate the application of this criterion from policy language that meets [Criterion C.2](#). This criterion can represent language in law that has the potential to complexly restrict pain care services, including the prescribing of controlled medications, to those patients who have a current diagnosis of dependence syndrome or a history of substance abuse. Conversely, [Criterion C.2](#) identified legal definitions with the potential to label and stigmatize patients with pain who are using controlled medicines and who subsequently develop physiological symptoms (such as a withdrawal syndrome) as having a "dependence syndrome."

Category B: Mandated consultation for all patients. Although consensus seems to exist that healthcare practitioners should seek consultation when appropriate based on clinician expertise and patient need (Kahan et al., 2011), it is possible that national policies can *require* specialist or other consultation before initiating treatment for patients with pain. There are a variety of ways in which this requirement can ultimately influence clinical practice when treating pain:

- (1) it excessively regulates pain management and the class of patients who have pain,
- (2) it initiates an inflexible standard that does not allow for the possibility that the patient needs immediate treatment,
- (3) it may be unnecessary if the practitioner is knowledgeable,
- (4) it can exacerbate the time and administrative burden for the healthcare practitioner, and
- (5) it does not account for the potential lack of available consultation resources, which includes the possibility of increased cost and long-distance travel for the patient.



SECTION VIII: RESEARCH CRITERIA

These factors suggest that government mandate of treatment consultation, while indeed intended to improve access to pain relief, can discourage pain management or limit patient access if such consultations are unavailable or difficult to obtain in a timely manner. Ultimately, with this requirement, the following question also needs to be considered: What is the legal liability of a healthcare practitioner who initiates opioid therapy to treat a patient with pain but fails to obtain the required consultation?

The RPAR initiative from the Temple University School of Law recognizes that it is valuable to ascertain the prevalence with which other countries have codified the requirement of consultation with at least one other healthcare professional, when prescribing pain medications, regardless of a patient's clinical needs. In fact, the RPAR (Case et al., 2008) was designed for international application, and includes the following evaluative criterion:

"2.0 Legal provisions related to pain management and treatment of opiate addiction

2.0 Using opiates in medical practice Include provisions related to physicians, nurses, and other allied health professionals who prescribe opiates (see below for questions specific to pharmacists and others who may dispense opiates)

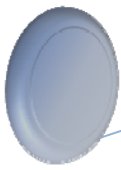
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2.2.Does the law restrict the use of opioids:

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. .

2.2.3 B: By requiring consultation with a second health care professional?" (pp. 58-59)

Category C: Restrictions regarding quantity prescribed or dispensed. This criterion is based on the fact that the Single Convention does not obligate any threshold on the quantity or duration of medications being prescribed or dispensed. Although this limitation is not imposed by international treaty, a review of policies throughout Europe identified several countries with restrictions on the quantity of opioids that could be prescribed (Cherny et al., 2010). It is likely that these policy provisions were included to prevent the non-medical use and diversion of controlled medications. However, the quantity or duration specified by government policy may be insufficient to meet the individual medical needs of patients under all legitimately-occurring circumstances, and can result in inadequate pain management.



SECTION VIII: RESEARCH CRITERIA

The WHO reiterated in its 2011 updated Guidelines document (2011a) that international drug control treaty does not limit the dose, amount, or duration of prescribing:

“The conventions do not define the length of a medical prescription or the amount of medicines to be prescribed by a health worker. If a prescription covers only the amount of medicines needed for a limited time span, or if the validity of prescriptions is limited, the patient will need to go frequently to the physician and the pharmacy.” (p. 27)

A recent Commission on Narcotic Drugs-related Discussion Paper also included insufficient thresholds on amounts or durations as an important regulatory barrier (United Nations Commission on Narcotic Drugs, 2011):

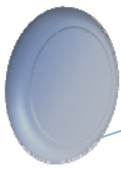
Examples of measures that may impede availability and that are not required by the Conventions include:

“(a) Limitations on the number of days’ supply that may be provided in a single prescription (with too short a period of time allowed);” (¶137)

“(b) Limitations on doses that may be prescribed in a single prescription (with allowed doses being too low);” (¶137)

CRITERION C.4: LENGTH OF PRESCRIPTION VALIDITY IS RESTRICTED

Although it is true that the Single Convention does not prevent countries from adopting stricter requirements than defined under international law, as a means of protecting public health and welfare (United Nations, 1961, Article 39), the principle of *Balance* in drug control laws dictates that effective measures against abuse and diversion must continue to ensure the availability of medicines for the relief of pain and suffering. In relation to this criterion, international drug control treaty does not specify a particular period of validity when issuing a prescription for a controlled medicine (i.e., the number of days within which the prescription must be dispensed following its issue). However, some national policies continue to impose a limit on a prescription’s validity period; this is done in an effort to reduce the likelihood that a prescription that is not quickly dispensed, yet remains valid, can be eventually filled and the medication ultimately diverted for illicit use (Mosoiu et al., 2006; Ponizovsky, Pchelintsev, Marom, & Zvartau, 2012). A new prescription must be issued once a prescription’s validity period has been surpassed, which likely would necessitate a return visit to the prescribing practitioner. As a result, unrealistically short validity periods can make it difficult for a patient to obtain medications without having to make sometimes expensive arrangements, especially when living in a rural setting or when other extenuating circumstances exist.



SECTION VIII: RESEARCH CRITERIA

The WHO's updated Guidelines document includes overly-restrictive limitations to prescription validity as an example of policy language that Governments should correct (World Health Organization, 2011a):

"The conventions do not define the length of a medical prescription or the amount of medicines to be prescribed by a health worker. If a prescription covers only the amount of medicines needed for a limited time span, or if the validity of prescriptions is limited, the patient will need to go frequently to the physician and the pharmacy." (p. 27)

For this evaluation, prescription validity periods for opioid pain medications, when limited to 15 days or less, were seen as fulfilling this criterion.

CRITERION C.5: PRACTITIONERS ARE SUBJECT TO UNDUE PRESCRIBING REQUIREMENTS

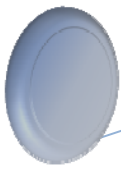
The Single Convention establishes several national obligations to ensure that adequate supplies of medications are available for legitimate medical and scientific uses and to prevent diversion of drugs from licit to illicit channels, among them that governments must regulate all entities that handle controlled medicines. The goal is to create a closed distribution system, including security and record keeping. Prescribing and dispensing to individuals must be done only for medical purposes by healthcare professionals authorized under national law, requiring "medical prescriptions" (United Nations, 1961, Article 30, Section 2(b)(i)). Distribution outside of the regulated system is prohibited, as a means to prevent diversion of controlled drugs from medical to non-medical uses.

Within the context of the Single Convention, however, the establishment of additional prescribing requirements also must continue to ensure the availability of these medications for the relief of pain and suffering (World Health Organization, 2011a). For example, requiring complex prescription forms or prescription books, which must be obtained from the government with considerable difficulty, at notable cost, and increased scrutiny, may in fact not meet this standard. In addition, efforts should evaluate the impact of this and similar requirements to determine their effectiveness at protecting the public health and welfare and promoting safe and effective patient care.

Four distinct categories of policy provisions have the potential to create undue prescribing requirements:

Category A: Requirements to use special prescription forms. To further promote governments' main responsibility to protect public health and safety, the Single Convention mentions that "counterfoil" prescription forms with several copies (which is an extension of the "medical prescriptions" requirement under the Single Convention) can be used; however, but they are not required. The 1961 Single Convention made this possibility explicit (United Nations, 1961):

"If the Parties deem these measures necessary or desirable, require that prescriptions for drugs in Schedule I [e.g., morphine] should be written on official forms to be issued in the form of counterfoil books by the competent governmental authorities or by authorized associations." (Article 30, Section 2(b)(ii))



SECTION VIII: RESEARCH CRITERIA

However, the WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (1990a) has addressed the potentially-restrictive aspects of special government prescription forms:

“Record-keeping and authorization requirements should not be such that, for all practical purposes, they eliminate the availability of opioids for medical purposes. [Programs that require multiple-copy prescription forms] are cited as means of reducing careless prescribing and ‘multiple doctoring’ (patients registering with several medical practitioners in order to obtain several prescriptions for the same, or similar, drugs). There is some justification for thus (sic), but the extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should also be questioned.” (p. 39)

The World Health Assembly (2005) later echoed this assessment, recognizing the need:

“to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system.” (p. 3)

In addition, both the Commission on Narcotic Drugs and the WHO’s updated Guidelines document have recently acknowledged legal obligations for the use of special prescription forms as an example of policy language that Governments should correct:

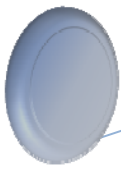
“Examples of measures that may impede availability and that are not required by the Conventions include:

-
-
-

(d) Special prescription procedures for opioids, for example, the use of specific prescription forms, which may be difficult to obtain, and/or a requirement that multiple copies of the prescription be maintained;” (United Nations Commission on Narcotic Drugs, 2011, ¶137)

“Requirements for duplicate prescriptions and special prescription forms increases the administrative burden both for healthcare workers and drug control authorities. The problem is compounded if forms are not readily available, or if health professionals need to pay for them. The conventions allow for duplicate prescriptions and special prescription forms if countries consider them necessary or desirable. Governments should ensure that this system does not impede the availability and accessibility of controlled medicines.” (World Health Organization, 2011a, p. 28)

Given such statements from international authoritative sources, this negative criterion is designed to identify country-level policy that requires a qualified healthcare professional to use a government-issued prescription form for opioid analgesics (or, as referred to in law, narcotic drugs) (such as codeine, morphine, and methadone) (Cherny et al., 2010; Hamunen, Paakkari, & Kalso, 2009; Human Rights Watch, 2011) Potential stigmatization of this important class of medications, coupled with consistent finding from available research data, suggest that the requirement of government-issued special forms for particular medications can impede appropriate prescribing (Cleary et al., 2013a; Cleary et al., 2013b; Cleary et al., 2013a; Cleary et al., 2013c; Cleary et al., 2013d). This situation can prompt practitioners to use medications for which the special form is not required instead of those that are clinically warranted.



SECTION VIII: RESEARCH CRITERIA

Category B: Requirement to report certain patients. This criterion also applies to another special requirement that healthcare practitioners must follow only for patients receiving prescriptions for opioid analgesics (or, as referred to in law, narcotic drugs). That is, a practitioner may be required to report to a government agency, or a national, state, or local database, the names of patients receiving these medications. Such reporting requirements also can include other prescription authorization processes such as practitioner submission of medical reports or patient clinical records.

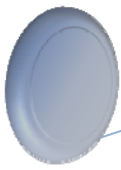
The potential for these requirements to be present in national policies contributed to the WHO's mention of this issue specifically, as an example of the type of provision that Governments should identify and remove:

"Some countries require a system of registration and authorization for patients to render themselves eligible to receive a prescription for a controlled medicine. There is no requirement for such a system by the drug control conventions. This system may be a barrier for accessing treatment and delay the onset of or adherence to treatment." (World Health Organization, 2011a, p. 27)

A related issue involves a practitioner who must report to a government agency the names of patients who meet legal definitions related to "dependence syndrome," or requires that such patients, when being treated, be registered in or reported to a national, state, or local database. Moreover, when practitioners are required to report patients with a "dependence syndrome" to a government agency or to a central registry, this could be improperly applied to patients who use opioids therapeutically in countries where laws define "dependence syndrome" as synonymous with physiological phenomena such as withdrawal syndrome (see [Criterion C.2](#) for additional information).

Category C: Requirement of a separate license/registration. National policies can impose the requirement that practitioners who prescribe opioids must obtain a license in addition to their general practice license (even while performing their professional responsibilities) (Cleary et al., 2013a; Cleary et al., 2013b; Cleary et al., 2013a; Cleary et al., 2013c; Cleary et al., 2013d); the potential consequence of this situation was made clear in a recent WHO report (2006b):

"...the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines." (p. 20)



SECTION VIII: RESEARCH CRITERIA

Again, the WHO Guidelines document from 2011 (2011a) identifies these requirements as potentially restricting healthcare practice, which can impede patient access to needed treatment, and as being in need of correction:

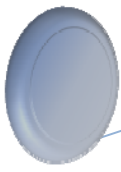
“Requirements for physicians to obtain a license for prescribing controlled substances may lead to limited access and availability. In all countries, all physicians should be sufficiently trained to treat pain and hence be allowed to prescribe opioid analgesics if necessary. Training for treatment of other conditions depends on whether a condition occurs or not within their specialty.” (p. 29)

This same standard also could apply to pharmacists (or even the pharmacy establishment) with general dispensing authority being prohibited from dispensing controlled medicines as part of their practice without requiring an additional license (World Health Organization, 2011a).

“In many countries, retail and hospital pharmacies and dispensaries are allowed to procure, stock, and dispense controlled medicines by virtue of their general license; however, some countries require them to obtain a special license. In some cases, application procedures for such licenses dissuade healthcare institutions from obtaining them; for example, through overly burdensome bureaucratic procedures, unnecessary levels of paperwork, excessive screening of staff authorized to handle controlled medicines, or overspecification of special storage facilities.” (p. 28)

“Guideline 12: Appropriately trained and qualified pharmacists at all levels of health care should be allowed to dispense controlled medicines, based on their general professional license, current medical knowledge and good practice without any further license requirements. As the need for controlled medicines can be present at all levels of health care, all pharmacists should be trained appropriately for the dispensing of these medicines. Requirements for pharmacists to obtain a license for prescribing controlled substances may limit access and availability.” (p. 30)

Category D: Requirement of an additional prescription authorization. Finally, although the 2011 WHO Guidelines document specifically recognizes that special licensing requirements for physicians or patient registration could create impediments to effective pain management (World Health Organization, 2011a), it is a logical extension that the legal establishment of additional prescription authorizations could similarly impose treatment barriers (Cleary et al., 2013a). As such, national policies that create an elaborate prescription authorization process, thereby obligating practitioners to fulfill a number of extra requirements only when prescribing opioid pain medications, would be considered an example of potentially-restrictive government regulations. Generally, special prescription procedures, stricter than the control measures required under international treaties, have been acknowledged as potential legislative or regulatory impediments by the WHO (2011a), the UNCND (2011), the UNECOSOC (2010), the INCB (1996; 2011), and RPAR (Case et al., 2008).



SECTION VIII: RESEARCH CRITERIA

CRITERION C.6: PROVISIONS THAT ARE AMBIGUOUS

This analysis also can identify several provisions having the potential to impede pain management due to ambiguity of language. The test we used to identify ambiguous provisions was whether the language would be clear to a person (professional or lay) who only reads the words of the provision to understand its meaning.

Four categories of policy provisions have the potential to create ambiguity:

Category A: Arbitrary standards for legitimate prescribing. This category is exemplified primarily by a country's policy that establishes a standard for professional practice (for physicians or other prescribers, or pharmacists or others who dispense) in which contextual terms or conditions necessary to characterize the standard are undefined. Left undefined, these terms or conditions may contribute to practitioners' uncertainty about what standard determines the legitimacy of a particular prescribing practice or who sets that standard.

Category B: Unclear intent leading to possible misinterpretation. This category recognizes vague statutory or regulatory language that can make it difficult for practitioners to understand the explicit meaning of the policy provision or the specific actions that the policy requires.

Category C: Conflicting or inconsistent policies or provisions. This category includes provisions in a country's drug control or health care policies that appear to contradict or do not conform to other policy provisions, thereby creating conflicting requirements. Such inconsistencies can occur between different policies (e.g., with statutory language that does not conform to the language created in regulations to implement the statute), or even for provisions in the same policies.

Category D: Unclear definitions of dependence syndrome. This category represents legal definitions in a country's drug control or health care policies that are unclear about whether they would be applicable to patients who are using controlled medicines for medical purposes. The implications of confusing terminology on patient care, as well as the need to avoid, remove, or modify such language, were directly and thoroughly addressed in the updated WHO Guidelines document (2011a):

"Guideline 10: Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse. Drug control legislation and policy have sometimes contributed to stigmatization of controlled medicines because of the use of inappropriate terminology. Confusion and discrimination relating to terminology can deter doctors from prescribing controlled medicines when it is legitimate to do so; it can also confuse authorities who wish to discriminate between legitimate and illegitimate use. Countries should therefore take steps to review policies to ensure the consistent use of medical terms and remove stigmatizing terminology from their legislation. These guidelines specifically recommend the use of non-stigmatizing terminology...A further confusion relates to the definition of 'dependence' and 'dependence syndrome'...The WHO definition of 'dependence syndrome' requires the presence of at least three out of six symptoms, including a strong desire or a sense of compulsion to take the drug and also the neglecting of interests and daily activities because of devotion to the use of psychoactive substances. It is clear that a patient requiring increasing doses of an opioid for pain relief because of pharmacological tolerance due to prolonged treatment does not normally fall into this category. Neither does a patient who develops withdrawal syndrome." (pp. 28-29)



SECTION VIII: RESEARCH CRITERIA

CRITERION C.7: OTHER PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

This analysis attempts to identify several additional provisions that are in conflict with the Central Principle of *Balance* and that have the potential to impede pain relief, but that are not related to a specific individual criterion. Three categories of policy provisions were conceptualized to denote additional language that, if implemented, could impede pain management:

Category A: Issues related to healthcare professionals. This category could be exemplified by provisions that require registries or lists of practitioners who prescribe opioid analgesics or other controlled medicines, or that require physicians to be responsible (either in some specified or unspecified way) if the medications that they prescribe are misused.

Category B: Issues related to patients. A relevant example of this criterion could restrict treatment options depending on the healthcare facility in which a patient is being treated. In some countries, laws can dictate prescribing or dispensation of opioid analgesics only to patients when they are being treated in a hospital or other healthcare facility, but not when they become ambulatory; therefore, treatment continuity may be difficult:

“It is essential that government policies ensure that patients are able to continue their treatment with controlled medicines when they are hospitalized in health facilities that normally do not use such medicines.” (World Health Organization, 2011a, p. 25)

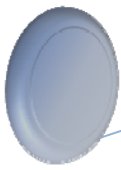
“When balancing drug control legislation and policies, it is wise to leave medical decisions up to those who are knowledgeable on medical issues. Therefore, the amount of medicine prescribed, the appropriate formulation and the duration of treatment should be the practitioner’s decision, based on individual patient needs and on sound scientific medical guidance (e.g., national or WHO treatment guidelines). An example of how this rule may sometimes be violated is the legal restriction on the maximum daily dosage of strong opioids. Another example is the limitation of the use of strong opioids only to certain conditions such as cancer pain or terminal cancer pain, while other moderate to severe pain remains unaddressed.” (World Health Organization, 2011a, p. 30)

Another example relates to patients who, as a qualification for receiving medication prescriptions, are required to obtain an NCA registration number, or become part of a separate national, state, or local data registry:

“Some countries require a system of registration and authorization for patients to render themselves eligible to receive a prescription for a controlled medicine. There is no requirement for such a system by the drug control conventions. This system may be a barrier for accessing treatment and delay the onset of or adherence to treatment.” (World Health Organization, 2011a, p. 27)

A Discussion Paper from the 54th session of the UNCND (2011) also viewed as an important regulatory barrier the requirement for registration of particular patients, as a method to gain access to appropriate treatment:

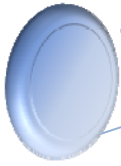
“Requirements that patients receive special permission or registration to render them eligible to receive opioid prescriptions;” (¶137(e))



SECTION VIII: RESEARCH CRITERIA

Category C: Other regulatory or policy issues. This criterion relates to the presence of additional requirements (those not identified through the previous criteria) found in legislative, regulatory, or other policies, such as requiring limited and very specific procedures for purchasing and acquiring official prescription forms. In addition, similar to the case of requiring different standards for licensure of healthcare professionals, this criterion category would be fulfilled when there are different licensing requirements depending on the healthcare facility under consideration, such as requiring special licenses for healthcare institutions that stock and dispense controlled medicines such as opioids.

“In many countries, retail and hospital pharmacies and dispensaries are allowed to procure, stock, and dispense controlled medicines by virtue of their general license; however, some countries require them to obtain a special license. In some cases, application procedures for such licenses dissuade healthcare institutions from obtaining them; for example, through overly burdensome bureaucratic procedures, unnecessary levels of paperwork, excessive screening of staff authorized to handle controlled medicines, or overspecification of special storage facilities.” (World Health Organization, 2011a, p. 28)



**SECTION IX: RESULTS – COUNTRY PROFILES OF
NATIONAL POLICIES ON DRUG CONTROL
MEDICAL PRACTICE**

Colombia



Population:
47,600,000

Mortality rates/100,000:
HIV/AIDS: 7.3
CANCER: 75.9

Human Development Index:
1980: 0.556
2010: 0.719

WHO Region:
AMRO

UN Region:
Americas

UN sub-region:
South America

Relevant language found in the following policies:

LEY 13 DE 1974
(Noviembre 29)
Diario Oficial No. 34.228 de 17 de Diciembre de 1974

LEY 30 DE 1986
(Enero 31)

DECRETO NUMERO 3788 DE 1986
(Diciembre 31)
Por el cual se reglamenta la Ley 30 de 1986 o Estatuto Nacional de Estupefacientes

MINISTERIO DE SALUD
RESOLUCIÓN NÚMERO 6980 DE 1991
(Mayo 28)
Por la cual se expiden normas para el control de la importación, exportación, fabricación, distribución y venta de medicamentos, materias primas y precursores de control especial

MINISTERIO DE PROTECCIÓN SOCIAL
RESOLUCIÓN 4651 DE 2005
(diciembre 15)
Diario Oficial No. 46.142 de 05 de enero de 2006
Por la cual se expiden normas para el control, seguimiento y vigilancia de la importación, exportación, procesamiento, síntesis, fabricación, distribución, dispensación, compra, venta, destrucción y uso de sustancias sometidas a fiscalización, medicamentos o cualquier otro producto que las contengan y sobre aquellas que son Monopolio del Estado

MINISTERIO DE LA PROTECCIÓN SOCIAL
RESOLUCIÓN NÚMERO 001478 DE 10 DE MAYO DE 2006
Por la cual se expiden normas para el control, seguimiento y vigilancia de la importación, exportación, procesamiento, síntesis, fabricación, distribución, dispensación, compra, venta, destrucción y uso de sustancias sometidas a fiscalización, medicamentos o cualquier otro producto que las contengan y sobre aquellas que son Monopolio del Estado

MINISTERIO DE LA PROTECCIÓN SOCIAL
RESOLUCIÓN NÚMERO 1403 DE 2007
(14 de mayo)
Por la cual se determina el Modelo de Gestión del Servicio Farmacéutico, se adopta el Manual de Condiciones Esenciales y Procedimientos y se dictan otras disposiciones

Ley 1384 de 2010
(Abril 19)
Ley Sandra Ceballos, por la cual se establecen las acciones para la atención integral del cancer en Colombia



Original Policy Language	Formal Translation
<p>LEY 13 DE 1974 (noviembre 29) Diario Oficial No. 34.228 de 17 de diciembre de 1974</p> <p>CONGRESO DE COLOMBIA Por medio de la cual se aprueba la "Convención Unica sobre estupefacientes", hecho, en Nueva York el 30 de marzo de 1961, y su Protocolo de Modificaciones, hecho en Ginebra el 25 de marzo de 1972.</p> <p>EL CONGRESO DE COLOMBIA DECRETA:</p> <p>ARTÍCULO PRIMERO. Apruébase la "Convención Unica sobre Estupefacientes", hecha en Nueva York, el 30 de marzo de 1961, y su Protocolo de Modificación, hecho en Ginebra el 25 de marzo de 1972.</p> <p>CONVENCION UNICA SOBRE ESTUPEFACIENTES Y SU PROTOCOLO DE MODIFICACION. P R E A M B U L O</p> <p>Las Partes, Preocupadas por la salud física y Moral de humanidad, Reconociendo que el uso médico de los estupefacientes continuará siendo indispensable para mitigar el dolor y que deben adoptarse las medidas necesarias para garantizar la disponibilidad de estupefacientes con tal fin, Reconociendo que la toxicomanía constituye un mal grave para el individuo y entraña un peligro social y económico para la humanidad, Conscientes de su obligación de prevenir y combatir ese mal, Considerando que para ser eficaces las medidas contra el uso indebido de estupefacientes se hace necesaria una acción concertada y universal, Estimando que esa acción universal exige una cooperación internacional orientada por principios idénticos y objetivos comunes, Reconociendo que las Naciones Unidas tienen competencia en materia de fiscalización de estupefacientes y deseando que los órganos internacionales competentes pertenezcan a esa Organización, Deseando concertar una convención internacional que sea de aceptación general, en sustitución de los tratados existentes sobre estupefacientes, por la que se limite el uso de estupefacientes a los fines médicos y científicos y se establezca una cooperación y una fiscalización internacionales conscientes para el logro de tales finalidades objetivas, Por la presente acuerdan lo siguiente:</p> <ul style="list-style-type: none"> . . . 	<p>Act 13 of 1974 (Nov. 29) Official Gazette No. 34,228 of December 17, 1974</p> <p>CONGRESS OF COLOMBIA By approving the "Single Convention on Narcotic Drugs", made in New York on March 30, 1961, and its Protocol of Amendment, done at Geneva on 25 March 1972.</p> <p>CONGRESS OF COLOMBIA Decreets:</p> <p>ARTICLE ONE. Approval of the "Single Convention on Narcotic Drugs", done at New York on March 30, 1961, and its Protocol of Amendment, done at Geneva on 25 March 1972.</p> <p>Single Convention on Narcotic Drugs and its Protocol of amendment. P R E A M B L E</p> <p>The Parties Concerned about the health and welfare of humanity, Recognizing that the medical use of narcotic drugs continues to be <u>indispensable</u> for pain and must make arrangements to <u>ensure the availability</u> of narcotic drugs for such purpose , recognizing that addiction is a serious evil for the individual and is fraught with social and economic danger to mankind, Conscious of their duty to prevent and combat this evil, Considering that effective measures against abuse of narcotic drugs require a concerted and universal Understanding that such universal action calls for international cooperation guided by the same principles and goals, recognizing that the United Nations have jurisdiction over narcotics control and desirous that the international bodies belong to that organization, Desiring to conclude an international convention that is general acceptance, replacing existing treaties on narcotic drugs, which limit the use of narcotic drugs to medical and scientific purposes and to establish cooperation and international oversight conscious for achieving these aims and objectives, hereby agree following:</p> <ul style="list-style-type: none"> . . .

(+) CRITERION A.1:
Acknowledges the intent to carry out drug control Conventions

(+) CRITERION A.4:
Recognizes the medical use of controlled substances as indispensable for the relief of pain and suffering, including being necessary for the public health

(+) CRITERION A.3:
Acknowledges the Government's responsibility to ensure availability of narcotic drugs for medical and scientific purposes

Criterion also identified in:
Resolución 4651 de 2005, Artículo 2
Ley No 1384 de 2010, Artículo 10, ¶12

(+) CRITERION A.5:
Represents the principle of Balance



Original Policy Language	Formal Translation
<p>LEY 30 DE 1986 (Enero 31) <u>Reglamentada por el Decreto Nacional 3788 de 1986</u></p> <p>CAPITULO I Principios generales</p> <p>Artículo 2o. Para efectos de la presente Ley se adoptarán las siguientes definiciones:</p> <ul style="list-style-type: none"> . . . <p>g) Adicción o Drogadicción: Es la dependencia de una droga con aparición de síntomas físicos cuando se suprime la droga.</p> <ul style="list-style-type: none"> . . . <p>CAPITULO IV Control de la importación, fabricación y distribución de sustancias que producen dependencias</p> <ul style="list-style-type: none"> . . . <p>Artículo 27. Los profesionales en medicina que formulan las drogas y medicamentos a que se refiere el artículo 26, a pacientes considerados como farmacodependientes, tienen la obligación de informar de ello a los Servicio Seccionales de Salud, los cuales deberán transmitir la información al Fondo Rotatorio de Estupefacientes del Ministerio de Salud, que deberá llevar un Registro Nacional de Farmacodependientes.</p> <ul style="list-style-type: none"> . . . <p>CAPITULO V De los delitos</p> <ul style="list-style-type: none"> . . . <p>Artículo 37._ El que suministre, administre o facilite a un menor de dieciséis (16) años, droga que produzca dependencia o lo induzca a usarla, incurrirá en prisión de seis (6) a doce (12) años.</p> <ul style="list-style-type: none"> . . . 	<p>LAW 30 OF 1986 (January 31) <u>Regulated by National Decree 3788 of 1986</u></p> <p>CHAPTER I General Principles</p> <p>Article 2. For the purposes of this Act, the following definitions are adopted:</p> <ul style="list-style-type: none"> . . . <p>g) Addiction or Drug Addiction: Dependency on a drug with the appearance of <u>physical symptoms</u> when the drug is removed.</p> <ul style="list-style-type: none"> . . . <p>CHAPTER IV Control of the Importation, Manufacturing, and Distribution of Substances That Produce Dependencies</p> <ul style="list-style-type: none"> . . . <p>Article 27. Medical professionals who prescribe the drugs and medicines referred to in Article 26 to patients considered drug-dependent persons are <u>required to inform Regional Health Services</u> of that, and Regional Health Services must send this information to the National Competent Authority of the Ministry of Health, which shall keep a National Register of Drug-Dependent Persons.</p> <ul style="list-style-type: none"> . . . <p>CHAPTER V Concerning Crimes</p> <ul style="list-style-type: none"> . . . <p>Article 37. Those who supply, administer or provide a drug that produces dependency or prompts use of it to a <u>minor who is under sixteen (16) years old</u> will be incur six (6) to twelve (12) years in prison.</p> <ul style="list-style-type: none"> . . .

(-) CRITERION C.2:
Withdrawal syndrome or analgesic tolerance are confused with dependence syndrome (i.e., "addiction")

(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category B: Requirements to report certain patients

Criterion also identified in:
Resolución 4651 de 2005, Artículo 57

(-) CRITERION C.3:
Restrictions that could limit medical decision-making

Category A: Restrictions based on patient characteristics



Original Policy Language	Formal Translation
<p>MINISTERIO DE SALUD RESOLUCIÓN NÚMERO 6980 DE 1991 (Mayo 28)</p> <p>"Por la cual se expiden normas para el control de la importación, exportación, fabricación, distribución y venta de medicamentos, materias primas y precursores de control especial".</p> <p>EL MINISTRO DE SALUD</p> <p>En uso de sus atribuciones legales, en especial las conferidas por la Ley 9a de 1979, Capítulo IV, Ley 30 de 1986, el Decreto Reglamentario 3788 de 1986, y oído el concepto de la Comisión Revisora de Productos Farmacéuticos,</p> <p>RESUELVE:</p> <p>.</p> <p>CAPÍTULO X Venta y consumo</p> <p>.</p> <p>ART. 52. Prohíbese a los establecimientos farmacéuticos debidamente autorizados, despachar fórmulas de medicamentos de control especial, cuando éstas tengan más de quince (15) días calendario de haber sido expedidas.</p> <p>ART. 53. Los hospitales, y los centros de salud adscritos al sistema de salud, están obligados a expender al público los medicamentos de control especial.</p> <p>.</p>	<p>MINISTRY OF HEALTH RESOLUTION NUMBER 6980 OF 1991 (May 28)</p> <p>"Whereby the regulations for the control of importing, exporting, manufacturing, distributing and selling specially controlled medicines, raw materials and precursors."</p> <p>THE MINISTRY OF HEALTH</p> <p>In exercise of its legal powers, in particular those conferred by Act 9a of 1979, Chapter IV, Act 30 of 1986 and Regulatory Decree 3788 of 1986, and having heard the opinion of the Pharmaceutical Products Review Commission,</p> <p>RESOLVES:</p> <p>.</p> <p>CHAPTER X Sale and Consumption</p> <p>.</p> <p>Article 52. It is prohibited for duly authorized pharmaceutical institutions to dispense prescriptions for specially controlled drugs when it has been more than <u>fifteen (15) calendar days</u> since they were issued.</p> <p>Article 53. Hospitals and health centers attached to the health system are required to dispense specially controlled drugs to the public.</p> <p>.</p>

(-) CRITERION C.4:
Length of prescription validity is restricted

Criterion also identified in:
Resolución 4651 de 2005,
Artículo 5(7)

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy issues

Comment: This provision permits controlled medicines to be dispensed from the place of care



Original Policy Language	Formal Translation
<p>MINISTERIO DE LA PROTECCIÓN SOCIAL RESOLUCIÓN NÚMERO 001478 DE 10 DE MAYO DE 2006</p> <p>Por la cual se expiden normas para el control, seguimiento y vigilancia de la importación, exportación, procesamiento, síntesis, fabricación, distribución, dispensación, compra, venta, destrucción y uso de sustancias sometidas a fiscalización, medicamentos o cualquier otro producto que las contengan y sobre aquellas que son Monopolio del Estado.</p> <p>EL MINISTRO DE LA PROTECCIÓN SOCIAL</p> <p>En uso de sus atribuciones legales y en especial las conferidas por Ley 36 de 1939, Ley 9 de 1979, Ley 30 de 1986 y Decreto Reglamentario 3788 de 1986</p> <p>RESUELVE:</p> <p>CAPÍTULO I DISPOSICIONES GENERALES, DEFINICIONES Y PROHIBICIONES</p> <p>.</p> <p>.</p> <p>.</p> <p>ARTÍCULO 2.- Para efectos de la presente Resolución se adoptan las siguientes definiciones:</p> <p>ABUSO: Es el uso indebido de drogas o medicamentos con fines no médicos. ADICCIÓN O DROGADICCIÓN: Es la dependencia a una droga.</p> <p>.</p> <p>.</p> <p>.</p> <p>CAPÍTULO XVII PRESCRIPCIÓN DE MEDICAMENTOS DE CONTROL ESPECIAL</p> <p>ARTÍCULO 80.- La cantidad total prescrita de medicamentos sometidos a fiscalización se hará, teniendo en cuenta los siguientes parámetros:</p> <p>a.- Medicamentos correspondientes a: "Analgésicos Narcóticos", "Analgésicos Moderadamente Narcóticos", a "Barbitúricos o Medicamentos, que contienen Barbitúricos, con excepción de Fenobarbital; a "Anfetaminas y Estimulantes Centrales"; a "Tranquilizantes e Hipnóticos no Barbitúricos" y demás medicamentos de control especial, hasta la dosis requerida para treinta (30) días calendario.</p> <p>b.- Medicamentos correspondientes a "Oxitócitos y Antihemorrágicos Uterinos", la dosis ordenada bajo la responsabilidad del médico tratante.</p> <p>c.- Fenobarbital, hasta las dosis requerida para noventa (90) días calendario.</p> <p style="text-align: right;">Continued on next page</p>	<p>MINISTRY OF SOCIAL PROTECTION RESOLUTION NUMBER 001478 OF 10 MAY 2006</p> <p>Whereby regulations are established for control of, monitoring and surveillance of importing, exporting, processing, synthesizing, manufacturing, distributing, dispensing, purchasing, selling, destroying and using controlled substances, drugs or any other product that contain these and substances that are related to those under State Monopoly.</p> <p>THE MINISTER OF SOCIAL PROTECTION</p> <p>In exercise of their legal powers, in particular those conferred by Act 9a of 1939, Chapter IV of Act 30 of 1986 and Decree 3788 of 1968 and</p> <p>RESOLVES:</p> <p>CHAPTER I General Provisions, Definitions, and Prohibitions</p> <p>.</p> <p>.</p> <p>.</p> <p>Article 2. For the purposes of this resolution, the following definitions are adopted:</p> <p>ABUSE: The misuse of drugs or medicines for non-medical purposes. ADDICTION OR DRUG ADDICTION: Dependency on a drug.</p> <p>.</p> <p>.</p> <p>.</p> <p>CHAPTER XVII Prescription of Specially Controlled Substances</p> <p>Article 80. The total amount prescribed for drugs subject to oversight will take into account the following parameters:</p> <p>a) Drugs corresponding to: "Analgesic Narcotics," "Moderately Analgesic Narcotics," "Barbiturates or Drugs Containing Barbiturates, with the exception of Phenobarbital"; to "Amphetamines and Central Stimulants"; to "Tranquilizers and Non-Barbiturate Hypnotic Agents," as well as specially controlled drugs, up to the dose required for thirty (30) calendar days.</p> <p>b) Drugs corresponding to "Oxytocins and Uterine Antihemorrhagics", the dose prescribed by the treating physician.</p> <p>c) Phenobarbital, up to the doses required for ninety (90) calendar days.</p> <p style="text-align: right;">Continued on next page</p>

(-) CRITERION C.6:

Provisions that are ambiguous

Category D: Unclear definitions of dependence syndrome

Comment: This definition is vague, and it is not clear if it could be applied inappropriately to a person taking controlled medicines for medical purposes.

Criterion also identified in:
Resolución 4651 de 2005, Artículo 2



Original Policy Language

Continued from previous page

ARTÍCULO 81.- Los médicos, médicos veterinarios y médicos veterinarios zootecnistas graduados y en ejercicio legal de su profesión son los únicos profesionales que podrán prescribir Medicamentos de control especial, franja violeta, en la fórmula del Recetario Oficial.

ARTÍCULO 82.- Los médicos veterinarios, médicos veterinarios zootecnistas, para prescribir Medicamentos sometidos a fiscalización, deberán estar inscritos en el Consejo Profesional de Medicina Veterinaria y de Zootecnia de Colombia – COMVEZCOL, donde obtienen el Registro y Matrícula Profesional, de acuerdo a la Ley 073 de 1985 y la Ley 576 de 2000, sobre los profesionales autorizados para prescribir medicamentos de sometidos a fiscalización.

CAPÍTULO XVIII RECETARIO OFICIAL

ARTÍCULO 84.- La prescripción de medicamentos de control especial para uso humano o veterinario solo se podrá efectuar en los recetarios oficiales suministrados por los Fondos Rotatorios de Estupefacientes, para médicos en ejercicio legal de su profesión y/o por COMVEZCOL para médicos veterinarios y médicos veterinarios zootecnistas. El Recetario debe ajustarse al formato prescrito en los ANEXOS No. 8 y 8A de la presente Resolución. Los profesionales que laboren en las instituciones podrán hacer uso del Recetario Oficial adquirido por la entidad. Los Fondos Rotatorios de Estupefacientes de las Secretarías, instituciones o Direcciones Departamentales de Salud, y/o COMVEZCOL para médicos veterinarios, son los únicos autorizados para emitir, distribuir y vender el Recetario Oficial para la prescripción.

PARÁGRAFO

Las instituciones que compren Recetarios Oficiales para su distribución a los médicos de su institución serán solidariamente responsables del manejo y buen uso que se les de a los mismos.

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Formal Translation

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Article 81. Physicians, veterinarians and doctors of veterinary science and animal husbandry who are qualified and legally practicing their profession are the only professionals who may prescribe specially controlled substances that have a purple stripe on the official prescription form.

Article 82. In order for veterinarians and doctors of veterinary science and animal husbandry to prescribe drugs subject to oversight, they must be registered in the Professional Council of Veterinary Medicine and Animal Science of Colombia — COMVEZCOL, where they obtain their professional license and registration, in accordance with Act 073 of 1985 and Act 576 of 2000 on professionals that are authorized to prescribe drugs subject to oversight.

CHAPTER XVIII Official Prescription Form Book

ARTICLE 84. - Prescription of specially controlled drugs that are for human or veterinary use may only be performed using the official prescription form books issued by Regional Competent Authority for physicians legally practicing their profession and/or by Comvezcol for veterinary doctors and doctors of veterinary science and animal husbandry. The prescription form must follow the format stipulated in ANNEXES No. 8 and 8A of this resolution. Professionals that work in institutions may use the Official Prescription Form Book acquired by the entity. The Secretariats' Regional Competent Authority, institutions or departmental health offices or their representatives, and/or COMVEZCOL for veterinary doctors, are the only ones authorized to issue, distribute and sell the official prescription forms for prescription.

PARAGRAPH

Institutions that purchase official prescription forms for distribution to the physicians of its institution will be jointly responsible for the management of proper use of these prescription forms.

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(+) CRITERION B.3:
Medical use of opioids is recognized as legitimate professional practice

Criterion also identified in:
Resolución 4651 de 2005,
Artículo 52

(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category A: Requirement to use special prescription forms

Criterion also identified in:
Resolución Numero 6980 de 1991, Artículo 41-45
Resolución 4651 de 2005,
Artículo 55-60



Original Policy Language

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ARTÍCULO 85.- Los Fondos Rotatorios de Estupefacientes y COMVEZCOL para la elaboración de los respectivos Recetarios Oficiales, tendrán en cuenta los lineamientos que para el efecto señale la U.A.E. Fondo Nacional de Estupefacientes del Ministerio de la Protección Social.

ARTÍCULO 86.- Los recetarios oficiales para la formulación de medicamentos de control especial tendrán un original, que quedará en el Establecimiento o Entidad que dispense, y dos copias, en las cuales se anotará que fue dispensado; una para el paciente y otra para el trámite administrativo pertinente.

PARÁGRAFO.

Ninguna entidad podrá exigir la presentación de una fórmula médica en dos (2) originales para soportar tramites internos administrativos.

ARTÍCULO 87.- Cuando a un profesional se le extravíe el Recetario Oficial, deberá formular la denuncia correspondiente e informar inmediatamente por escrito al Fondo Rotatorio de Estupefacientes de la respectiva Dirección Departamental de Salud, allegando copia de la denuncia.

ARTÍCULO 88.- Para el caso de que un medicamento sea formulado en un Departamento diferente al de adquisición o compra, se podrá autorizar la fórmula por parte de la U.A.E. Fondo Nacional de Estupefacientes o del Fondo Rotatorio de Estupefacientes Departamental.

ARTÍCULO 89.- El Recetario Oficial debe contener como mínimo los siguientes datos:

1. Codificación
2. Nombre del prescriptor, dirección y teléfono.
3. Fecha de expedición de la prescripción.
4. Nombre del paciente, dirección y número del documento de identidad si es el caso.
5. Denominación Común Internacional del medicamento, concentración y forma farmacéutica, cantidad total en números y letras y dosis diaria (frecuencia de administración), vía de administración y tiempo de tratamiento.
6. Firma del prescriptor con su respectivo número de registro profesional.

ARTÍCULO 90.- La fórmula médica debe ser única para los medicamentos de control especial. En ella no deben prescribirse otros medicamentos diferentes a los sometidos a control especial. Una vez dispensado el medicamento se deberá colocar sello de dispensado en la prescripción correspondiente.

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Formal Translation

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Article 85. Regional Competent Authority and COMVEZCOL must adhere to the guidelines issued by the Ministry of Health's National Competent Authority when preparing their respective official prescription forms.

Article 86. Official prescription forms for prescribing specially controlled drugs must have an original copy to be kept at the establishment or entity that dispenses it, and there must be two copies that note what was dispensed; one for the patient and one for the appropriate administrative procedure.

PARAGRAPH

No entity may require that two (2) original copies of a medical prescription must be present for the purposes of internal administrative procedure.

Article 87. If a professional misplaces the official prescription form, they must fill out the appropriate report and immediately inform the Regional Competent Authority of the respective Departmental Health Bureau or its acting agencies, in writing, and attach a copy of the report.

Article 88. In the event that a drug is prescribed in a different department than the one where it is to be acquired or purchased, the form must be authorized by the National Narcotics Fund U.A.E. or the Departmental Regional Competent Authority.

Article 89. The official prescription form must contain the following information at minimum:

1. Coding.
2. Name of the prescriber, their address and their telephone number.
3. Date that the prescription was issued.
4. Name of the patient, their address and their identification number if applicable.
5. The International Non-Proprietary Name of the drug, its concentration and pharmaceutical form, its total quantity in numbers and writing and the daily dose (frequency of administration), its route of administration and the duration of treatment.
6. Signature of the prescriber and their respective professional registration number.

Article 90. The medical form must be the original copy for specially controlled drugs. It should not list other prescribed drugs that are not subject to special control. Once the drug is dispensed, the dispensed label should be placed on the prescription.

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Original Policy Language	Formal Translation
<p>LEY 1384 DE 2010 (abril 19)</p> <p>Ley Sandra Ceballos, por la cual se establecen las acciones para la atención integral del cáncer en Colombia.</p> <p>EL CONGRESO DE COLOMBIA</p> <p>DECRETA:</p> <p>.</p> <p>.</p> <p>.</p> <p>ARTÍCULO 10. CUIDADO PALIATIVO. Las Entidades Promotoras de Salud, los regímenes de excepción y especiales y las entidades territoriales responsables de la población pobre no asegurada, las demás entidades de aseguramiento y las Instituciones Prestadoras de Servicios de Salud públicas y privadas, deberán garantizar el acceso de los pacientes oncológicos a Programas de Cuidado Paliativo y que cumpla con los criterios antes descritos.</p> <p>PARÁGRAFO 1o. El Ministerio de la Protección Social, con asesoría del Instituto Nacional de Cancerología y las Sociedades Científicas Clínicas y/o Quirúrgicas relacionadas directamente con temas de oncología y un representante de las asociaciones de pacientes debidamente organizadas, definirá el Modelo de Atención para el Cáncer desde la promoción hasta la Rehabilitación, con indicadores de evaluación de calidad que permitan eliminar las barreras de acceso y definir incentivos o sanciones por parte del Consejo Nacional de Seguridad Social en Salud, CNSSS, o quien haga sus veces, la Comisión de Regulación en Salud, CRES.</p> <p>PARÁGRAFO 2o. El Ministerio de la Protección Social, a través del Fondo Nacional de Estupefacientes, garantizará la distribución, accesibilidad, disponibilidad y otorgará las autorizaciones necesarias para garantizar la suficiencia y la oportunidad para el acceso a los medicamentos opioides de control especial para el manejo del dolor.</p> <p>.</p> <p>.</p> <p>.</p> <p>ARTÍCULO 20. INSPECCIÓN, VIGILANCIA Y CONTROL. Para garantizar en debida forma los derechos de los usuarios, la Superintendencia Nacional de Salud, las Direcciones Territoriales de Salud y concurrirá como garante la Defensoría del Pueblo, de conjunto serán las encargadas de la inspección, vigilancia y control en el acceso y la prestación de servicios oncológicos por parte de las Entidades Promotoras de Salud de ambos regímenes, de los responsables de la población pobre no asegurada y de las instituciones habilitadas para la prestación con calidad de los servicios oncológicos.</p> <p style="text-align: right;">Continued on next page</p>	<p>Law No. 1384 (19 April 2010)</p> <p>"SANDRA CEBALLOS LAW, WHICH ARE ESTABLISHED BY SHARES For Comprehensive CANCER IN COLOMBIA ".</p> <p>CONGRESS OF COLOMBIA</p> <p>Decrees:</p> <p>.</p> <p>.</p> <p>.</p> <p>ARTICLE 10. Palliative Care. Health promoting entities, states of emergency and special and local authorities responsible for uninsured poor, other insurance entities and institutions providing services to private and public health, should guarantee access of cancer patients to palliative care programs and comply with the criteria described above.</p> <p>Paragraph 1. The Ministry of Social Welfare Institute with advice Nacional of Oncology and clinical scientific societies and / or related surgical directly with issues of oncology and representative associations d patients properly organized, define the Care Model for Cancer from promotion to rehabilitation, quality assessment indicators to remove existing barriers and define incentives or sanctions by National Council of Social Security in Health, CNSSS, or his substitute, the Health Regulatory Commission, CRES.</p> <p>Paragraph 2. The Ministry of Social Welfare, through the National Narcotics Fund, ensure the distribution, accessibility, availability and grant the necessary authorizations to ensure the adequacy and opportunity for access to special control opioid medications for pain management.</p> <p>.</p> <p>.</p> <p>.</p> <p>ARTICLE 20. Inspection, monitoring and control. To ensure the duly user rights, the National Health Directorates Territorial Health and concur as guarantor, the Ombudsman, set will be responsible for the inspection, supervision and control of access and provision oncology services by the Health Promotion Entities from both regimes, those responsible for the poor and uninsured institutions authorized to provide quality cancer services.</p> <p style="text-align: right;">Continued on next page</p>

(+) CRITERION B.4:
Pain management is encouraged

Category A: Ensures treatment of certain patient populations



Original Policy Language

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PARÁGRAFO 1o. El Gobierno Nacional contará con un plazo máximo de seis meses a partir de la expedición de la presente ley para establecer las medidas de vigilancia y control, incluyendo los indicadores de seguimiento necesarios para verificar la entrega completa y oportuna de medicamentos formulados a sus afiliados. En caso de investigaciones que lleve a cabo la Superintendencia de Salud o quien esta delegue, relacionadas con el desabastecimiento o entrega interrumpida de medicamentos a personas que requieren entregas permanentes y oportunas, se invertirá la carga de prueba debiendo la entidad demandada probar la entrega. Además, estos procesos se adelantarán con el fin de obtener una decisión final, la que no podrá sobrepasar en su investigación y decisión final más de tres meses.

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Formal Translation

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Paragraph 1. The National Government will have a maximum period of six months from the issuance of this law to establish surveillance and control measures, including monitoring indicators necessary to verify complete and timely delivery of prescription medications to members. In case of investigations carried out by the Superintendent of Health or delegate who is related to the shortage or interrupted delivery of medicines to people who need permanent and timely deliveries will reverse the burden of proof must prove the defendant entity delivery. Furthermore, these processes will be advanced in order to obtain a final decision, which may not exceed in their research and final decision over three months.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category B: Issues related to patients

Comment: This provision attempts to ensure continuous treatment for patients in need of palliative care services.

Guatemala



Population: 15,100,000

Mortality rates/100,000:

HIV/AIDS: 17.4

CANCER: 67.2

Human Development Index:

1980: 0.432

2010: 0.581

WHO Region:

AMRO

UN Region:

Americas

UN sub-region:

Central America

Relevant language found in the following policies:

DECRETO NUMERO 76-75

Del Congreso de la Republica de Guatemala

LEY CONTRA LA NARCOACTIVIDAD

DECRETO 48-92

Del Congreso de la Republica de Guatemala

23 de Septiembre de 1992

CONSTITUCIÓN POLÍTICA DE LA REPÚBLICA DE GUATEMALA

(Reformada por Acuerdo legislativo No. 18-93 del 17 de Noviembre de 1993)

CÓDIGO DE SALUD

DECRETO Nº 90- 97

1997

Organismo Legislativo

Congreso de la República de Guatemala

ACUERDO GUBERNATIVO NUMERO 712-99

Guatemala, 17 de septiembre de 1999

El Presidente de la República

DIRECCION GENERAL DE REGULACION, VIGILANCIA Y CONTROL DE LA SALUD DEPARTAMENTO DE REGULACIÓN Y CONTROL DE PRODUCTOS FARMACÉUTICOS Y AFINES3ra. calle final 2-10 Colonia Valles de Vista Hermosa Zona 15VENTANILLA DE SERVICIOS DEL MINISTERIO DE SALUD5ta av. 13-27 zona 9, tel. 236-299-801

NORMATIVA 22-2001

Guatemala 2 de Agosto del 2002

Versión 2

NORMATIVA 16-2002

Guatemala 15 de Mayo del 2002

Base Legal

La Jefatura del Departamento de Regulacion y Control de Productos Farmaceuticos y Afines

NORMATIVA 17-2002

Guatemala 16 de Mayo del 2002

Base Legal

La Jefatura del Departamento de Regulacion y Control de Productos Farmaceuticos y Afines



Original Policy Language

DECRETO NUMERO 76-75
EL CONGRESO DE LA REPUBLICA DE GUATEMALA,

CONSIDERANDO:

Que con fecha 25 de marzo de 1972 fue firmado en Ginebra, Suiza, el Protocolo que modifica la Convención Unica sobre Estupefacientes suscrita en Nueva York el 30 de marzo de 1961, introduciendo reformas que permiten más flexibilidad a los Estados para el combate y control del uso, producción, cultivo manufactura y distribución de drogas y estupefacientes.

CONSIDERANDO:

Que el contenido de la referida convención no contraviene normas constitucionales ni de ninguna otra ley vigente en el país;

CONSIDERANDO:

Que el Consejo de Estado, el Ministerio de Salud Publica y la Dirección de asuntos Jurídicos y Tratados del Ministerio de Relaciones Exteriores, emitieron opinión favorable a la aprobación del referido instrumento internacional, dadas las ventajas que representa para nuestro país.

POR TANTO,

En uso de las facultades que le confiere el inciso 14 del artículo 170 de la Constitución de la República,

DECRETA:

ARTICULO 1. Se aprueba el Protocolo firmado en Ginebra, Suiza, el 25 de marzo de 1972, que modifica la Convención Unica sobre Estupefacientes, suscrita en Nueva York el 30 de marzo de 1961.

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PROTOCOLO DE MODIFICACION DE LA CONVENCION UNICA DE 1961 SOBRE ESTUPEFACIENTES

PREAMBULO

Las Partes en el presente Protocolo, Considerando las disposiciones de la Convención Unica de 1961 sobre Estupefacientes, hecha en Nueva York el 30 de marzo de 1961 (que en lo sucesivo se denominará la Convención Unica), descosas de modificar la Convención Unica. Han convenido en lo siguiente:

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Formal Translation

DECREE NUMBER 76-75
THE CONGRESS OF THE REPUBLIC OF GUATEMALA,

CONSIDERING:

That on 25 March 1972 in Geneva, Switzerland, the protocol that amended the Single Convention on Narcotic Drugs, signed in New York on 30 March 1961, was signed and introduced reforms that allowed for more flexibility for States to combat and control the use, production, cultivation, manufacture, and distribution of drugs and narcotic drugs.

CONSIDERING:

That the content of this protocol does not contravene constitutional regulations or another other law in effect in the country;

CONSIDERING:

That the State Council, the Minister of Public Health and the Department of Legal Affairs and Treaties of the Ministry of Foreign Affairs issued a favorable opinion of the approval of the international legal document referred to above, given the benefits it represented for our country.

THEREFORE,

In exercise of the powers under Paragraph 14 of Article 170 of the Constitution of the Republic,

DECREES:

Article 1. The protocol signed in Geneva, Switzerland on 25 March 1972, which amends the Single Convention on Narcotic Drugs, signed in New York on 30 March 1961, is approved.

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PROTOCOL AMENDING THE SINGLE CONVENTION OF 1961 ON NARCOTIC DRUGS

PREAMBLE

The Parties in this Protocol, considering the provisions of the Single Convention of 1961 on Narcotic Drugs, created in New York on 30 March 1961 (herein after called the Single Convention), and that the Single Convention is permanently amended, have agreed as follows:

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(+) CRITERION A.1:
Acknowledges the intent to carry out drug control Conventions



Original Policy Language

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ARTICULO 2.Modificaciones del título del artículo 9 de la Convención Unica y de su párrafo 1, e inserción de los nuevos párrafos 4 y 5.

El título del artículo 9 de la Convención Unica quedará modificado en la siguiente forma:

"Composición y funciones de la Junta"

El párrafo 1 del artículo 9 de la Convención Unica quedará modificado en la siguiente forma:

"1. La Junta se compondrá de (TRECE) tener miembros, que el Consejo designará en la forma siguiente:

- a) Tres miembros que posean experiencia médica, farmacológica o farmacéutica, elegidos de una lista de cinco personas, por lo menos propuestas por la Organización Mundial de la Salud.
- b) Diez miembros elegidos de una lista de personas propuestas por los Estados Miembros de las Naciones Unidas y por las Partes que no sean miembros de las Naciones Unidas".

A continuación del párrafo 3 del artículo 9 de la Convención Unica se insertarán los nuevos párrafos siguientes:

"4. La Junta, en cooperación con los gobiernos y con sujeción a las disposiciones de la presente Convención, tratará de limitar el cultivo, la producción, la fabricación y el uso de estupefacientes a la cantidad adecuada necesaria para fines médicos y científicos, de asegurar su disponibilidad para tales fines y de impedir el cultivo, la producción, la fabricación, el tráfico y el uso ilícitos de estupefacientes.

5. Todas las medidas adoptadas por la Junta en virtud de la presente Convención serán las más adecuadas al propósito de fomentar la operación de los gobiernos con la Junta y de establecer un mecanismo para mantener un diálogo constante contra los gobiernos y la Junta que promueva y facilite una acción nacional efectiva para alcanzar los objetivos de la presente Convención."

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Formal Translation

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Article 2. Amendments to the Title of Article 9 of the Single Convention and to Paragraph 1 and the Insertion of New Paragraphs 4 and 5.

The title of Article 9 of the Single Convention shall be amended as follows:

"Composition and functions of the Board"

Article 9, Paragraph 1, of the Single Convention shall be amended as follows:

"1. The Board shall consist of thirteen members to be elected by the Council as follows:

- a) Three members with medical, pharmacological or pharmaceutical experience, elected from a list of at least five persons nominated by the World Health Organization
- b) Ten members elected from a list of persons nominated by the Members of the United Nations and by Parties which are not Members of the United Nations."

The following new paragraphs shall be inserted after Paragraph 3 of Article 9 of the Single Convention:

"4. The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavor to limit the cultivation, production, manufacture and use of drugs to the adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs.

5. All measures taken by the Board under this Convention shall be those most consistent with the intent to further the co-operation of governments with the Board and to provide a mechanism for a continuing dialog between governments and the Board, which will lend assistance to and facilitate effective national action to attain the aims of this Convention."

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(+) CRITERION A.3:
Acknowledges the Government's responsibility to ensure availability of narcotic drugs for medical and scientific purposes

(+) CRITERION A.5:
Represents the principle of Balance



Original Policy Language	Formal Translation
<p>LEY CONTRA LA NARCOACTIVIDAD DECRETO 48-92</p> <p>DEL CONGRESO DE LA REPUBLICA DE GUATEMALA</p> <p>23 DE SEPTIEMBRE DE 1992</p> <p>.</p> <p>.</p> <p>.</p> <p>DECRETA</p> <p>La siguiente; LEY CONTRA LA NARCOACTIVIDAD</p> <p>.</p> <p>.</p> <p>Artículo 2.- Definiciones. Para los efectos de la presente Ley, se entiende por:</p> <p>.</p> <p>.</p> <p>.</p> <p>c) Adicción: Dependencia física o psíquica entendida la primera como sujeción que obliga a la persona a consumir drogas y que al suspender su administración, provoca perturbaciones físicas y/o corporales y la segunda como el impulso que exige la administración periódica y continua de drogas para suprimir un malestar psíquico,</p> <p>.</p> <p>.</p> <p>.</p>	<p>LAW AGAINST DRUG ACTIVITY DECREE 48 -92</p> <p>THE CONGRESS OF THE REPUBLIC OF GUATEMALA,</p> <p>23 SEPTEMBER 1992</p> <p>.</p> <p>.</p> <p>.</p> <p>DECREES:</p> <p>The following; LAW AGAINST DRUG ACTIVITY</p> <p>.</p> <p>.</p> <p>.</p> <p>Article 2. Definitions for the Purposes of This Law</p> <p>.</p> <p>.</p> <p>.</p> <p>c) Addiction: Physical or psychological dependency understood firstly as a fixation that compels the person to consume drugs and that when the use of the drug is suspended, it <u>results in physical and/or corporeal disturbances</u>, and secondly as the impulse that demands periodic and continuous administration of drugs to <u>suppress physical discomfort</u>.</p> <p>.</p> <p>.</p> <p>.</p>

(-) CRITERION C.2:
Withdrawal syndrome or analgesic tolerance are confused with dependence syndrome (i.e., "addiction")



Original Policy Language

CÓDIGO DE SALUD
1997

ORGANISMO LEGISLATIVO
CONGRESO DE LA REPÚBLICA DE GUATEMALA

DECRETO Nº 90- 97

EL CONGRESO DE LA REPÚBLICA DE GUATEMALA

CONSIDERANDO:

Que La Constitución Política de la República organiza el Estado para proteger a la persona y a la familia, para alcanzar el fin supremo en la realización del bien común y le asigna, los deberes de garantizarle a los habitantes de la República, la vida, la seguridad y el desarrollo integral de la persona,

CONSIDERANDO

Que la misma Constitución Política de la República reconoce que el goce de la salud es derecho fundamental del ser humano sin discriminación alguna, y obliga al Estado a velar por la misma, desarrollando a través de sus instituciones acciones de prevención, promoción, recuperación y rehabilitación, a fin de procurarles a los habitantes el más completo bienestar físico, mental y social, reconociendo, asimismo, que la salud de los habitantes de la Nación es un bien público,

CONSIDERANDO

Que para el logro de tan loables fines se hace necesario la estructuración de políticas coherentes de Estado en materia de salud, que garanticen la participación de todos los guatemaltecos en la búsqueda de la salud, sobre la base de las estrategias de descentralización y desconcentración de los programas y servicios, en participación social, promovida en base a los principios de equidad, solidaridad y subsidiaridad,

CONSIDERANDO

Que las instituciones encargadas de velar por la salud y bienestar de los guatemaltecos y los servicios y prestaciones, requieren de una efectiva modernización y coordinación de su infraestructura, personal, políticas, programas y servicios, a efectos de lograr la universalidad en la cobertura de los servicios,

CONSIDERANDO

Que para el logro de 105 mandatos constitucionales, deben elaborarse políticas de Estado, que a largo plazo, en materia de salud, permitan la modernización y reestructuración del sector salud,

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Formal Translation

HEALTH CODE
1997

LEGISLATIVE BODY
THE CONGRESS OF THE REPUBLIC OF GUATEMALA

DECREE NO. 90-97

THE CONGRESS OF THE REPUBLIC OF GUATEMALA

WHEREAS:

The Political Constitution of the Republic organizes the State to protect individuals and the family to achieve the supreme goal of achieving the common good and assigns it the duties of ensuring life, safety and comprehensive personal development to the inhabitants of the Republic,

WHEREAS:

The Political Constitution of the Republic itself recognizes that the enjoyment of health is a basic human right without discrimination and obliges the State to ensure it by taking actions for disease prevention, and health promotion, recovery and rehabilitation through its institutions in order to bring inhabitants the most complete physical, mental and social well-being and also recognizing that the health of the nation's inhabitants is a public good,

WHEREAS:

The achievement of such praiseworthy goals makes necessary the structuring of coherent State policies on health that guarantee the participation of all Guatemalans in the search for health, based on strategies of decentralization and deconcentration of programs and services and on social participation promoted based on the principles of equity, solidarity and subsidization,

WHEREAS:

Institutions charged with ensuring the health and well-being of Guatemalans and services and benefits require an effective modernization and coordination of their infrastructure, personnel, policies, programs and services in order to achieve the universality of coverage of services,

WHEREAS:

To achieve these 105 constitutional mandates, State health policies must enable long-term modernization and restructuring of the health sector,

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Original Policy Language	Formal Translation
<p style="text-align: right;">Continued from previous page</p> <p>Por Tanto En ejercicio de las atribuciones que le confiere el Artículo 171 literal a) de la Constitución Política de Guatemala,</p> <p>DECRETA</p> <p>CODICO DE SALUD LIBRO I Disposiciones Generales</p> <p>TITULO ÚNICO . . . CAPITULO IV ORGANIZACI6N y FUNCIONES DEL MINISTERIO DE SALUD . . . ARTÍCULO 17. Funciones del Ministerio de Salud. El Ministerio de Salud tendrá las funciones siguientes:</p> <p>a) Ejercer la rectoría del desarrollo de las acciones de salud a nivel nacional; b) Formular políticas nacionales de salud; c) Coordinar las acciones en salud que ejecute cada una de sus dependencias y otras instituciones sectoriales; d) Normar, monitorear, supervisar y evaluar los programas y servicios que sus unidades ejecutoras desarrollen como entes descentralizados; e) Velar por el cumplimiento de los tratados y convenios internacionales relacionados con la salud; . . .</p>	<p style="text-align: right;">Continued from previous page</p> <p>Therefore In exercise of the powers conferred to it through Article 171 a), the Political Constitution of Guatemala</p> <p>DECREES:</p> <p>HEALTH CODE BOOK I General Provisions</p> <p>TITLE I . . . CHAPTER IV ORGANIZATION AND DUTIES OF THE MINISTRY OF HEALTH . . . Article 17. Duties of the Ministry of Health <u>Duties of the Ministry of Health will be the following:</u></p> <p>a) Give guidance on the development of national health activities; b) Formulate national health policies; c) Coordinate health activities that each of its offices and other sector institutions will carry out; d) Regulate, monitor, supervise and assess the programs and services developed by its executing units acting as decentralized entities; e) <u>Ensure compliance with international health treaties and conventions;</u> . . .</p>

(+) **CRITERION A.2:**
Designates administrative responsibility to implement the Conventions in the country



Original Policy Language

ACUERDO GUBERNATIVO NUMERO 712-99

Guatemala, 17 de septiembre de 1999.

El Presidente de la República,

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ACUERDA:

Emitir el siguiente:

REGLAMENTO PARA EL CONTROL SANITARIO DE LOS MEDICAMENTOS Y PRODUCTOS AFINES

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TITULO III

ESTUPEFACIENTES, PSICOTRÓPICOS Y PRECURSORES.

CAPITULO UNICO

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ARTICULO 61. RESPONSABILIDAD DEL PRESCRIPTOR.

Aquellas recetas que se emitan tendrán respaldo terapéutico y el prescriptor debe estar en capacidad técnica de demostrar objetivamente la razón de la prescripción. En caso de que no haya el suficiente sustento científico en cuanto al uso y dosis utilizada, el prescriptor debe responder ante EL DEPARTAMENTO, sin perjuicio de las sanciones que puedan corresponder en virtud de delito o falta.

Sin embargo, cuando se trate de cualquier prescripción de las que deben ser formuladas en el recetario oficial, previo a su despacho tendrán que ser autorizadas por EL DEPARTAMENTO. Cuando sean horas inhábiles, las farmacias están obligadas a enviar las recetas originales dentro de las veinticuatro horas siguientes a su despacho, para su autorización y registro.

ARTICULO 62. DE LA UTILIZACION Y PRESCRIPCION DE ESTUPEFACIENTES Y PSICOTROPICOS.

Sólo los profesionales universitarios médicos, odontólogos y veterinarios, debidamente colegiados y autorizados para el efecto por EL DEPARTAMENTO, podrán aplicar en sus respectivos pacientes las drogas contenidas en los instrumentos a que se hace mención el Artículo 57 de este Reglamento.

Las prescripciones de estupefacientes y psicotrópicos sólo deben hacerse con fines terapéuticos, empleándose las especialidades farmacéuticas registradas, o fórmulas oficiales y magistrales, en las concentraciones máximas que fije EL DEPARTAMENTO.

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Formal Translation

GOVERNMENT AGREEMENT NO. 712-99

Guatemala, 17 September 1999

The President of the Republic,

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AGREES:

To issue the following:

HEALTH REGULATIONS FOR THE CONTROL OF DRUGS AND RELATED PRODUCTS

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TITLE III

Narcotic Drugs, Psychotropics, and Precursors

CHAPTER I

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Article 61. The Responsibility of the Prescriber

Prescriptions that are issued are for therapeutic purposes and the prescriber must have the technical capability to objectively demonstrate the reason for the prescription. In the event that there is not sufficient scientific evidence for use and the dose used, the prescriber must answer to the DEPARTMENT, without prejudice to the penalties that may apply as a result of the crime or offense.

However, when this concerns any prescription that must be prescribed using the official prescription form book, this prescription must first be authorized by the DEPARTMENT before it is released. During non-business hours, pharmacies are obligated to send their original prescription forms for authorization and registration within twenty-four hours of their release.

Article 62. Use and Prescription of Narcotic Drugs and Psychotropics

Only qualified medical professionals, dentists and veterinarians that are members of the necessary professional bodies and are authorized to prescribe by the DEPARTMENT can administer drugs contained in the instruments noted in Article 57 of this regulation, to their patients.

Prescriptions for narcotic and psychotropic drugs may only be used for therapeutic purposes and by employing the registered pharmaceutical specialties, or the official and magistral formulas, in the maximum concentrations established by the DEPARTMENT.

Continued on next page

(-) CRITERION C.6: Provisions that are ambiguous

Category A: Arbitrary standards for legitimate prescribing

Comment: It is unclear what information is required to fulfill the standard of "objectively demonstrate" and "sufficient scientific evidence."

Criterion also identified in:
Normativa 16-2002, Art. 3.1

(-) CRITERION C.5: Practitioners are subject to undue prescribing requirements

Category D: Requirement for an additional prescribing authorization

Criterion also identified in:
Normativa 16-2002, Art. 3.2
Normativa 17-2002, Art. 6.2

(+) CRITERION B.3: Medical use of opioids is recognized as legitimate professional practice

Criterion also identified in:
Decreto No 48-92, Art. 3
Decreto No 90-97, Art.181
Normativa 22-2001, Art. 3

(-) CRITERION C.3: Restrictions that could limit medical decision-making

Category C: Restrictions regarding quantity prescribed or dispensed

Criterion also identified in:
Normativa 22-2001, Art. 3



Original Policy Language

Continued from previous page

Las recetas de productos estupefacientes que expidan los profesionales mencionados en este artículo deberá llevar la fecha de emisión, nombre y dirección del paciente, nombre, firma, número de colegiado activo y sello registrado por el profesional ante EL DEPARTAMENTO. También debe indicarse claramente el nombre de la droga prescrita, la cantidad en números y letras. No se despachará recetas de psicotrópicos y estupefacientes a menores de edad.

ARTICULO 63. DEL FORMULARIO PARA LA EXTENSION DE RECETAS DE ESTUPEFACIENTES YPSICOTROPICOS.

Se establece un formulario oficial para la receta de productos que contengan cualquiera de las substancias contempladas en la lista I de la Convención Única de 1961 sobre Estupefacientes, en el Convenio sobre Substancias Sicotrópicas de 1971 y en la Convención de las Naciones Unidas contra el Tráfico Ilícito de Estupefacientes y Sustancias Sicotrópicas.

Estos recetarios serán proporcionados a los médicos por EL DEPARTAMENTO, a precio de costo; tendrán un formato especial y contendrán los datos que sean necesarios para dicha dependencia.

Las farmacias despacharán recetas que estén formuladas en el recetario oficial y autorizadas por EL DEPARTAMENTO. En caso contrario, el despacho de tales medicamentos en cosiderado como suministro ilegal de estupefacientes y sancionado como tal.

En caso de extravío o sustracción de un recetario, el médico está obligado a reportarlo inmediatamente a EL DEPARTAMENTO para que esta oficina lo haga del conocimiento de todos los directores técnicos de farmacias a fin de evitar su uso fraudulento.

ARTICULO 64. DE LAS CUOTAS AUTORIZADAS PARA DESPACHO.

EL DEPARTAMENTO debe formular la nómina de los productos estupefacientes y psicotrópicos, con la dosis permitida para veinticuatro (24) horas.

Sin embargo, es permitido que los profesionales en ejercicio legal, puedan prescribir y las farmacias despachar dosis mayores, siempre que su aplicación sea controlada directamente por el facultativo y autorizada por EL DEPARTAMENTO, siendo el médico tratante el responsable por el mal uso de su prescripción se hiciere.

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Formal Translation

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Prescriptions for narcotic products issued by the professionals referred to in this Article must note the date of issue, the name and address of the patient, and the name, signature, active professional registration number and professional seal of the professional as recorded by the DEPARTMENT. The name of the drug prescribed and the quantity should be clearly indicated in numbers and in writing. Narcotic and psychotropic drugs can not be prescribed to minors.

Article 63. Form for Extending the Prescription of Narcotic and Psychotropic Drugs

There is an official form for the prescription of products that contain any of the substances included in Schedule I of the Single Convention on Narcotic Drugs of 1961, in the Convention on Psychotropic Substances of 1971 and in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

These official prescription forms shall be distributed to doctors by the DEPARTMENT at cost; they shall have a special format and will contain the information necessary for that organization.

Pharmacies shall fill prescriptions that are prescribed in the official prescription book and authorized by the DEPARTMENT. Otherwise, the release of these drugs will be regarded as illegally supplying narcotic drugs and will be penalized as such.

In case of loss or theft of a prescription form book, the doctor is required to immediately report this to the DEPARTMENT so that it can notify all technical directors of pharmacies in order to prevent misuse.

Article 64. Amounts Authorized for Release

The DEPARTMENT must compile a list of narcotic and psychotropic products along with the permitted doses for twenty-four (24) hours.

However, legally practicing professionals are allowed to prescribe, and pharmacies may release, higher doses, provided that their administration is directly controlled by the physician and authorized by the DEPARTMENT, it being understood that the treating physician is responsible for misuse of the prescription should it occur.

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(-) CRITERION C.3:
Restrictions that could limit medical decision-making

Category C: Restrictions based on patient characteristics

Criterion also identified in:
Normativa 22-2001, Art. 4

(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category A: Requirement to use special prescription form

Criterion also identified in:
Normativa 22-2001, Art. 5
Normativa 16-2002, Art. 3.2 & 4
Normativa 17-2002, Art. 4

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category A: Issues related to healthcare professionals

Comment: Creates an exemption to the requirement above in Artículo 64.

(-) CRITERION C.7:
Other provisions that may impede pain management

Category A: Issues related to healthcare professionals

Comment: Although it is reasonable to expect physicians to avoid contributing to diversion, this provision creates a daunting standard. Physicians are responsible for a patient's misuse of a prescription, for which physicians have little or no control.



Original Policy Language

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Es obligación del facultativo, además, cuando tenga que administrar estupefacientes por períodos mayores de ocho días, informar a EL DEPARTAMENTO el diagnóstico y la dosis a usar diariamente y solicitar la cuota correspondiente, semanal o quincenal, según el caso, la que será sometida a consideración de la dependencia mencionada, la que en consulta puede autorizarla o denegarla.

Cuando se trate de personas que se hayan habituado al uso de estupefacientes, los médicos tratantes deberán informarlo a EL DEPARTAMENTO y se procederá en la forma indicada en el párrafo anterior.

Las recetas para los toxicómanos deben ser extendidas en el formulario oficial por un médico del Centro de salud respectivo, debiendo especificarse el número y fecha del acuerdo por el que la dependencia designada autorizó la cuota. Estas recetas se entregarán personalmente al interesado semanal, quincenal o mensualmente, según el caso, y serán firmadas y selladas por el jefe de dicha dependencia.

Los médicos están obligados a informar a EL DEPARTAMENTO cuando dejen de asistir a estos pacientes, o de su fallecimiento, en su caso, dentro de los treinta (30) días siguientes, con el fin de proceder a la cancelación de la cuota que tuvieran autorizada.

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Formal Translation

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In addition, when the period for administering narcotic drugs exceeds eight days, the physician must inform the DEPARTMENT of the diagnosis and the daily doses to be employed and request the appropriate amount, weekly or monthly, according to the case, which will be assessed by the pertinent organization, which will either approve or deny this request.

In the case of persons who have become habituated to the use of narcotic drugs, treating physicians must note this to the DEPARTMENT and proceed in the manner indicated in the paragraph above.

Prescriptions for drug-dependent persons must be submitted on the official form by a doctor at the respective health center, and must specify the number and date of the agreement for the amount as authorized by the given organization. These prescription forms will be personally delivered to the interested party either weekly or monthly, according to the case, and will be signed and will bear the seal of the head of the given organization.

Doctors must inform the DEPARTMENT when they stop treating these patients, or if the patient dies, within thirty (30) days, so that the amount authorized for them may be canceled.

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(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category D: Requirement for an additional prescribing authorization

Criterion also identified in:
Normativa 16-2002, Art. 3.3

(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category B: Requirement to report certain patients

Criterion also identified in:
Normativa 16-2002, Art. 3.4 & 3.6



Original Policy Language

NORMATIVA 16-2002
Guatemala 15 de Mayo del 2002

BASE LEGAL.

LA JEFATURA DEL DEPARTAMENTO DE REGULACION Y CONTROL DE PRODUCTOS FARMACEUTICOS Y AFINES

CONSIDERANDO QUE:

El Reglamento para el Control Sanitario de los Productos Farmacéuticos y Afines en su artículo 4 confiere a este Departamento la potestad de emitir los normativos y formularios necesarios para la puesta en práctica de los diferentes procesos y procedimientos que se detallan en el presente reglamento,

CONSIDERANDO QUE:

En el Reglamento Orgánico del Ministerio, Acuerdo Gubernativo No. 115-99 artículo 35 le asigna funciones para diseñar, emitir, actualizar y reajustar periódicamente las normas técnicas para el control y seguridad de productos farmacéuticos y Afines.

BASADA EN LOS SIGUIENTES ARTICULOS:

Artículo 96 de la Constitución Política de la República de Guatemala, artículos 178, 179 y 181 del Código de Salud, artículos 57, 60, 61, 62, 63, 64 Y 67 del Reglamento para el Control Sanitario de los Medicamentos y Productos Afines.

ACUERDA EMITIR LA PRESENTE NORMATIVA
ADQUISICION DEL TALONARIO PARA EXTENSION DE RECETAS DE ESTUPEFACIENTES

2. OBJETIVO

- 2.1 Establecer un procedimiento para la adquisición de talonarios para extension recetas de estupefacientes
- 2.2 Contar con un registro de profesionales autorizados para emitir recetas de estupefacientes.

3. RESPONSABILIDAD DEL PRESCRIPTOR

Los Profesionales universitarios, médicos, odontólogos, veterinarios, debidamente colegiados, y registrados en este Departamento, son los responsables del manejo y uso de los recetarios y quedan obligados a:

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Formal Translation

REGULATION 16-2002
Guatemala 15 May 2002

LEGAL BASIS

THE HEAD OFFICE OF THE DEPARTMENT OF REGULATION AND CONTROL OF PHARMACEUTICAL PRODUCTS AND RELATED PRODUCTS

WHEREAS:

The Regulation for Health Control of Pharmaceutical Products and Other Products in Article 4 confers to this Department the authority to issue the policies and forms necessary to implement various processes and procedures that are outlined in this regulation.

WHEREAS:

The Organic Regulation of the Ministry, Government Agreement No. 115-99, Article 35, assigns duties that concern designing, issuing, updating, and periodically amending the technical standards for the safety and control of pharmaceutical products and related products.

BASED ON THE FOLLOWING ARTICLES:

Article 96 of the Political Constitution of the Republic of Guatemala; Articles 178, 179 and 181 of the Health Code; Articles 57, 60, 61, 62, 63, 64 and 67 of the Regulation for Health Inspection of Drugs and Related Products.

AGREES TO ISSUE THIS REGULATION
ACQUIRING A PRESCRIPTION PAD FOR ISSUING
PRESCRIPTION FORMS FOR NARCOTIC DRUGS

2. PURPOSE

- 2.1 To establish a procedure for acquiring prescription pads for issuing prescription forms for narcotic drugs
- 2.2 To have a **register of professionals** authorized to issue prescription forms for narcotic drugs.

3. THE RESPONSIBILITY OF THE PRESCRIBER

Qualified medical professionals, dentists and veterinarians that are members of the necessary professional bodies and registered with the Department are responsible for the management and use of prescription forms and are required to do the following:

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(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category C: Requirement of a separate license/ registration



Original Policy Language

Continued from previous page

3.1 Las recetas que se emitan deben tener respaldo terapéutico y el prescriptor debe estar en capacidad técnica de demostrar objetivamente la razón de la prescripción. En caso que no haya suficiente sustento científico en cuanto al uso y dosis utilizada, el prescriptor debe responder ante El Departamento, sin perjuicio de las sanciones que puedan corresponder en virtud de delito o falta.

3.2 Prescribir estupefacientes en la receta estipulada y enviarlas a El Departamento para su autorización, previo despacho de la misma en el establecimiento farmacéutico.

3.3 Cuando tenga que administrar estupefacientes por períodos mayores de ocho días, informar a El Departamento el diagnóstico y la dosis a usar diariamente y solicitar la cuota correspondiente, semanal o quincenal, según el caso, utilizando para ello el Formulario As-g-009, proporcionado en el Departamento.

3.4 Cuando se trate de personas que se hayan habituado al uso de estupefacientes el médico tratante deberá informarlo a El Departamento y se procederá en la forma indicada en el párrafo anterior.

3.5 Cuando desee cambiar la cuota solicitada, informarlo de forma escrita a este Departamento.

3.6 Informar a El Departamento cuando dejen de asistir a estos pacientes, o de su fallecimiento, en su caso, dentro de los treinta (30) días siguientes, con el fin de proceder a la cancelación de la cuota que tuvieron autorizada.

4. ANTECEDENTES

Se estableció un talonario oficial para las recetas de productos que tengan cualquiera de las sustancias contempladas en la lista I de la Convención Única de 1961 sobre Estupefacientes. Dichas sustancias son las siguientes:

- 4.1 Buprenorfina
- 4.2 Morfina Clorhidrato
- 4.3 Morfina Sulfato
- 4.4 Petidina
- 4.5 Otros incluidos en el listado I

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Formal Translation

Continued from previous page

3.1 Prescriptions that are issued are for therapeutic purposes and the prescriber must have the technical capability to objectively demonstrate the reason for the prescription. In the event that there is not sufficient scientific evidence for use and the dose used, the prescriber must answer to the Department, without prejudice to the penalties that may apply as a result of the crime or offense.

3.2 Prescribe narcotic drugs using the designated prescription form and sending it to the Department for authorization before releasing the drug through the pharmaceutical establishment.

3.3 When the period for administering narcotic drugs exceeds eight days, the physician must inform the Department of the diagnosis and the daily doses to be employed and request the appropriate amount, weekly or monthly, according to the case, using Form As-g-009, issued by the Department.

3.4 In the case of persons who have become habituated to the use of narcotic drugs, treating physicians must report this to the Department and proceed in the manner indicated in the paragraph above.

3.5 If the requested amount needs to be adjusted, a request in writing must be sent to the Department.

3.6 Inform the Department when they stop treating these patients, or if the patient dies, within thirty (30) days, so that the amount authorized for them may be canceled.

4. BACKGROUND

An official form was established for the prescription of products that contain any of the substances included in Schedule I of the Single Convention on Narcotic Drugs of 1961. These substances are the following:

- 4.1 Buprenorphine
- 4.2 Morphine Hydrochloride
- 4.3 Morphine sulfate
- 4.4 Pethidine
- 4.5 Others included in Schedule I

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(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category D: Requirement of an additional prescribing authorization



Original Policy Language

Continued from previous page

5. Lugar de Adquisición.
Estos talonarios serán proporcionados a los médicos en el Departamento de Regulación y Control de Productos Farmacéuticos y Afines 11 Av. A 11-56 zona 7, previa cancelación del costo del mismo en ventanilla del Banco de Guatemala y cumplimiento de los requisitos estipulados para el efecto.

6. Requisitos.

6.1 Llenar el formato de solicitud As-g-008, proporcionado por El Departamento, en el que se compromete a enviar el codo del recetario correspondiente, antes de solicitar uno nuevo.

6.2 Adjuntar una hoja en blanco con la impresión de su sello profesional y su firma

6.3 Colegiado activo.

6.4 Presentación de copia de boleta de pago de su costo en Banco de Guatemala

7. Procedimiento de pago en Banco de Guatemala

7.1 El pago del talonario se realiza llenando una boleta de depósito monetario proporcionada en el Banco de Guatemala

7.2 Se abona a la cuenta No 111798-5

7.3 A nombre de Gobierno de la República de Guatemala, Fondos Privativos de Salud Pública, Departamento de Regulación y Control de Productos Farmacéuticos y Afines

7.4 Referencia: pago de talonario de recetas para Estupeficientes.

7.5 Después de efectuado el pago, la copia de la boleta se adjunta a la solicitud de compra de talonario.

8. Vigencia

Inmediata a su emisión

Formal Translation

Continued from previous page

5. PLACE OF PURCHASE

These prescription pads will be distributed to doctors in the Department of Regulation and Control of Pharmaceutical Products and Related Products 11 Av. A 11-56 zona 7, following payment for the cost of these at the teller window at the Bank of Guatemala and fulfilling the requirements stipulated for this purpose.

6. REQUIREMENTS

6.1 Fill out request form As-g-008, distributed by the Department, upon which it is agreed to send the corresponding prescription form book before requesting a new one.

6.2 Attach a blank sheet with the professional stamp on it and a signature.

6.3 Active professional membership.

6.4 Submit the payslip copy of the cost to the Bank of Guatemala.

7. PAYMENT PROCEDURE AT THE BANK OF GUATEMALA

7.1 Payment for the prescription form book is carried out by filling out the deposit slip provided at the Bank of Guatemala.

7.2 Make payment to account No. 111798-5.

7.3 Made out to the Government of Republic of Guatemala, Restricted Public Health Funds, Department of Regulation and Control of Pharmaceutical Products and Related Products.

7.4 Reference: Payment for narcotic drug prescription form pad

7.5 After payment, a copy of the slip is attached to the request for purchasing the prescription form book.

8. VALIDITY

Immediately upon issuance.

(-) CRITERION C.7:
Other provisions that may impede pain management

Category C: Other regulatory or policy issues

Comment: The procedures for purchasing and obtaining required prescription forms are limited and very specific. In addition, the addresses provided for the Department of Regulation and the Bank of Guatemala are outdated.



Original Policy Language

NORMATIVA 17-2002
Guatemala 16 de Mayo del 2002

BASE LEGAL.

LA JEFATURA DEL DEPARTAMENTO DE REGULACION Y CONTROL DE PRODUCTOS FARMACEUTICOS Y AFINES

CONSIDERANDO QUE:

El Reglamento para el Control Sanitario de los Productos Farmacéuticos y Afines en su artículo 4 confiere a este Departamento la potestad de emitir los normativos y formularios necesarios para la puesta en práctica de los diferentes procesos y procedimientos que se detallan en el presente reglamento,

CONSIDERANDO QUE:

En el Reglamento Orgánico del Ministerio, Acuerdo Gubernativo No. 115-99 artículo 35 le asigna funciones para diseñar, emitir, actualizar y reajustar periódicamente las normas técnicas para el control y seguridad de productos farmacéuticos y Afines.

BASADA EN LOS SIGUIENTES ARTICULOS:

Artículo 96 de la Constitución Política de la República de Guatemala, artículos 178, 179 y 181 del Código de Salud, artículos 57, 60, 61, 62, 63, 64 Y 67 del Reglamento para el Control Sanitario de los Medicamentos y Productos Afines.

ACUERDA EMITIR LA PRESENTE NORMATIVA: AUTORIZACIÓN DE RECETAS DE ESTUPEFACIENTES

2. DEFINICIÓN DE ESTUPEFACIENTE

Se entiende cualquiera de las sustancias de las listas I y II naturales o sintéticas de la convención única de 1961 sobre estupefacientes.

3. JUSTIFICACIÓN

Contar con una normativa que de los lineamientos sobre el procedimiento a seguir para la autorización de recetas de estupefacientes.

4. DE LAS RECETAS

La prescripción de estos productos debe hacerse únicamente en las recetas del talonario proporcionado por El Departamento. Se autorizarán las recetas hasta treinta días después de su emisión.

Continued on next page

Formal Translation

REGULATION 17-2002
Guatemala 16 May 2002

LEGAL BASIS

THE HEAD OFFICE OF THE DEPARTMENT OF REGULATION AND CONTROL OF PHARMACEUTICAL PRODUCTS AND RELATED PRODUCTS

WHEREAS:

The Regulation for Health Control of Pharmaceutical Products and Other Products in Article 4 confers to this Department the authority to issue the policies and forms necessary to implement various processes and procedures that are outlined in this regulation.

WHEREAS:

The Organic Regulation of the Ministry, Government Agreement No. 115-99, Article 35, assigns duties that concern designing, issuing, updating, and periodically amending the technical standards for the safety and control of pharmaceutical products and related products.

BASED ON THE FOLLOWING ARTICLES:

Article 96 of the Political Constitution of the Republic of Guatemala; Articles 178, 179, and 181 of the Health Code; Articles 57, 60, 61, 62, 63, 64 and 67 of the Regulation for Health Inspection of Drugs and Related Products.

AGREES TO ISSUE THIS REGULATION: AUTHORIZATION OF NARCOTIC DRUG PRESCRIPTION FORMS

2. DEFINITION OF NARCOTIC DRUG

This means any of the natural or synthetic substances in Schedule I and II of the Single Convention on Narcotic Drugs of 1961.

3. PURPOSE

To have a regulation with guidelines on the procedure to be followed for authorization of prescriptions for narcotic drugs.

4. PRESCRIPTION FORMS

Prescription of these products must only be performed using the prescription forms in the prescription pads distributed by the Department. Prescription forms must be authorized within thirty days of their issuance.

Continued on next page



Original Policy Language

Continued from previous page

Las recetas, para que sean autorizadas, deben consignar la siguiente información:

- 4.1 Fecha de emisión
- 4.2 Nombre y dirección del paciente
- 4.3 Nombre del medicamento prescrito
- 4.4 Presentación y concentración
- 4.5 Indicaciones de uso
- 4.6 Cantidad prescrita en letras y números
- 4.7 A excepción de la primera receta, se debe consignar el número de dictamen, otorgado en este Departamento.
- 4.8 Firma y sello del profesional

5. PROCEDIMIENTO

- 5.1 El interesado ingresa la receta que le fuera prescrita por el medico acompañada del formato F-As-g-009 cuando los tratamientos sean por períodos mayor de ocho días o presentaran solamente la receta cuando el tratamiento sea para período menor de ocho días.
 - 5.2 Cuando la receta ingresa acompañada del formato F-As-g-009, (anexo 1) se procede de la siguiente forma:
 - 5.2.1 Se registran los datos de la receta en el libro correspondiente, se le asigna un número de autorización y se coloca la fecha.
 - 5.2.2 Se le entrega al paciente un carnet que tiene registrado el número de dictamen que le fuera asignado, el cual debe hacerlo del conocimiento del médico tratante para que lo consigne en las próximas recetas.
 - 5.2.3 El personal responsable sella de autorizada la receta, le coloca el número de autorización.
 - 5.2.4 La receta pasa a firma de profesional designado
 - 5.2.5 Es entregada de vuelta, al usuario en ventanilla.
 - 5.3 Cuando solamente se ingresa la receta:
 - 5.3.1 El personal responsable, registra datos en libro correspondiente, la sella
 - 5.3.2 Pasa a profesional designado para que la firma
 - 5.3.3 Es entregada de vuelta, al usuario en ventanilla
6. ESTABLECIMIENTOS DE DISPENSACION DE ESTUPEFACIENTES
- 6.1 Los establecimientos que comercializan con estupefacientes: farmacias, droguerías y laboratorios despacharán los mismos solamente cuando las recetas estén formuladas en el recetario oficial y autorizadas por El Departamento. En caso contrario es despacho de tales medicamentos es considerado como suministro ilegal de estupefacientes y sancionado como tal.

Continued on next page

Formal Translation

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Prescription forms must include the following information in order to be authorized.

- 4.1 The date of issue
- 4.2 The patient's name and address
- 4.3 Name of the prescribed drug
- 4.4 Packaging and concentration
- 4.5 Indications for use
- 4.6 Quantity prescribed; in numbers and in writing
- 4.7 With the exception of the first prescription form, the authorization number assigned & issued in the Department.
- 4.8. Medical professional's signature and seal

5. PROCEDURE

- 5.1 The interested party enters the prescription form that was prescribed by the doctor, accompanied by Form F-As-g-009 when treatment is to exceed a period of eight days, or submits only the prescription when the treatment is less than eight days.
 - 5.2 When prescription form is submitted along with Form F-As-g-009 (Annex 1), proceed as follows:
 - 5.2.1 Record the information on the prescription form in the corresponding book, assign it an authorization number and enter the date.
 - 5.2.2. Give the patient a card that bears the authorization number assigned to it, which will indicate to the treating physician that this number is to be used for subsequent prescription forms.
 - 5.2.3. The personnel member responsible for such authorizes the prescription form with their seal and assigns it the authorization number.
 - 5.2.4 The prescription form is then signed by the appropriate professional.
 - 5.2.5 The prescription form is returned to the customer at the window.
 - 5.3. When the prescription form alone is entered:
 - 5.3.1 The personnel member in charge records the information in the corresponding book and then places their seal on it.
 - 5.3.2 The prescription form is signed by the appropriate professional.
 - 5.3.3 The prescription form is returned to the customer at the window.
6. AUTHORIZATION OF NARCOTIC DRUG PRESCRIPTION FORMS
- 6.1 Establishments that sell narcotic drugs, such as pharmacies, drugstores and laboratories, shall release these drugs only when the prescriptions forms are from the official prescription form book and authorized by the Department. Otherwise, the release of these drugs will be regarded as illegally supplying narcotic drugs and will be penalized as such.

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(-) CRITERION C.7: Other provisions that may impede pain management

Category B: Issues related to patients

Comment: Requiring a patient to be issued an NCA authorization number for being prescribed opioid analgesics for more than 8 days has the potential to stigmatize patients who medically require such medications for prolonged treatment periods.



Original Policy Language

Continued from previous page

6.2 Cuando se trata de horas inhábiles, las farmacias, ubicadas en la ciudad capital, están obligadas a enviar las recetas originales dentro de las veinticuatro horas siguientes a su despacho, para su autorización y registro.

6.3 Para las farmacias ubicadas en los Departamentos y que deseen prestar el servicio de despacho de estupefacientes, deben comprometerse a enviar cada fin de mes, junto con su reporte de movimiento de sustancias sicotrópicas, las recetas de estupefacientes que despachó durante el mes para su autorización y registro en este Departamento.

7. VIGENCIA
Inmediata a su emisión

Formal Translation

Continued from previous page

6.2 Pharmacies located in the capital city are required to send, during non-business hours, their original prescription forms for their authorization and registration within twenty-four hours of their release.

6.3 For pharmacies located in the Departments that wish to provide narcotic drug dispensing services, they must commit to sending the receipts for narcotic drugs dispensed during the month, along with its report on the movement of psychotropic substances, at the end of each month for authorization and registration by the Department.

7. VALIDITY
Immediately upon issuance.

Mexico



Population:
116,100,000

Mortality rates/100,000:
HIV/AIDS: 4.7
CANCER: 66.2

Human Development Index:
1980: 0.598
2010: 0.775

WHO Region:
AMRO

UN Region:
Americas

UN sub-region:
Central America

Relevant language found in the following policies:

LEY GENERAL DE SALUD

Diario Oficial de la Federación 7 de febrero de 1984

Última reforma publicada DOF 24-04-2013

Al margen un sello con el Escudo Nacional que dice: Estados Unidos Mexicanos.- Presidencia de la República

REGLAMENTO 1-18-88

REGLAMENTO DE LA LEY GENERAL DE SALUD EN MATERIA DE CONTROL SANITARIO DE ACTIVIDADES, ESTABLECIMIENTOS, PRODUCTOS Y SERVICIOS

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República

REGLAMENTO DE INSUMOS PARA LA SALUD

Publicado en el Diario Oficial de la Federación el 04 de febrero de 1998

Última reforma publicada DOF 09 de octubre de 2012

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República

NORMA Oficial Mexicana NOM-028-SSA2-2009

Para la prevención, tratamiento y control de las adicciones

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Secretaría de Salud

NORMA Oficial Mexicana NOM-072-SSA1-2012

Etiquetado de medicamentos y de remedios herbolarios

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Secretaría de Salud

DOF: 01/11/2013

DECRETO por el que se reforman y adicionan diversas disposiciones del Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República



Original Policy Language

LEY GENERAL DE SALUD

Diario Oficial de la Federación 7 de febrero de 1984
Última reforma publicada DOF 24-04-2013

Al margen un sello con el Escudo Nacional que dice: Estados Unidos Mexicanos.- Presidencia de la República.

MIGUEL DE LA MADRID HURTADO, Presidente Constitucional de los Estados Unidos Mexicanos, a sus habitantes, sabed:

Que el H. Congreso de la Unión se ha servido dirigirme el siguiente:

D E C R E T O

"El Congreso de los Estados Unidos Mexicanos, decreta:

LEY GENERAL DE SALUD

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TITULO TERCERO

Prestación de los Servicios de Salud

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CAPITULO I

Disposiciones Comunes

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Artículo 29.- Del Cuadro Básico de Insumos del Sector Salud, la Secretaría de Salud determinará la lista de medicamentos y otros insumos esenciales para la salud, y garantizará su existencia permanente y disponibilidad a la población que los requiera, en coordinación con las autoridades competentes.

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CAPITULO II

Atención Médica

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Artículo 33.- Las actividades de atención médica son:

I. Preventivas, que incluyen las de promoción general y las de protección específica;

II. Curativas, que tienen como fin efectuar un diagnóstico temprano y proporcionar tratamiento oportuno;

III. De rehabilitación, que incluyen acciones tendientes a corregir las invalideces físicas o mentales, y

IV. Paliativas, que incluyen el cuidado integral para preservar la calidad de vida del paciente, a través de la prevención, tratamiento y control del dolor, y otros síntomas físicos y emocionales por parte de un equipo profesional multidisciplinario.

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Formal Translation

GENERAL HEALTH LAW

Official Gazette of the Federation 7 February 1984
Last amended version published DOF-24-04-2013

In the margin there is a seal with the national emblem that says: United States of Mexico — Presidency of the Republic

MIGUEL DE LA MADRID HURTADO, Constitutional President of the United States of Mexico, let it be known to its residents:

That the Honorable Congress of the Union has submitted the following:

DECREE

"The Congress of the United Mexican States, decrees:

GENERAL HEALTH LAW

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TITLE III

Provision of Health Services

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CHAPTER I

Common Provisions

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Article 29. From the Basic Medical Supplies for the Health Sector, the Secretary of Health determines the list of drugs and other supplies essential for health and ensures their continuous supply and availability to the population that requires them, in cooperation with competent authorities.

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CHAPTER II

Medical Care

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Article 33. Medical care activities are:

I. Preventative care activities, including the general promotion of these activities and specific protection for these activities.

II. Curative care activities that are used to make early diagnoses and provide timely treatment;

III. Rehabilitation, which includes actions aimed to correct physical or mental disabilities.

IV. Palliative care activities, which include comprehensive care to preserve the patient's quality of life through prevention, pain treatment and control, and other physical and emotional symptoms, carried out by a multidisciplinary team.

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(+) CRITERION A.3:
Acknowledges the Government's responsibility to ensure availability of narcotic drugs for medical and scientific reasons

(+) CRITERION B.2:
Pain management is recognized as part of general healthcare practice

Criterion also identified in:
DOF-01-11-2013, Art. 7 & 8



Original Policy Language	Formal Translation
<p style="text-align: right;">Continued from previous page</p> <p>TITULO SEPTIMO Promoción de la Salud . . . CAPITULO II Educación para la Salud</p> <p>Artículo 112.- La educación para la salud tiene por objeto: I. Fomentar en la población el desarrollo de actitudes y conductas que le permitan participar en la prevención de enfermedades individuales, colectivas y accidentes, y protegerse de los riesgos que pongan en peligro su salud; II. Proporcionar a la población los conocimientos sobre las causas de las enfermedades y de los daños provocados por los efectos nocivos del ambiente en la salud, y III. Orientar y capacitar a la población preferentemente en materia de nutrición, salud mental, salud bucal, educación sexual, planificación familiar, cuidados paliativos, riesgos de automedicación, prevención de farmacodependencia, salud ocupacional, salud visual, salud auditiva, uso adecuado de los servicios de salud, prevención de accidentes, prevención y rehabilitación de la invalidez y detección oportuna de enfermedades. . . . TITULO OCTAVO Prevención y Control de Enfermedades y Accidentes . . . TITULO OCTAVO BIS De los Cuidados Paliativos a los Enfermos en Situación Terminal . . . Continued on next page</p>	<p style="text-align: right;">Continued from previous page</p> <p>TITLE VII Health Promotion . . . CHAPTER II Health Education</p> <p>Article 112. Health education aims to: I. Encourage the population to develop attitudes and behaviors that enable them to participate in the prevention of individual and collective disease, accidents, and protect themselves from risks that threaten their health. II. Provide the population with knowledge on the causes of diseases and the consequences that result from the harmful effects of the environment on health. III. <u>To orient and train the population</u> preferably to nutrition, mental health, oral health, sexual education, family planning, <u>palliative care</u>, risks associated with self-medicating, prevention of drug-dependency, occupational health, visual health, appropriate use of health services, accident prevention, prevention and rehabilitation of disabilities and timely detection of disease. . . . TITULO VIII Prevention and Control of Diseases and Accidents . . . TITULO VIII BIS Palliative Care for Terminally Ill Patients . . . Continued on next page</p>

(+) CRITERION B.4:
Pain Management is encouraged

Category C: Promotes patient or public awareness

Comment: Although this provision relates specifically to palliative care, pain management is part of palliative care



Original Policy Language

Continued on next page

CAPÍTULO I Disposiciones Comunes

Artículo 166 Bis. El presente título tiene por objeto:

- I. Salvaguardar la dignidad de los enfermos en situación terminal, para garantizar una vida de calidad a través de los cuidados y atenciones médicas, necesarios para ello;
- II. Garantizar una muerte natural en condiciones dignas a los enfermos en situación terminal;
- III. Establecer y garantizar los derechos del enfermo en situación terminal en relación con su tratamiento;
- IV. Dar a conocer los límites entre el tratamiento curativo y el paliativo;
- V. Determinar los medios ordinarios y extraordinarios en los tratamientos; y
- VI. Establecer los límites entre la defensa de la vida del enfermo en situación terminal y la obstinación terapéutica.

Artículo 166 Bis 1. Para los efectos de este Título, se entenderá por:

- I. Enfermedad en estado terminal. A todo padecimiento reconocido, irreversible, progresivo e incurable que se encuentra en estado avanzado y cuyo pronóstico de vida para el paciente sea menor a 6 meses;
- II. Cuidados básicos. La higiene, alimentación e hidratación, y en su caso el manejo de la vía aérea permeable;
- III. Cuidados Paliativos. Es el cuidado activo y total de aquellas enfermedades que no responden a tratamiento curativo. El control del dolor, y de otros síntomas, así como la atención de aspectos psicológicos, sociales y espirituales;

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CAPÍTULO II De los Derechos de los Enfermos en Situación Terminal

Artículo 166 Bis 3. Los pacientes enfermos en situación terminal tienen los siguientes derechos:

- I. Recibir atención médica integral;
- II. Ingresar a las instituciones de salud cuando requiera atención médica;
- III. Dejar voluntariamente la institución de salud en que esté hospitalizado, de conformidad a las disposiciones aplicables;
- IV. Recibir un trato digno, respetuoso y profesional procurando preservar su calidad de vida;
- V. Recibir información clara, oportuna y suficiente sobre las condiciones y efectos de su enfermedad y los tipos de tratamientos por los cuales puede optar según la enfermedad que padezca;
- VI. Dar su consentimiento informado por escrito para la aplicación o no de tratamientos, medicamentos y cuidados paliativos adecuados a su enfermedad, necesidades y calidad de vida;
- VII. Solicitar al médico que le administre medicamentos que mitiguen el dolor;

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Formal Translation

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CHAPTER I Common Provisions

Article 166 Bis. This title aims to:

- I. Safeguard the dignity of terminally ill patients in order to ensure quality of life through the medical care and attention necessary for that purpose;
- II. Ensure a natural death with dignity for terminally ill patients;
- III. Establish and ensure the rights of the terminally ill with regard to their treatment;
- IV. Introduce the boundaries between curative and palliative care;
- V. Determine ordinary and extraordinary measures in treatments; and
- VI. Establish the limits between supporting the life of a terminally ill patient and therapeutic obstinacy.

Article 166 Bis. 1. For the purposes of the this title, the following shall apply:

- I. Illness in Terminal State. The ailment is completely recognized, irreversible, progressive and incurable as it is discovered in an advanced state and for which the prognosis of life expectancy for the patient is less than 6 months;
- II. Basic Care. Hygiene, food and hydration, and if necessary, keeping the airway open;
- III. Palliative Care. Active and total care of illnesses that do not respond to curative treatment. Pain control and control of other symptoms, such as attention to the psychological, social and spiritual aspects;

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CHAPTER II The Rights of Terminally Ill Patients

Article 166 Bis. 3. Terminally ill persons have the following rights:

- I. To receive comprehensive medical attention;
- II. To check into health institutions when they require medical attention;
- III. To voluntarily leave the health institution in which they are hospitalized, in accordance with applicable provisions;
- IV. To receive humane, respectful, and professional treatment while seeking to preserve their quality of life;
- V. To receive clear, timely, and sufficient information on the conditions and effects of their disease and the types of treatments available according to the type of disease involved;
- VI. To provide informed consent in writing for the application or non-application of treatments, drugs and palliative care appropriate to their disease, needs and quality of life;
- VII. To ask the doctor to administer medicine to relieve the pain;

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(+) CRITERION B.4:
Pain management is encouraged

Category A: Ensures treatment of certain patient populations

(+) CRITERION B.1:
Patients have a right to pain management



Original Policy Language

Continued from previous page

CAPÍTULO IV

De los Derechos, Facultades y Obligaciones de los Médicos y Personal Sanitario

Artículo 166 Bis 14. Los médicos tratantes y el equipo sanitario que preste los cuidados paliativos, para el mejor desempeño de sus servicios, deberán estar debidamente capacitados humana y técnicamente, por instituciones autorizadas para ello.

Artículo 166 Bis 16. Los médicos tratantes podrán suministrar fármacos paliativos a un enfermo en situación terminal, aún cuando con ello se pierda estado de alerta o se acorte la vida del paciente, siempre y cuando se suministren dichos fármacos paliativos con el objeto de aliviar el dolor del paciente.

Podrán hacer uso, de ser necesario de acuerdo con lo estipulado en la presente Ley de analgésicos del grupo de los opioides. En estos casos será necesario el consentimiento del enfermo.

CAPITULO IV

Programa Contra la Farmacodependencia

Artículo 192a.- Para los efectos del programa nacional se entiende por:

I. Farmacodependiente: Toda persona que presenta algún signo o síntoma de dependencia a estupefacientes o psicotrópicos;

TITULO DECIMO SEGUNDO

Control Sanitario de Productos y Servicios de su Importación y Exportación

Continued on next page

Formal Translation

Continued on next page

CHAPTER IV

Rights, Powers and Duties of Doctors and Health Care Personnel

Article 166 Bis. 14. Treating physicians and the health care team that provides palliative care for the best performance of their services, should be properly trained technically and personally by the institutions authorized to do so.

Article 166 Bis. 16. The treating physician may provide palliative drugs to a terminally ill patient, even if they cause the patient to lose alertness or shorten the patient's life, as long as these palliative drugs are provided to relieve the patient's pain.

Opioid analgesics may be used if necessary, and in accordance with what is stipulated in this law. In these cases, the patient's consent is necessary.

CHAPTER IV

Program Against Drug Dependency

Article 192 Bis. The following should be understood for the purposes of the national program:

I. Drug-dependent person: Any person that presents any sign or symptom of dependence on narcotic or psychotropic drugs;

TITLE XII

Sanitary Control of Products and Services and their Importation and Exportation

Continued on next page

(+) CRITERION B.4:
Pain management is encouraged

Category B: Promotes training of healthcare professionals

Comment: Although this provision relates specifically to palliative care, pain management is part of palliative care.

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category A: Issues related to healthcare professionals

Comment: This provision clarifies for physicians the important distinction between physician-assisted suicide and prescribing controlled medications for pain relief; this language identifies a clinical misperception that is pervasive in end-of-life care and attempts to lessen its impact on patient treatment, and the practitioners who provide it.

(-) CRITERION C.6:
Provisions that are ambiguous

Category D: Unclear definitions of dependence syndrome

Comment: This definition is vague, and it is not clear if it could be applied inappropriately to a person taking controlled medicines for medical purposes.



Original Policy Language

Continued from previous page

CAPITULO V Estupeficientes

Artículo 240.- Sólo podrán prescribir estupeficientes los profesionales que a continuación se mencionan, siempre que tengan título registrado por las autoridades educativas competentes, cumplan con las condiciones que señala esta Ley y sus reglamentos y con los requisitos que determine la Secretaría de Salud:

- I. Los médicos cirujanos;
- II. Los médicos veterinarios, cuando los prescriban para la aplicación en animales, y
- III. Los cirujanos dentistas, para casos odontológicos.

Los pasantes de medicina, durante la prestación del servicio social, podrán prescribir estupeficientes, con las limitaciones que la Secretaría de Salud determine.

Artículo 241.- La prescripción de estupeficientes se hará en recetas especiales, que contendrán, para su control, un código de barras asignado por la Secretaría de Salud, o por las autoridades sanitarias estatales, en los siguientes términos:

- I. Las recetas especiales serán formuladas por los profesionales autorizados en los términos del artículo 240 de esta ley, para tratamientos no mayores de treinta días, y
- II. La cantidad máxima de unidades prescritas por día, deberá ajustarse a las indicaciones terapéuticas del producto.

Artículo 242.- Las prescripciones de estupeficientes a que se refiere el Artículo anterior, sólo podrán ser surtidas por los establecimientos autorizados para tal fin.

Formal Translation

Continued from previous page

CHAPTER V Narcotics

Article 240. - Only professionals who can prescribe narcotics are mentioned below, provided they have registration title by educational authorities, comply with the conditions specified in this Law and its regulations and the requirements determined by the Ministry of Health:

- I. Physicians surgeons;
- II. Veterinarians, when prescribed for use in animals, and
- III. The dental surgeons for dental cases.

The medical interns during social service provision, prescribe drugs, with the limitations that the Health Department determined.

Article 241. - The narcotic prescription will be in special forms that contain, for control, a bar code assigned by the Ministry of Health, or by the health authorities state, in the following terms:

- I. The special prescription forms are used by licensed professionals from Article 240 of this law, for treatments over thirty days and
- II. The maximum number of units prescribed per day, must comply with the therapeutic instructions for the product.

Article 242. - The requirements of drugs referred to in the preceding article may only be filled by professionals licensed for this purpose.

(+) CRITERION B.3:
Medical use of opioids is recognized as legitimate professional practice

Criterion also identified in:
Reglamento de Insumos Para la Salud DDF-09-10-2012

(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category A: Requirement to use special prescription forms

Criterion also identified in:
Reglamento de la Ley General de Salud en Materia de Control Sanitario de Actividades, Establecimientos, Productos y Servicios 1-18-88, Artículo 146(II)(c)
Norma Oficial Mexicana NOM-072-SSA1-2012, Artículo 6.1.1
Reglamento de Insumos Para la Salud DDF-09-10-2012, Artículo 50

(-) CRITERION C.6:
Provisions that are ambiguous

Category B: Unclear intent leading to possible misinterpretation

Comment: This provision could potentially create a treatment barrier depending on whether the maximum number of dosage units defined by the therapeutic instructions is insufficient for pain relief for a particular patient.

(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category C: Requirement of a separate license/ registration



Original Policy Language

NORMA Oficial Mexicana NOM-028-SSA2-2009,
Para la prevención, tratamiento y control de las adicciones.

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Secretaría de Salud.

MODIFICACION A LA NORMA OFICIAL MEXICANA NOM-028-SSA2-1999, PARA LA PREVENCIÓN, TRATAMIENTO Y CONTROL DE LAS ADICCIONES, PARA QUEDAR COMO NORMA OFICIAL MEXICANA NOM-028-SSA2-2009, PARA LA PREVENCIÓN, TRATAMIENTO Y CONTROL DE LAS ADICCIONES.

MAURICIO HERNANDEZ AVILA, Subsecretario de Prevención y Promoción de la Salud y Presidente del Comité Consultivo Nacional de Normalización de Prevención y Control de Enfermedades, con fundamento en los artículos 39 de la Ley Orgánica de la Administración Pública Federal; 4o. de la Ley Federal de Procedimiento Administrativo; 3o. fracciones XXI, XXII y XXIII, 13, apartado A) fracciones I y II, 133 fracciones I y II, 184 bis, 185, 186, 187, 191, 192 y 193 de la Ley General de Salud; 3o. fracción XI, 38 fracción II, 40 fracciones III y XI, 41, 43 y 47 de la Ley Federal sobre Metrología y Normalización; 4o. del Reglamento de la Ley General de Salud en materia de Prestación de Servicios de Atención Médica; 28 y 34 del Reglamento de la Ley Federal sobre Metrología y Normalización, y 8o. fracción V, 10 fracciones VII y XVI, y 33 fracción IV, del Reglamento Interior de la Secretaría de Salud, he tenido a bien ordenar la publicación en el Diario Oficial de la Federación la Modificación a la Norma Oficial Mexicana NOM-028-SSA2-1999, Para la prevención, tratamiento y control de las adicciones para quedar como Norma Oficial Mexicana NOM-028-SSA2-1999, Para la prevención, tratamiento y control de las adicciones.

Considerando

Que con fecha 29 de noviembre de 2005, en cumplimiento de lo previsto en el artículo 46 fracción I de la Ley Federal sobre Metrología y Normalización, el Secretariado Técnico del Consejo Nacional contra las Adicciones en su carácter de Coordinador del Subcomité de Adicciones y Salud Mental, órgano colegiado donde participaron representantes de los sectores público, social y privado, presentó al Comité Consultivo Nacional de Normalización de Prevención y Control de Enfermedades, el Anteproyecto de Modificación a la Norma Oficial Mexicana NOM-028-SSA2-1999.

Que con fecha 31 de julio del 2006, en cumplimiento del acuerdo del Comité y en lo previsto en el artículo 47 fracción I de la Ley Federal sobre Metrología y Normalización, se publicó en el Diario Oficial de la Federación, el Proyecto de Modificación a la Norma, a efecto de que dentro de los siguientes sesenta días naturales posteriores a dicha publicación, los interesados presentaran sus comentarios al Comité Consultivo Nacional de Normalización de Prevención y Control de Enfermedades.

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Formal Translation

Mexican Official Standard NOM-028-SSA2-2009,
for the prevention, treatment and control of addiction.

The margin a seal with the national emblem, which reads:
United Mexican States. - Ministry of Health.

AMENDMENT TO THE OFFICIAL STANDARD NOM-028-SSA2-1999, FOR THE PREVENTION, TREATMENT AND CONTROL OF ADDICTIONS TO BE AS MEXICAN OFFICIAL STANDARD NOM-028-SSA2 2009, PREVENTION, TREATMENT AND CONTROL OF ADDICTIONS.

MAURICIO HERNANDEZ AVILA, Undersecretary of Prevention and Health Promotion and Chairman of the National Advisory Committee for Prevention and Disease Control, based on Article 39 of the Organic Law of Federal Public Administration; 4o. of the Federal Administrative Procedure Act, the 3rd. fractions XXI, XXII and XXIII, 13, section A) Sections I and II, Sections I and II 133, 184a, 185, 186, 187, 191, 192 and 193 of the General Health Law, the 3rd. Section XI, 38 fraction II, III and XI fractions 40, 41, 43 and 47 of the Federal Law on Metrology and Standardization; 4o. the Regulations of the General Health Law on Provision of Health Care Services, 28 and 34 of the Regulations of the Federal Law on Metrology and Standardization, and 8th. fraction V, VII and XVI 10 fractions, and 33, Section IV, the Internal Regulations of the Ministry of Health, I have been pleased to order the publication in the Official Journal of the Federation Amendment to the Official Mexican Standard NOM-028-SSA2- 1999, for the prevention, treatment and control of addiction to read as Norma Oficial Mexicana NOM-028-SSA2-1999, for prevention, treatment and control of addictions.

Considering

That on November 29, 2005, pursuant to the provisions of Article 46, Section I of the Federal Law on Metrology and Standardization, Technical Secretariat of the National Council Against Addictions in his capacity as Coordinator of the Subcommittee on Mental Health and Addictions collegiate body where representatives of the public, social and private, introduced the National Advisory Committee for Prevention and Disease Control, the Draft Amendments to the Official Mexican Standard NOM-028-SSA2-1999.

That on July 31, 2006, pursuant to the agreement of the Committee, as provided in Article 47, Section I of the Federal Law on Metrology and Standardization, was published in the Official Journal of the Federation, the Draft Amendment to the Norma, to the effect that within the next sixty calendar days after such publication, interested parties submit their comments to National Advisory Committee for Prevention and Disease Control.

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Original Policy Language

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Que con fecha previa, fueron publicados en el Diario Oficial de la Federación las respuestas a los comentarios recibidos por el mencionado Comité, en los términos del artículo 47 fracción III de la Ley Federal sobre Metrología y Normalización.

Que en atención a las anteriores consideraciones y contando con la aprobación del Comité Consultivo Nacional de Normalización de Prevención y Control de Enfermedades, se expide la siguiente:

NORMA OFICIAL MEXICANA NOM-028-SSA2-2009, PARA LA PREVENCIÓN, TRATAMIENTO Y CONTROL DE LAS ADICCIONES.

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3. Definiciones

Para efectos de esta Norma Oficial Mexicana, se entiende por:

3.1 Adicción o dependencia, al conjunto de fenómenos del comportamiento, cognoscitivos y fisiológicos, que se desarrollan luego del consumo repetido de una sustancia psicoactiva.

3.2 Adicto o farmacodependiente, a la persona con dependencia a una o más sustancias psicoactivas.

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Formal Translation

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That on prior, were published in the Official Journal of the Federation responses to comments received by the said Committee, pursuant to Article 47 section III of the Federal Law on Metrology and Standardization.

That in accordance with the foregoing and with the approval of the National Advisory Committee for Prevention and Disease Control, is issued as follows:

MEXICAN OFFICIAL STANDARD NOM-028-SSA2 2009, PREVENTION, TREATMENT AND CONTROL OF ADDICTIONS.

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3. DEFINITIONS

For the purposes of this Mexican Official Standard, the following definitions apply:

3.1 Addiction or dependence: all behavioral, cognitive and physiological phenomena that develop after repeated consumption of a psychoactive substance.

3.2 Addict or drug-dependent individual: the person with a dependency on one or more psychoactive substances.

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(+) CRITERION B.7:
Withdrawal syndrome or analgesic tolerance are not confused with dependence syndrome (i.e., "addiction")



Original Policy Language

DOF: 01/11/2013

DECRETO por el que se reforman y adicionan diversas disposiciones del Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica

Al margen un sello con el Escudo Nacional, que dice: Estados Unidos Mexicanos.- Presidencia de la República.

ENRIQUE PEÑA NIETO, Presidente de los Estados Unidos Mexicanos, en ejercicio de la facultad que me confiere el artículo 89, fracción I, de la Constitución Política de los Estados Unidos Mexicanos, y con fundamento en los artículos 39 de la Ley Orgánica de la Administración Pública Federal; 3o., fracción XXVII Bis; 27, fracción III; 33, fracción IV; 112, fracción III, y 166 Bis a 166 Bis 21 de la Ley General de Salud, he tenido a bien expedir el siguiente

DECRETO POR EL QUE SE REFORMAN Y ADICIONAN DIVERSAS DISPOSICIONES DEL REGLAMENTO DE LA LEY GENERAL DE SALUD EN MATERIA DE PRESTACIÓN DE SERVICIOS DE ATENCIÓN MÉDICA

ARTÍCULO ÚNICO.- Se REFORMAN los artículos 4o; 7o; 8o, fracción III; 10, fracciones I y V, segundo párrafo; 12, Segundo párrafo; 14; 17, último párrafo; 21; 26; 28; 33, primer párrafo; 37, fracciones IV y V; 39; 41; 42; 47; 59, fracción VI; 60; 62; 63; 68; 69; 70, fracciones I, último párrafo, II y III; 76; 77; 80, primer párrafo; 82, fracciones V y VI; 83, segundo párrafo; 84; 87; 88; 89, último párrafo; 90; 91, último párrafo; 93; 94; 100; 104; 108; 109; 110, fracción II; 116; 118; 120; 122; 123, en su encabezado; 126; 127; 130; 136; 137; 141; 142; 144, fracción IV; 150; 152; 157; 158; 162; 166; 167; 169; 172; 175, fracciones I, II, III y VIII; 176; 178, fracciones I y II; 179; 180; 181; 190; 192; 197; 203; 209; 214; 217; 218; 222, fracción VIII; 223, fracción III; 225; 228; 230; 233, primer párrafo; 234; 237, primer párrafo; 242 y 246, primer párrafo y se ADICIONAN la fracción IV al artículo 8o; el artículo 30 Bis; un segundo párrafo al artículo 80, recorriéndose el actual para pasar a ser tercer párrafo; la fracción VII al artículo 82; el CAPÍTULO VIII BIS denominado "Disposiciones para la Prestación de Servicios de Cuidados Paliativos" que comprende los artículos 138 Bis a 138 Bis 27 y el artículo 242 Bis, del Reglamento de la Ley General de Salud en Materia de Prestación de Servicios de Atención Médica, para quedar como sigue:

ARTÍCULO 4o.- Corresponde a la Secretaría emitir las normas oficiales mexicanas a que se ajustará, en todo el territorio nacional, la prestación de los servicios de salud en materia de atención médica, las que se publicarán en el Diario Oficial de la Federación para su debida observancia.

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Formal Translation

DOF: 01/11/2013

DECREE amending and supplementing a number of provisions of the Regulations of the General Health Law in the Matter of Delivery of Medical Care Services

In the margin, a stamp with the National Seal, Reading: United Mexican States.- Presidency of the Republic.

ENRIQUE PEÑA NIETO, President of the United Mexican States, in exercise of my powers under Article 89, Section I, of the Political Constitution of the United Mexican States, and pursuant to Article 39 of the Federal Public Administration Organic Law, the 3rd, Section XXVII Bis, 27 paragraph III, 33, section IV, 112, section III, and 166 Bis to 166 Bis 21 of the General Health Law, I hereby issue the following

DECREE TO AMEND AND SUPPLEMENT A NUMBER OF PROVISIONS OF THE REGULATIONS OF THE GENERAL HEALTH LAW IN THE MATTER OF DELIVERY OF MEDICAL CARE SERVICES

SOLE ARTICLE. - It AMENDS articles 4th, 7th, 8th, Section III, 10, Sections I and V, second paragraph, 12, second paragraph, 14, 17, last paragraph, 21, 26, 28, 33, first paragraph; 37, sections IV and V, 39, 41, 42, 47, 59, Section VI, 60, 62, 63, 68, 69, 70, sections I, last paragraph, II and III, 76, 77, 80, first paragraph, 82, Sections V and VI, 83, second paragraph, 84, 87, 88, 89, last paragraph, 90, 91, last paragraph, 93, 94, 100, 104, 108, 109, 110, Section II, 116; 118, 120, 122, 123, in its header, 126, 127, 130, 136, 137, 141, 142, 144, section IV, 150, 152, 157, 158, 162, 166, 167, 169, 172, 175, sections I, II, III and VIII, 176, 178, sections I and II, 179, 180, 181, 190, 192, 197, 203, 209, 214, 217, 218, 222, Section VIII, 223, Section III, 225, 228, 230, 233, first paragraph, 234, 237, first paragraph, 242 and 246, first paragraph and it is ADDED section IV to article 8, article 30 Bis, a second paragraph to Article 80, moving the current one to become third paragraph, section VII to Article 82, CHAPTER VIII BIS called "Regulations for Palliative Care Services Provision" comprising articles 138 Bis to 138 Bis 27 and Article 242 Bis of the General Health Law Provision in the Matter of Delivery of Medical Care Services, to read as follows:

ARTICLE 4. - The Secretariat will be responsible for issuing the official Mexican standards to be adjusted throughout the national territory, the provision of health services in the area of health care, to be published in the Official Journal of the Federation for due observance.

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Original Policy Language

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ARTÍCULO 7o.- Para los efectos de este Reglamento se entiende por:

I.- ATENCIÓN MÉDICA.- El conjunto de servicios que se proporcionan al usuario con el fin de proteger, promover y restaurar su salud, así como brindarle los cuidados paliativos al paciente en situación terminal;

II.- DEMANDANTE.- Toda aquella persona que para sí o para otro, solicite la prestación de servicios de atención médica;

III.- ESTABLECIMIENTO PARA LA ATENCIÓN MÉDICA.- Todo aquel, público, social o privado, fijo o móvil cualquiera que sea su denominación, que preste servicios de atención médica, ya sea ambulatoria o para internamiento de enfermos, excepto consultorios;

IV.- PACIENTE AMBULATORIO.- Todo aquel usuario de servicios de atención médica que no necesite hospitalización;

V.- SERVICIO DE ATENCIÓN MÉDICA.- El conjunto de recursos que intervienen sistemáticamente para la prevención, curación y cuidados paliativos de las enfermedades que afectan a los usuarios, así como de la rehabilitación de los mismos, y

VI.- USUARIO.- Toda aquella persona que requiera y obtenga la prestación de servicios de atención médica.

ARTÍCULO 8o.- ...

I.- y II.- ...

III.- DE REHABILITACIÓN: Que incluyen acciones tendientes a limitar el daño y corregir la invalidez física o mental, y

IV.- PALIATIVAS: Que incluyen el cuidado integral para preservar la calidad de vida del usuario, a través de la prevención, tratamiento y control del dolor, y otros síntomas físicos y emocionales, por parte de un equipo multidisciplinario.

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CAPÍTULO VIII BIS

Disposiciones para la Prestación de Servicios de Cuidados Paliativos

ARTÍCULO 138 Bis.- El presente Capítulo tiene por objeto establecer los procedimientos generales para la prestación de cuidados paliativos adecuados a los usuarios de cualquier edad que cursan una enfermedad en estado terminal.

ARTÍCULO 138 Bis 1.- Los objetivos de los cuidados paliativos son:

I.- Proporcionar bienestar y una calidad de vida digna hasta el momento de su muerte;

II.- Prevenir posibles acciones y conductas que tengan como consecuencia el abandono u obstinación terapéutica, así como la aplicación de medios extraordinarios, respetando en todo momento la dignidad de la persona;

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Formal Translation

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ARTICLE 7. - For the purposes of this Regulation the term:

I. - HEALTH CARE. – Means the services provided to the user in order to protect, promote and restore health and to provide palliative care to terminally ill patients;

II. - PETITIONER. - Any person requesting to receive for himself/herself or for somebody else, health care services;

III. - HEALTH CARE CENTRE FACILITY. - Any public, social or private place, whether permanent or ambulatory, whatever their denomination is, that provides health care services for outpatient or inpatients hospitalization of patients, excluding doctor's offices;

IV. - OUTPATIENT. - Any user of health care services that do not require hospitalization;

V. - MEDICAL CARE. - All the resources systematically involved in the prevention, cure and palliation of diseases affecting users, as well as their rehabilitation, and

VI. - USER. - Any person who requests and obtains delivery of medical care services.

ARTICLE 8th. - ...

I. - and II. - ...

III. - REHABILITATION: They include actions tending to limit the damage and to correct physical or mental disability, and

IV. - PALLIATIVE CARE: Includes comprehensive care to preserve the individual's quality of life, through prevention, treatment and control of pain and other physical and emotional symptoms, by a multidisciplinary team of practitioners.

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CHAPTER VIII BIS

Arrangements for the Provision of Palliative Care Services

ARTICLE 138 Bis. - This Chapter's goal is to establish the general procedures for the provision of adequate palliative care to users of any age who are terminally ill.

ARTICLE 138 Bis 1. - The goals of palliative care are:

I. - To provide the well-being and a decent quality of life until their death;

II. - To prevent possible actions and behaviors which result in the abandonment or therapeutic obstinacy, as well as the application of extraordinary methods, always respecting the person's dignity;

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(+) CRITERION B.2:
Pain management is recognized as part of general healthcare practice

Criterion also identified in:
Ley General de Salud DOF
24-04-2013, Article 33(IV)

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (policy and procedures) to ensure that pain management and palliative care are essential parts of care for patients with a terminal illness.



Original Policy Language

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- III.- Proporcionar alivio del dolor y otros síntomas severos asociados a las enfermedades en estado terminal;
 IV.- Establecer los protocolos de tratamiento que se proporcionen a los enfermos en situación terminal a través de cuidados paliativos, a fin de que no se interfiera con el proceso natural de la muerte;
 V.- Proporcionar al enfermo en situación terminal, los apoyos físicos, psicológicos, sociales y espirituales que se requieran, a fin de brindarle la mejor calidad de vida posible, y
 VI.- Dar apoyo a la familia o a la persona de su confianza para ayudarla a sobrellevar la enfermedad del paciente y, en su caso, el duelo.

ARTÍCULO 138 Bis 2.- Para los efectos de este Capítulo, además de las definiciones previstas en el artículo 166 Bis 1 de la Ley, se entiende por:

- I.- DIRECTRICES ANTICIPADAS: El documento a que se refiere el artículo 166 Bis 4 de la Ley;
 II.- DOLOR: Es la experiencia sensorial de sufrimiento físico y emocional, de intensidad variable, que puede presentarse acompañada de daño real o potencial de tejido del paciente;

III.- EQUIPO MULTIDISCIPLINARIO: Personal profesional, técnico y auxiliar de diversas disciplinas del área de la salud, que intervienen en la atención médica integral del enfermo en situación terminal;

IV.- MÉDICO TRATANTE: El profesional de la salud responsable de la atención y seguimiento del plan de cuidados paliativos;

V.- TRATAMIENTO CURATIVO: Todas las medidas sustentadas en la evidencia científica y principios éticos encaminadas a ofrecer posibilidades de curación de una enfermedad, y

VI.- PLAN DE CUIDADOS PALIATIVOS: El conjunto de acciones indicadas, programadas y organizadas por el médico tratante, complementadas y supervisadas por el equipo multidisciplinario, las cuales deben proporcionarse en función del padecimiento específico del enfermo, otorgando de manera completa y permanente la posibilidad del control de los síntomas asociados a su padecimiento. Puede incluir la participación de familiares y personal voluntario.

ARTÍCULO 138 Bis 3.- La Secretaría emitirá la norma oficial mexicana que prevea, entre otros aspectos, los criterios para la atención de enfermos en situación terminal a través de cuidados paliativos que deben cumplir las instituciones y establecimientos de atención médica del Sistema Nacional de Salud que proporcionen estos servicios.

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Formal Translation

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- III. - To provide relief from pain and other severe symptoms associated with end-stage diseases;
 IV. - To establish treatment protocols provided to terminally ill patients through palliative care, so as not to interfere with the natural process of death;

V. - To provide the patient in a terminally-ill condition, with the physical, psychological, social and spiritual support required, in order to provide the highest quality of life possible, and

VI. - To provide support to the family or the person of his/her trust to help cope with the disease of the patient and, where appropriate, the mourning.

ARTICLE 138 Bis 2. - For the purposes of this Chapter, in addition to the definitions laid down in Article 166 Bis 1 of the Act, the term:

I. - ADVANCE DIRECTIVES: Is the document referred to in Article 166 Bis 4 of the Act;

II. - PAIN: It is the sensory experience of physical and emotional suffering, of varying intensity, which is sometimes accompanied by actual or potential harm to patient's tissues;

III. - MULTIDISCIPLINARY TEAM: Professional, technical and assistance staff of various disciplines in the area of health, involved in the comprehensive care of the patient in a terminal condition;

IV. - PHYSICIAN: The health care professional responsible for the care and monitoring of palliative care plan;

V. - HEALING TREATMENT: All methods supported by scientific evidence and ethical principles designed to provide opportunities for curing a disease, and

VI. - PALLIATIVE CARE PLAN: The set of actions identified, planned and organized by the treating physician, supplemented and supervised by the multidisciplinary team, which should be provided according to the specific condition of the patient, providing a possible complete and permanent way to control the symptoms associated with their condition. It can include family and volunteers involvement.

ARTICLE 138 Bis 3. - The Secretariat will issue the official Mexican norms that provide, among other things, the criteria for the care of terminally-ill patients through palliative care to be met by institutions and health care facilities of the National Health System that provide these services.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category A: Issues related to healthcare professionals

Comment: Recognizes the need for a multidisciplinary approach to pain management and palliative care.

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (written palliative care plan) to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.



Original Policy Language

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ARTÍCULO 138 Bis 4.- La Secretaría proporcionará la asesoría y apoyo técnico que se requiera en las instituciones y establecimientos de atención médica, de los sectores público, social y privado para la prestación de los servicios de cuidados paliativos.

ARTÍCULO 138 Bis 5.- Los prestadores de servicios de atención médica de los sectores público, social y privado que proporcionen cuidados paliativos, deberán brindar gratuitamente dentro del establecimiento, información, orientación y motivación sobre los cuidados paliativos, de acuerdo con la normativa aplicable.

SECCIÓN PRIMERA

De los Derechos de los Enfermos en Situación Terminal

ARTÍCULO 138 Bis 6.- El paciente tiene derecho a que se le informe de manera oportuna, comprensible y suficiente acerca de que el tratamiento curativo ya no está ofreciendo resultados positivos tanto para su pronóstico como para su calidad de vida, informándole y, en caso de que este así lo autorice, al tutor, representante legal, a la familia o persona de su confianza, el diagnóstico de una enfermedad en estado terminal, así como las opciones de cuidados paliativos disponibles. En caso de dudas, el paciente puede solicitar información adicional y explicaciones, mismas que deberán serle proporcionadas en la forma antes descrita. Asimismo, puede solicitar una segunda opinión.

ARTÍCULO 138 Bis 7.- Además de los derechos que establece el artículo 166 Bis 3 de la Ley, los pacientes enfermos en situación terminal tienen los siguientes:

- I.- Recibir atención ambulatoria y hospitalaria;
- II.- A que se le proporcionen servicios de orientación y asesoramiento a él, a su familia o persona de su confianza, así como seguimiento respecto de su estado de salud;
- III.- A que se respete su voluntad expresada en el documento de directrices anticipadas, y
- IV.- Los demás que señalen las disposiciones aplicables.

ARTÍCULO 138 Bis 8.- Las directrices anticipadas podrán ser revocadas en cualquier momento únicamente por la persona que las suscribió.

Cuando por el avance de la medicina surgieran tratamientos curativos nuevos o en fase de experimentación que pudieran aplicarse al enfermo en situación terminal, se le informará de ese hecho, a efecto de que pueda ratificar por escrito su voluntad de no recibir cuidados paliativos o de revocarla por escrito para someterse a dichos tratamientos.

Si el estado de salud del enfermo en situación terminal le impide estar consciente o en pleno uso de sus facultades mentales, la decisión a que se refiere el párrafo anterior podrá tomarla su familiar, tutor, representante legal o persona de su confianza.

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Formal Translation

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ARTICLE 138 Bis. 4 - The Secretariat will provide the technical advice and support required in institutions and health care facilities, of public, social and private sectors for the provision of palliative care services.

ARTICLE 138 Bis 5. - The providers of health care services to the public, social and private sectors, that provide palliative care, must provide within the facility, free information, guidance and motivation on palliative care, in accordance with applicable regulations.

SECTION ONE

On the Rights of the Terminally-Ill Patients

ARTICLE 138 Bis 6. - The patient has the right to be informed in a timely, easy to understand and adequate manner about the curative treatment that is no longer offering positive results both for prognosis and for his/her quality of life, informing him/her, and if that this so authorized, to the guardian, legal representative, family or someone he/she trusts, a diagnosis of end-stage disease and palliative care options available. If in doubt, the patient may request additional information and explanations, which shall be provided in the same manner described above. He/she can also ask for a second opinion.

ARTICLE 138 Bis 7. - In addition to the rights set out in Article 166 Bis 3 of the Act, terminally-ill patients will have the following:

- I. - Receive ambulatory and hospital care;
- II. - A service that will provide guidance and advice to him/her, his/her family or someone he/she trusts in and follow up on their health status;
- III. - Respect for his/her wishes expressed in the Advance Directives, and
- IV. - Other things indicates in the applicable provisions.

ARTICLE 138 Bis 8. - Advance directives may be revoked at any time only by the person who signed them.

If new curative treatments arise in the advance of medicine or are in experimental phase and could be applied to the patient in a terminal condition, he/she will be informed of that fact, so that he/she may ratify in writing his/her desire not to receive palliative care or to revoke it in writing, to undergo such treatments.

If the health status of the patient in a terminal condition prevents him/her from being aware or to be in full possession of his mental faculties, the decision referred to in the preceding paragraph may be made by his/her family, guardian, legal representative or person of his/her trust.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (information, guidance, and motivation) for healthcare facilities to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category B: Issues related to patients

Comment: Establishes a mechanism (rights of patients) to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.



Original Policy Language

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ARTÍCULO 138 Bis 9.- Sin menoscabo de lo previsto en el artículo 166 Bis 8 de la Ley, a los menores de edad se les proporcionará la información completa y veraz que por su edad, madurez y circunstancias especiales, requieran acerca de su enfermedad en situación terminal y los cuidados paliativos correspondientes.

ARTÍCULO 138 Bis 10.- A partir de que se diagnostique con certeza la situación terminal de la enfermedad por el médico tratante, se proporcionarán los cuidados paliativos, con base en el plan de cuidados paliativos establecido por dicho médico. No se podrá proporcionar estos cuidados si no se cuenta con dicho plan.

ARTÍCULO 138 Bis 11.- La prestación de servicios de atención ambulatoria en materia de cuidados paliativos se ajustará, en lo general, a lo dispuesto por el Capítulo III de este Reglamento, así como en lo previsto en el presente Capítulo.

SECCIÓN SEGUNDA

De las Facultades y Obligaciones de las Instituciones de Salud

ARTÍCULO 138 Bis 12.- Las instituciones del Sistema Nacional de Salud promoverán que la capacitación y actualización de los profesionales, técnicos y auxiliares de la salud en materia de cuidados paliativos se realice por lo menos una vez al año.

Para efectos de fomentar la creación de áreas especializadas que dispone la Ley en la fracción V del artículo 166 Bis 13, las instituciones del Sistema Nacional de Salud, de acuerdo con el grado de complejidad, capacidad resolutive, disponibilidad de recursos financieros, organización y funcionamiento, contarán con la infraestructura, personal idóneo y recursos materiales y tecnológicos adecuados para la atención médica de cuidados paliativos, de conformidad con la norma oficial mexicana que para este efecto emita la Secretaría.

Las instituciones y establecimientos de atención médica que proporcionen cuidados paliativos deberán contar con el abasto suficiente de fármacos e insumos para el manejo del dolor del enfermo en situación terminal.

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Formal Translation

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ARTICLE 138 Bis 9. - Without prejudice to the provisions of Article 166 Bis 8 of the Act, minors will be provided with complete and accurate information that they require because of their age, maturity and circumstances, about their disease, in a terminally-ill condition, and the corresponding palliative care.

ARTICLE 138 Bis 10. - Once being diagnosed with certainty about their terminally-ill condition by the treating physician, palliative care will be provided, based on the palliative care plan established by such physician. No such care may be provided if there is no such plan.

ARTICLE 138 Bis 11. - The provision of ambulatory care services in palliative care will be adjusted, in general, according to the provisions of Chapter III of his Regulation, as well as to the provisions of this Chapter.

SECTION TWO

Of the Powers and Duties of Health Institutions

ARTICLE 138 Bis 12. - The institutions of the National Health System will promote that training and upgrading of professionals, technical and assistant health staff in palliative care should be performed at least once a year.

For the purpose of encouraging the creation of specialized areas available to the Act in section V of article 166 Bis 13, the institutions of the National Health System, according to their degree of complexity, response capacity, availability of financial resources, organization and operation, shall have the infrastructure, qualified staff and adequate and technological material resources in order to provide palliative health care services in accordance with the official Mexican norms issued by the Secretariat for this effect.

Institutions and health care facilities that provide palliative care should have sufficient supply of drugs and supplies for pain management in terminally-ill patients.

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(+) CRITERION B.4: Pain management is encouraged

Category A: Ensures treatment of certain patient populations

Comment: Although this provision relates specifically to palliative care, pain management is part of palliative care.

(+) CRITERION B.8: Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (training and increased resources) for healthcare facilities to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.

(+) CRITERION B.8: Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (medication supplies and other resources) for healthcare facilities to ensure that pain management and palliative care are essential parts of care for patients with a terminal illness.



Original Policy Language

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ARTÍCULO 138 Bis 13.- Los médicos tratantes en cuidados paliativos en las instituciones y establecimientos de segundo y tercer nivel y equivalentes del sector social y privado, tendrán las siguientes obligaciones:

- I.- Proporcionar información al enfermo en situación terminal, sobre los resultados esperados y posibles consecuencias de la enfermedad o el tratamiento, respetando en todo momento su dignidad;
- II.- Prescribir el plan de cuidados paliativos, atendiendo a las características y necesidades específicas de cada enfermo en situación terminal;
- III.- Cumplir con las directrices anticipadas;
- IV.- Conducirse de conformidad con lo señalado en la Ley, el presente Reglamento y demás disposiciones aplicables;
- V.- Participar en la elaboración y aplicación de planes y protocolos de tratamiento de cuidados paliativos, así como en la evaluación de la eficacia de los mismos;
- VI.- Brindar apoyo psicológico a los familiares o la persona de su confianza para afrontar la enfermedad del paciente y, en su caso, sobrellevar el duelo;
- VII.- Capacitar, auxiliar y supervisar al paciente para fomentar el autocuidado de su salud, así como a su familia o responsable de su cuidado, preservando la dignidad de la persona enferma y favoreciendo su autoestima y autonomía;
- VIII.- Prescribir los fármacos que requiera la condición del enfermo en situación terminal sujeto al plan y protocolo de tratamiento de cuidados paliativos, y
- IX.- Las demás que señalen las disposiciones aplicables.

ARTÍCULO 138 Bis 14.- Es responsabilidad del médico tratante y del equipo multidisciplinario identificar, valorar y atender en forma oportuna, el dolor y síntomas asociados que el usuario refiera, sin importar las distintas localizaciones o grados de intensidad de los mismos, indicar el tratamiento adecuado a cada síntoma según las mejores evidencias médicas, con apego a los principios científicos y éticos que orientan la práctica médica, sin incurrir en ningún momento en acciones o conductas consideradas como obstinación terapéutica ni que tengan como finalidad terminar con la vida del paciente.

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Formal Translation

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ARTICLE 138 Bis 13. - Physicians providing palliative care in second- and third-level institutions and equivalent of the social and private sectors, have the following obligations:

- I. - To provide information to the patient in a terminal condition, about the expected results and possible consequences of the disease or treatment, always respecting their dignity;
- II. - To prescribe a palliative care plan, according to the characteristics and needs of each patient in a terminal condition;
- III. - To comply with the Advance Directives;
- IV. - To conduct themselves in accordance with the provisions in the Act, this Regulation and other applicable laws;
- V. - To participate in the development and implementation of treatment plans and protocols of palliative care, as well as in the evaluation of their effectiveness;
- VI. - To provide psychological support to family members or his/her trusted person to deal with the patient's condition and, if applicable, bereavement;
- VII. - To train, help and monitor the patient for self-care in order to promote health, as well as his/her family or the person responsible for his/her care, preserving the dignity of the sick person and promoting his/her self-esteem and autonomy;
- VIII. - To prescribe drugs required by the condition of the patient in a terminal condition, according to the plan and treatment protocol for palliative care, and
- IX. - Other things indicated in the applicable provisions.

ARTICLE 138 Bis 14. - It is the responsibility of the treating physician and the multidisciplinary team to identify, assess and take care, in a timely manner, of the associated pain and symptoms mentioned by the user, regardless their location or levels of intensity, indicating the appropriate treatment for each symptom according to the best medical evidence, subject to scientific and ethical principles that guide medical practice, without incurring in any actions or behavior considered as therapeutic obstinacy or which are designed to end the patient's life.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy issues

Comment: Establishes a mechanism (practitioner obligation) for healthcare facilities to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.



Original Policy Language

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ARTÍCULO 138 Bis 15.- El plan de cuidados paliativos deberá considerar aquellas acciones que se deban llevar a cabo en el domicilio del enfermo en situación terminal, por parte de los familiares, cuidadores o personal voluntario, tomando en cuenta lossiguientes criterios:

- I.- Deberán ser indicados por el médico tratante, de acuerdo con las características específicas y condición del usuario. Este hecho deberá ser registrado en el expediente clínico del enfermo en situación terminal;
- II.- Se deberá involucrar al equipo multidisciplinario de la institución o establecimiento de atención médica que proporciona los cuidados paliativos;
- III.- El equipo multidisciplinario brindará la capacitación que corresponda en los distintos ámbitos de competencia profesional, a los familiares, cuidadores o personal voluntario, que tendrá a su cargo la atención y cuidados básicos domiciliarios del enfermo en situación terminal;
- IV.- El equipo multidisciplinario supervisará el cumplimiento de las acciones y cuidados básicos domiciliarios indicados por el médico tratante, dentro del plan de cuidados paliativos. Los hallazgos deberán ser reportados al médico tratante y registrados en el expediente clínico del enfermo en situación terminal, y
- V.- Los demás que determinen las disposiciones aplicables.

ARTÍCULO 138 Bis 16.- Para el caso de que los cuidados paliativos se lleven a cabo en el domicilio del enfermo en situación terminal y se requiera asistencia telefónica, la Secretaría deberá:

- I.- Ser expedita, atenta, respetuosa y suficiente para satisfacer las necesidades de información de la persona que llama;
- II.- Documentar y anexar el reporte de la llamada al expediente clínico del enfermo en situación terminal, y
- III.- Satisfacer los demás requisitos que al efecto se establezcan.

ARTÍCULO 138 Bis 17.- Todo aquel establecimiento que preste servicios de cuidados paliativos a enfermos en situación terminal deberá contar con los recursos físicos, humanos y materiales necesarios para la protección, seguridad y atención con calidad de los usuarios, de conformidad con las normas oficiales mexicanas que emita la Secretaría.

ARTÍCULO 138 Bis 18.- Para efectos de obtener la autorización a que se refieren los artículos 80 y 81 del presente Reglamento, y demás disposiciones jurídicas aplicables, se le deberá explicar al usuario el motivo por el cual se da fin al tratamiento curativo y se sugiere la aplicación de los cuidados paliativos.

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Formal Translation

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ARTICLE 138 Bis 15. - The palliative care plan must consider those actions to be performed in the patient's home in a terminal condition, by family members, caregivers or volunteers, taking into account the following criteria:

- I. - They must be prescribed by the physician, according to the specific characteristics and condition of the user. This fact must be written down in the clinical record of the patient in a terminal condition;
- II. - It should involve the multidisciplinary team of the institution or health care facility that provides palliative care;
- III. - The multidisciplinary team will provide appropriate training in various areas of professional competence, to his/her relatives, caregivers or volunteers, who will be responsible for the residential care of the patient in a terminal condition;
- IV. - The multidisciplinary team will monitor compliance with the actions and basic household care, indicated by the attending physician, within the palliative care plan. The findings shall be reported to the treating physician and recorded in the clinical record of the patient in a terminal condition, and
- V. - Everything else indicated in the applicable provisions.

ARTICLE 138 Bis 16. - In the case that palliative care is carried out in the patient's home who is in a terminal condition, and telephone assistance is required, the Secretariat shall:

- I. - Be swift, attentive, respectful and adequate to meet the information needs of the caller;
- II. - Document and attach the report of the call to the patient's clinical record in a terminal condition, and
- III. - To meet other requirements established for this purpose.

ARTICLE 138 Bis 17. - Any institution providing palliative care services to terminally-ill patients should have the physical, human and material resources for the protection, safety and quality care for users, in accordance with official Mexican norms issued by the Ministry.

ARTICLE 138 Bis 18. - For purposes of obtaining the authorization referred to in Articles 80 and 81 of this Regulation and other applicable legal provisions, you must explain to the user the reason for terminating the curative treatment and to suggest the implementation of palliative care.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (home care) for healthcare facilities to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.



Original Policy Language

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ARTÍCULO 138 Bis 19.- El equipo multidisciplinario estará integrado, al menos, por:

- I.- Médico tratante;
- II.- Enfermera;
- III.- Fisioterapeuta;
- IV.- Trabajador Social o su equivalente;
- V.- Psicólogo;
- VI.- Algólogo o Anestesiólogo;
- VII.- Nutriólogo, y
- VIII.- Los demás profesionales, técnicos y auxiliares que requiera cada caso en particular.

ARTÍCULO 138 Bis 20.- La información personal que se proporcione al médico tratante o al equipo multidisciplinario en cuidados paliativos por el enfermo en situación terminal, será utilizada con confidencialidad y empleada únicamente con fines científicos o terapéuticos en los términos que disponga la norma oficial mexicana que al efecto expida la Secretaría y demás disposiciones aplicables.

ARTÍCULO 138 Bis 21.- Los comités de bioética de las instituciones de salud, tratándose de cuidados paliativos, deberán:

- I.- Avalar el plan de cuidados paliativos, a solicitud del médico tratante, en aquellos casos que sean difíciles o complicados por la naturaleza de la enfermedad en situación terminal o las circunstancias en que esta se desarrolle, cuidando que durante el análisis del plan se proporcionen los medicamentos necesarios para mitigar el dolor, salvo que estos pongan en riesgo su vida;
- II.- Proponer políticas y protocolos para el buen funcionamiento del equipo tratante multidisciplinario en cuidados paliativos, y
- III.- Lo que le establezcan las demás disposiciones jurídicas aplicables.

SECCIÓN TERCERA
De las Directrices Anticipadas

ARTÍCULO 138 Bis 22.- Las instituciones del Sistema Nacional de Salud deberán observar la voluntad expresada en las directrices anticipadas. Cuando no se ejecute de manera exacta la voluntad expresada en las directrices anticipadas, se estará a las sanciones que establezcan las leyes aplicables.

Se exceptúa de lo previsto en el párrafo anterior aquellas disposiciones que sean contrarias al orden jurídico mexicano, particularmente por lo que hace al tipo penal equivalente a la eutanasia y al suicidio asistido. La ejecución de esas disposiciones por el personal médico, técnico y auxiliar de la salud no los exime de las responsabilidades de cualquier tipo que pudieran contraer.

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Formal Translation

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ARTICLE 138 Bis 19. - The multidisciplinary team shall consist of, at least:

- I. - A physician;
- II. - A nurse;
- III. - Physiotherapist;
- IV. - Social Worker or equivalent;
- V. - Psychologist;
- VI. - Algologist or Anesthesiologist;
- VII. - Nutritionist, and
- VIII. - Other professionals, technicians and assistance staff required for each case.

ARTICLE 138 Bis 20. - Personal information provided by the terminally ill patient to the physician or palliative care multidisciplinary team, will be confidential and used only for scientific or therapeutic purposes according to the official Mexican norms issued by the Secretariat and other applicable provisions.

ARTICLE 138 Bis 21. - Bioethics committees of health institutions, providing palliative care services shall:

- I. - Support the palliative care plan, at the request of the treating physician, in cases that are difficult or complicated by the nature of the disease in a terminal condition or the circumstances in which it develops, ensuring that during the analysis of the plan, they provide the necessary medicines to reduce pain, unless these are life-threatening;
- II. - Propose policies and protocols for the proper functioning of the multidisciplinary treatment team in palliative care, and
- III. - Whatever is established by other applicable legal provisions.

SECTION THREE
Of Advance Directives

ARTICLE 138 Bis 22. -The institutions of the National Health System shall comply with the wishes indicated in the Advance Directives. When the Advance Directives are not accurately executed, penalties provided by the Act will be applicable.

Exempted from the provisions of the preceding paragraph are those that are contrary to the Mexican law, especially for what it does to the criminal equivalent of euthanasia and assisted suicide. The implementation of these provisions by the medical, technical and assistance health staff does not relieve the responsibilities of any kind in which they may incur.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (Bioethics Committee) for healthcare facilities to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy Issues

Comment: Establishes a mechanism (Advanced Directives) to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.



Original Policy Language

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ARTÍCULO 138 Bis 23.- Las directrices anticipadas podrán ser suscritas por cualquier persona mayor de edad en pleno uso de sus facultades mentales, independientemente del momento en que se diagnostique como enfermo en situación terminal.

ARTÍCULO 138 Bis 24.- El documento de directrices anticipadas deberá contar con las siguientes formalidades y requisitos:

- I.- Realizarse por escrito, con el nombre, firma o huella digital del suscriptor y de dos testigos;
- II.- Constar que la voluntad se ha manifestado de manera personal, libre e inequívoca;
- III.- La manifestación, expresa o no, respecto a la disposición de órganos susceptibles de ser donados;
- IV.- La indicación de recibir o no cualquier tratamiento, en caso de padecer una enfermedad en situación terminal, y
- V.- En su caso, el nombramiento de uno o varios representantes para corroborar la ejecución de la voluntad del enfermo en situación terminal.

La aceptación de la representación a que se refiere el párrafo anterior, deberá realizarse en el mismo acto en que se suscriban las directrices anticipadas y deberá constar en el mismo documento.

ARTÍCULO 138 Bis 25.- Serán nulas las directrices anticipadas que establezcan el pedimento para asistir o provocar intencionalmente la muerte, particularmente, por lo que hace a la eutanasia y el suicidio asistido. Asimismo, se considerarán nulas las directrices, cuando contravenga lo establecido en la Ley, el presente Reglamento y demás disposiciones jurídicas aplicables.

ARTÍCULO 138 Bis 26.- Son obligaciones de los representantes, a que se refiere el artículo 138 Bis 24 de este Reglamento:

- I.- Corroborar la ejecución de la voluntad del enfermo en situación terminal, en los términos establecidos por este en las directrices anticipadas;
- II.- Revisar los cambios y modificaciones que se realicen en las directrices anticipadas con posterioridad a la aceptación de la representación, y
- III.- Las demás que le señalen las disposiciones jurídicas aplicables.

ARTÍCULO 138 Bis 27.- En caso de que el enfermo en situación terminal decida revocar o modificar las directrices anticipadas, deberá cumplir con las mismas formalidades y requisitos que se exigieron para su suscripción.

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Formal Translation

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ARTICLE 138 Bis 23. - Advance Directives may be subscribed by any adult in full possession of his/her mental faculties, regardless of when it is diagnosed as terminally ill.

ARTICLE 138 Bis 24. - Advance Directives must have the following formalities and requirements:

- I. - Be made in writing, with the name, signature or fingerprint of the subscriber and two witnesses;
- II. - Be stated that the patient's will has been expressed in a personal, free and clear way;
- III. - The evidence of assent put into words or not, regarding the availability of organs that can be donated;
- IV. - The indication of receiving or not receiving any treatment, in case of a terminal illness, and
- V. - If applicable, the appointment of one or more representatives to confirm the execution of the will of the patient in a terminal condition.

The acceptance of representation referred to in the preceding paragraph, shall be performed in the same act to be signed in the Advance Directives, and must appear in the same document.

ARTICLE 138 Bis 25. - Advance Directives will be void if they are established in the motion to attend or intentionally cause death, particularly in the case of euthanasia and assisted suicide. Furthermore, the guidelines will be considered as void when they contravene the provisions of the Act, this Regulation and other applicable legal provisions.

ARTICLE 138 Bis 26. - It is the responsibility of the representatives referred to in Article 138 Bis 24 of this Regulation:

- I. - To confirm the execution of the will of the patient in a terminal condition, in the terms established by these Directives;
- II. - To review changes and modifications made in advance directives after the acceptance of representation, and
- III. - The others indicated in the applicable legal provisions.

ARTICLE 138 Bis 27. - In case the patient in terminal condition decides to revoke or modify the Advance Directives, it must comply with the formalities and requirements demanded for its subscription.

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Panama



Population: 3,600,000

Mortality rates/100,000:

HIV/AIDS: 18.7

CANCER: 87.9

Human Development Index:

1980: 0.634

2010: 0.78

WHO Region:

AMRO

UN Region:

Americas

UN sub-region:

Central America

Relevant language found in the following policies:

LEY NÚMERO 59

(de 4 de junio de 1942)

Por la cual se fijan penas por la posesión, uso y tráfico ilícito de drogas heroicas

CODIGO SANITARIO LEY 66

(de 10 de noviembre de 1947)

LEY NÚMERO 23

(de 16 de Febrero de 1954)

Por el cual se reglamenta la importación, manejo y uso de las drogas enervantes, estupefacientes o narcóticos, productos de patentes que los contengan, y se disponen sanciones para las infracciones de la misma

CREASE EL COLEGIO NACIONAL DE FARMACEUTICOS Y REGLAMENTASE EL FUNCIONAMIENTO DE LOS ESTABLECIMIENTOS FARMACEUTICOS

LEY NUMERO 24

(de 29 de enero de 1963)

Por medio de la cual se crea el Colegio Nacional de Farmacéuticos y se reglamenta el funcionamiento de los establecimientos farmacéuticos

GACETA OFICIAL N°17.193

DEL 27 DE SEPTIEMBRE DE 1972

DECRETO DE GABINETE NÚMERO 154

(de 14 de septiembre de 1972)

Por el cual se aprueba el PROTOCOLO DE MODIFICACIÓN DE LA CONVENCIÓN DE 1961 SOBRE ESTUPEFACIENTES, adoptado en la Conferencia de las Naciones Unidas para examinar Enmiendas a la convención Única de 1961, sobre estupefacientes, celebrada en la ciudad de Ginebra, Suiza del 6 al 24 de marzo de 1972

ASAMBLEA LEGISLATIVA LEY N°1

(de 10 de enero de 2001)

Sobre Medicamentos y otros Productos para la Salud Humana LA ASAMBLEA

DECRETO EJECUTIVO No. 178

(De 12 de julio de 2001)

Que reglamenta la Ley 1 de 10 de enero de 2001, Sobre Medicamentos y otros Productos para la Salud Humana

LEY No. 68

(De 20 de noviembre de 2003)

Que regula los derechos y obligaciones de los pacientes, en materia de información y de decisión libre e informada

Resolución No.39,490-2007-J.D.

(De 27 de marzo de 2007)

La Junta Directiva de la Caja de Seguro Social, en uso de sus facultades legales

REPUBLICA DE PANAMÁ

MINISTERIO DE SALUD

DECRETO EJECUTIVO No.320

(De 17 de junio de 2009)

Por el cual se modifican los artículos 321, 324 y 325, del Decreto Ejecutivo 178 de 12 de julio de 2001, referentes a las recetas de sustancias controladas



Original Policy Language

LEY NÚMERO 23
(de 16 de Febrero de 1954)

Por el cual se reglamenta la importación, manejo y uso de las drogas enervantes, estupefacientes o narcóticos, productos de patentes que los contengan, y se disponen sanciones para las infracciones de la misma.

Artículo 21°: Todo establecimiento farmacéutico que importe o expende drogas enervantes, o estupefacientes o narcóticos o especialidades que las contengan en una proporción mayor de 0.015 gramos por dosis total diaria, está en la obligación de abrir un libro especial de control de Narcóticos, Contante de cien (100) páginas por lo menos, el cual debe ser abierto, sellado y firmado por la Dirección de Farmacia, Drogas y Alimentos y en el que se adherirán estampillas Fiscales por valor de un (1) centésimo de balboa por página. Este libro será controlado únicamente por el farmacéutico regente y en él se anotarán con detalles, las entradas y salidas de los renglones enervantes, estupefacientes o narcóticos que hubieren, indicando las cantidades exactas, en sistemas métricos decimal, de la droga usada, o vendida en orden cronológico, con nombre, fecha y número de la receta firmada solamente por médico registrado, cuando se trate de despachos efectuados por farmacia o por regente farmacéutico, así se trate de preparación u ordenes de compra cuando éstas se hicieran por Farmacia o Droguería, Agencias, Depósito o Laboratorios o Viceversa.

Formal Translation

LAW NUMBER 23
(from February 16, 1954)

By which importation, handling and use of stimulant or narcotic drugs and patented products containing them are regulated, and punishments for infractions against it are set forth.

Article 21. Any pharmaceutical facility that imports or circulates stimulant or narcotic drugs or specialties containing a proportion higher than 0.015 grams per total daily dose is obligated to open a special Narcotics control book, having at least one hundred (100) pages, which must be opened, stamped and signed by the Office of Pharmacy, Drugs and Foods and in which tax stamps will be adhered for the value of one (1) one hundredth of a balboa per page. This book will be under the control of only the managing pharmacist and in it will be noted in detail the entry and exit of the stimulant or narcotic lines, indicating the exact quantities in the decimal metric system of the drug used or sold in chronological order, with the name, date and number of the prescription signed only by a registered physician, when for sales made by pharmacy or by managing pharmacist, as well as for preparation or purchase orders when they are made by Pharmacy or Drug Store, Agencies, Warehouse or Laboratories or vice versa.

(-) CRITERION C.7: Other provisions that may impede pain management

Category A: Issues related to healthcare professionals

Comment: This provision requires use of a special Narcotics Control book along with a variety of documentation standards. Mistakes or omissions done in this registry or in the process are subject to penalties.



Original Policy Language	Formal Translation
<p>CREASE EL COLEGIO NACIONAL DE FARMACEUTICOS Y REGLAMENTASE EL FUNCIONAMIENTO DE LOS ESTABLECIMIENTOS FARMACEUTICOS.</p> <p>LEY NUMERO 24 (de 29 de enero de 1963)</p> <p>Por medio de la cual se crea el Colegio Nacional de Farmacéuticos y se reglamenta el funcionamiento de los establecimientos farmacéuticos. LA ASAMBLEA DE PANAMA CONSIDERANDO: Que según el artículo 41 de la Constitución Nacional, el ejercicio libre de cualquier profesión u oficio "queda sujeto a los reglamentos que establezca la Ley en lo relativo a idoneidad, moralidad, seguridad y salud pública.". Que según el artículo 92 del mismo Estatuto "es función esencial del Estado velar por la salud pública, y el individuo tiene derecho a la protección, conservación y restitución de su salud, y la obligación de conservarla. Que siendo la profesión farmacéutica una de las que inciden directamente en la salud pública es, por tanto conveniente que los profesionales que ejerzan esta ciencia se encuentren debidamente organizados y sujetos a normas éticas y disciplinarias de forzoso cumplimiento para garantía de los asociados.</p> <p>DECRETA:</p> <p>.</p> <p>.</p> <p>.</p> <p>CAPÍTULO IV Del expendio de Preparados Farmacéuticos, Químicos y Biológicos</p> <p>.</p> <p>.</p> <p>.</p> <p>Artículo 28º. La Dirección de Farmacias, Drogas y Alimentos, suministrará periódicamente a los establecimientos farmacéuticos una lista con los nombres de los médicos, dentistas y veterinarios que ejercen legalmente en el territorio de la República y solamente se despacharán recetas expedidas por los profesionales que estén en esta lista.</p>	<p>THE NATIONAL COLLEGE OF PHARMACISTS IS CREATED AND THE OPERATION OF PHARMACEUTICAL ESTABLISHMENTS IS REGULATED.</p> <p>LAW NUMBER 24 (from January 29, 1963)</p> <p>By which the National College of Pharmacists is created and the operation of pharmaceutical establishments is regulated. THE ASSEMBLY OF PANAMA CONSIDERING: That according to Article 41 of the National Constitution, the free exercise of any profession or office "is subject to the regulations established by Law related to suitability, morality, safety and public health." That according to Article 92 of the same Statute, "it is an essential function of the State to protect public health, and the individual has the right to the protection, maintenance and restoration of his or her health, and the obligation to maintain it. That since the pharmaceutical profession is one of those that directly impacts public health, it is therefore appropriate for the professionals who practice this science to be properly organized and subject to mandatory ethical and disciplinary standards as a guarantee to the citizens.</p> <p>DECREES:</p> <p>.</p> <p>.</p> <p>.</p> <p>CHAPTER IV About the sale of Pharmaceutical, Chemical and Biological Preparations</p> <p>.</p> <p>.</p> <p>.</p> <p>Article 28. The Office of Pharmacy, Drugs and Foods will periodically supply pharmaceutical establishments with a list of the names of the physicians, dentists and veterinarians who practice legally within the territory of the Republic and only prescriptions issued by the professionals on this list will be filled.</p>

(-) CRITERION C.7: Other provisions that may impede pain management

Category A: Issues related to healthcare professionals

Comment: This requirement could potentially create a treatment barrier depending on the frequency with which the lists are provided and the extent that it includes all relevant practitioners.



Original Policy Language

GACETA OFICIAL N°17.193
DEL 27 DE SEPTIEMBRE DE 1972

DECRETO DE GABINETE NÚMERO 154
(de 14 de septiembre de 1972)

Por el cual se aprueba el PROTOCOLO DE MODIFICACIÓN DE LA CONVENCIÓN DE 1961 SOBRE ESTUPEFACIENTES, adoptado en la Conferencia de las Naciones Unidas para examinar Enmiendas a la convención Única de 1961, sobre estupefacientes, celebrada en la ciudad de Ginebra, Suiza del 6 al 24 de marzo de 1972. LA JUNTA PROVISIONAL DE GOBIERNO DECRETA: ARTICULO ÚNICO: Apruébase el PROTOCOLO DE MODIFICACIÓN DE LA CONVENCIÓN ÚNICA DE 1961, SOBRE ESTUPEFACIENTES, con la siguiente RESERVA hecha por el Representante de la República de Panamá ante la Organización de las Naciones Unidas, en el momento de la firma, el 18 de mayo de 1972, referente a la enmienda que el artículo 14 del protocolo, introduce al párrafo 2 del artículo 36 de la Convención Única de 1961 sobre Estupefacientes : "Por cuanto de conformidad con su Constitución política de la República de Panamá, no puede por ningún tratado internacional obligarse a entregar a sus propios nacionales, firma este Protocolo de Modificación de la Convención Única de 1961 sobre estupefacientes, formulando expresa RESERVA de que la enmienda que el artículo 14 de Protocolo introduce al párrafo 2 del Artículo 36 de la Convención Única de 1961 sobre Estupefacientes: a) no modifica los tratados de extradición de los cuales es parte la República de Panamá; b) no obliga a la República de Panamá, a incluir, en los tratados de extradición que celebre en el futuro, disposición alguna por la cual se obligue a entregar a sus propios nacionales; y c) no podrá interpretarse ni aplicarse en sentido alguno que dé lugar a obligación de la República de Panamá de entregar uno de sus propios nacionales".

ARTICULO 2

Modificaciones del título del artículo 9 de la Convención Única y de su párrafo 1, e inserción de los nuevos párrafos 4 y 5.

El título del artículo 9 de la Convención Única quedará modificado en la siguiente forma: "Composición y funciones de la Junta" El párrafo 1 del artículo 9 de la Convención Única quedará modificado en la siguiente forma:

Continued on next page

Formal Translation

OFFICIAL GAZETTE No. 17.193
FROM SEPTEMBER 27, 1972

CABINET DECREE NUMBER 154
(from September 14, 1972)

By which the PROTOCOL AMENDING THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, adopted by the United Nations Conference in order to consider Amendments to the Single Convention on Narcotic Drugs, 1961, held in the city of Geneva, Switzerland from March 6 to 24, 1972 is approved. THE PROVISIONAL BOARD OF DIRECTORS DECREES: SINGLE ARTICLE: The PROTOCOL AMENDING THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961 is approved with the following RESERVATION made by the Representative of the Republic of Panama before the Organization of the United Nations at the time of signing on May 18, 1972, with regard to the amendment that Article 14 of the protocol adds to Paragraph 2 of Article 36 of the Single Convention on Narcotic Drugs, 1961: "Since in accordance with the political Constitution of the Republic of Panama, it may not by any international treaty obligate itself to deliver its own nationals, signs this Protocol Amending the Single Convention on Narcotic Drugs, 1961, formulating an express RESERVATION that the amendment made by Article 14 of the Protocol to Paragraph 2 of Article 36 of the Single Convention on Narcotic Drugs, 1961: a) does not modify the extradition treaties of which the Republic of Panama is a party; b) does not obligate the Republic of Panama to include in those extradition treaties that it signs in the future any provision obligating it to deliver its own nationals; and c) may not be interpreted nor applied in any sense that gives rise to an obligation for the Republic of Panama to deliver one of its own nationals."

Article 2.

Amendments to the title of Article 9 of the Single Convention and of Paragraph 1 of that Article, and insertion of new Paragraphs 4 and 5.

The title of Article 9 of the Single Convention will be amended in the following manner: "Composition and functions of the Board" Paragraph 1 of Article 9 of the Single Convention will be amended as follows:

Continued on next page

(+) CRITERION A.1:
Acknowledges intent to
carry out drug control
Conventions



Original Policy Language

Continued from previous page

1. La forma se compondrá de trece miembros, que el Consejo designará en la forma siguiente:

- a) Tres miembros que posean experiencia médica, farmacológica o farmacéutica, elegidos de una lista de cinco personas, por lo menos, propuestas por la Organización Mundial de la Salud;
- b) Diez miembros elegidos de una lista de personas propuestas por los Estados Miembros de las Naciones Unidas y por las partes que no sean miembros de las Naciones Unidas.

A continuación del párrafo 3 del artículo 9 de la Convención Única se insertarán los nuevos párrafos siguientes: “

4. La Junta, en cooperación con los gobiernos y con sujeción a las disposiciones de la presente Convención, tratará de limitar el cultivo, la producción, la fabricación y el uso de estupefacientes a la cantidad adecuada necesaria para fines médicos y científicos, de asegurar su disponibilidad para tales fines y de impedir el cultivo, la producción, la fabricación, el tráfico y el uso ilícito de estupefacientes.

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ARTICULO 5

Modificación del párrafo 5 del artículo 12 de la Convención Única. El párrafo 5 del artículo 12 de la Convención Única quedará modificado en la siguiente forma:

“5. La Junta, con miras a limitar el uso y la distribución de estupefacientes a la cantidad adecuada necesaria para fines médicos y científicos y a asegurar su disponibilidad para tales fines, confirmará lo más rápido posible las previsiones, incluso las suplementarias, o podrá modificarse con el consentimiento del gobierno interesado. En caso de desacuerdo entre el gobierno y la Junta ésta última tendrá derecho a establecer, comunicar y publicar sus propias previsiones, incluso las suplementarias”.

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Formal Translation

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1. The entity will be made up of thirteen members, who the Council will designate in the following manner:

- a) Three members with medical, pharmacological or pharmaceutical experience, chosen from a list of at least five individuals proposed by the World Health Organization;
- b) Ten members chosen from a list of individuals proposed by the Member States of the United Nations and by the parties who are not members of the United Nations.

Below Paragraph 3 of Article 9 of the Single Convention, the following new paragraphs will be inserted:

“4. The Board, in cooperation with the governments and subject to the provisions of this Convention, will try to limit the cultivation, production, manufacture and use of narcotics to the adequate quantity necessary for medical and scientific purposes, to assure their availability for these purposes, and to prevent the illicit cultivations, production, manufacture, traffic and illicit use of narcotics.

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Article 5.

Amendment of Paragraph 5 of Article 12 of the Single Convention. Paragraph 5 of Article 12 of the Single Convention will be amended in the following manner:

“5. The Board, with the intention of limiting the use and distribution of narcotics to the adequate quantity necessary for medical and scientific purposes and assuring their availability for those purposes, will confirm the estimates, including supplementary ones, as quickly as possible, or it may be amended with the consent of the government involved. In the event of disagreement between the government and the Board, the latter will have the right to establish, communicate and publish its own estimates, including supplementary ones.”

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(+) CRITERION A.3:
Acknowledges the Government's responsibility to ensure availability of narcotic drugs for medical and scientific purposes

(+) CRITERION A.5:
Represents the principle of Balance

Criterion also identified in:
Decreto Ejecutivo 320 de 2009, Considerando



Original Policy Language

DECRETO EJECUTIVO No. 178
(De 12 de julio de 2001)

Que reglamenta la Ley 1 de 10 de enero de 2001, Sobre Medicamentos y otros Productos para la Salud Humana

El PRESIDENTE DE LA REPÚBLICA, en uso de sus facultades constitucionales y legales,

CONSIDERANDO:

Que el 12 de enero de 2001, se publicó, en la Gaceta Oficial 24,218, la Ley 1 de 10 de enero de 2001, Sobre Medicamentos y otros Productos para la Salud Humana. Que el artículo 180 de la precitada Ley establece que entrará en vigencia transcurridos ciento ochenta días a partir de su promulgación, salvo los artículos que expresamente indiquen otra fecha de entrada en vigencia. Que el numeral 14 del artículo 179 de la Constitución Política preceptúa que es función del Presidente de la República con la participación del ministro respectivo, reglamentar las leyes que lo requieran para su mejor cumplimiento, sin apartarse en ningún caso de su texto o de su espíritu. Que el artículo 8 de la referida Ley 1 de 2001 establece que su interpretación y reglamentación deberá efectuarse necesariamente en estricta concordancia con los objetivos y principios enunciados en ella.

Que por lo tanto, es necesario reglamentar múltiples aspectos a los cuales hace referencia la Ley 1 de 10 de enero de 2001.

DECRETA:

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Título I

De las Definiciones y Competencias

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Capítulo III

Tasas por los Servicios que presta la Dirección Nacional de Farmacia y Drogas

Art. 5.

Se establecen nuevas tasas en concepto de servicios, las cuales deberán pagarse en la Dirección Nacional de Farmacia y Drogas, con la presentación de la solicitud respectiva, según se detalla a continuación:

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Licencia anual de operación de estupefacientes, psicotrópicos y precursores químicos de uso medicinal 25.00

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Formal Translation

EXECUTIVE DECREE No. 178
(from July 12, 2001)

Which regulates Law 1 from January 10, 2001, Concerning Medications and other Products for Human Health

THE PRESIDENT OF THE REPUBLIC, in exercise of his constitutional and legal authorities,

CONSIDERING:

That on January 12, 2001, Law 1 dated January 10, 2001, Concerning Medications and other Products for Human Health, was published in Official Gazette 24,218. That Article 180 of the afore mentioned Law establishes that it will go into effect one hundred and eighty days after its enactment, except for the Articles that expressly indicate another effective date. That numeral 14 of Article 179 of the Constitution establishes that it is the role of the President of the Republic, with the participation of the respective ministry, to regulate the laws that require it for their better fulfillment, without deviating in any case from their text or spirit. That Article 8 of the indicated Law 1 from 2001 establishes that its interpretation and regulation must necessarily be carried out in strict adherence to the objectives and principles enunciated in it.

That it is therefore necessary to regulate multiples aspects referred to in Law 1 dated January 10, 2001.

DECREES:

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Title I

Definitions and Competencies

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Chapter III

Fees for Services provided by the National Pharmacy and Drugs

Article 5.

Establishing new fees for services, which shall be paid in the National Pharmacy and Drugs, with the filing respectively, as detailed below:

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Annual operating license of narcotics, psychotropic substances and precursor chemicals for medicinal use 25.00

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**(-) CRITERION C.7:
Other provisions that may
impede pain management**

Category C: Other regulatory or policy issues

Comment: This provision seems to establish different licensing requirements depending on the healthcare facility.

Criterion also identified in:
Ley Numero 23 de 1954,
Artículo 4
Decreto Numero 524 de 1956



Original Policy Language

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TITULO III DE LA COMERCIALIZACIÓN

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CAPÍTULO VI DE LA CLASIFICACIÓN DE LOS PRODUCTOS FARMACÉUTICOS POR LA AUTORIDAD DE SALUD

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SECCIÓN 1 ASPECTOS GENERALES DE LA RECETA

Artículo 304. Toda receta deberá cumplir con los siguientes requisitos generales:

- a. Nombre de la institución de salud pública o privada o del médico que prescribe
- b. Nombre completo del paciente, edad y fecha de prescripción.
- c. Número de seguro social (opcional si lo tiene).
- d. Nombre genérico y comercial del producto (este último es opcional).
- e. Concentración o potencia, forma farmacéutica, vía de administración, cantidad, dosis del producto y días de tratamiento. La cantidad y dosis recetada debe coincidir con los días de tratamiento.
- f. Nombre completo, número de registro profesional, especialidad y teléfono del médico prescriptor. Estos datos deben estar escritos en letra imprenta legible o a través de un sello litografiado.
- g. Instrucciones de uso.
- h. Firma por puño y letra y con tinta del médico prescriptor.

- i. La receta institucional deberá llevar el sello de la unidad ejecutora donde se expide.

Parágrafo:

Se prohíbe colocar en la receta la frase "Uso indicado" o similar.

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SECCIÓN III DE LAS RECETAS DE SUSTANCIAS CONTROLADAS

Artículo 318. Las sustancias controladas son aquellas sustancias que están incluidas en los listados de los convenios internacionales de psicotrópicos, estupefacientes y sustancias utilizadas frecuentemente en la fabricación ilícita de estupefacientes y sustancias psicotrópicas y cualquiera otra sustancia que por su naturaleza el Ministerio de Salud decida someter a controles especiales.

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Formal Translation

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TITLE III On Marketing

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CHAPTER VI On Classification of Pharmaceutical Products By the Health Authority

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SECTION I General Aspects of the Prescription

Article 304. Every prescription must meet the following general requirements:

- a. Name of the prescribing public or private health institution or physician;
- b. Patient's full name, age, and date of prescription;

- c. Social security number (optional if he/she has one);
- d. Generic and commercial name of the product (the latter is optional);
- e. Concentration or potency, pharmaceutical form, route of administration, quantity, dose of product and days of treatment. The quantity and dose prescribed must match the days of treatment;
- f. Full name, professional registration number, specialization and telephone number of the prescribing physician. This information must be written in legible print or with a lithographic stamp;
- g. Instructions for use;
- h. Hand-made signature and printed name in ink of the prescribing physician; and
- i. The institutional prescription must bear a stamp from the executive entity where it is issued.

PARAGRAPH

It is prohibited to put the phrase "Indicated use" or anything similar on the prescription.

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SECTION III On Prescriptions for Controlled Substances

Article 318. Controlled substances are those substances that are included on the lists in international conventions on psychotropics, narcotics and substances frequently used in the illicit manufacture of narcotics and psychotropic substances, and any other substance which, due to its nature, the Ministry of Health decides to make subject to special controls

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(-) CRITERION C.5:
Practitioners are subject to undue prescribing requirements

Category D: Requirement for an additional prescribing authorization



Original Policy Language

Artículo 319. Las prescripciones de productos con contenido de psicotrópicos y estupefacientes deberán cumplir con los requisitos generales exigidos en esta reglamentación. Adicionalmente el farmacéutico que dispense el producto, está en la obligación de indicar en la parte de atrás de la receta el nombre comercial del producto que dispensó, su firma y número de registro.

Artículo 320. En el revés de todas las recetas dispensadas debe aparecer el nombre y el número de cédula de la persona que retira el producto.

Artículo 321. Ninguna farmacia privada o estatal dispensará las recetas de productos con contenido de psicotrópicos y estupefacientes después de pasadas cuarenta y ocho (48) horas de su prescripción.

Artículo 322. En el caso que el paciente no pueda comprar la totalidad del medicamento con contenido de psicotrópicos y estupefacientes indicada en la receta, se permitirá que la farmacia haga despacho parcial según la dosificación prescrita. La persona que recibe el producto deberá firmar en el revés de la receta las veces que retire el producto, indicando el número de la cédula, fecha y cantidad retirada. En cada retiro el farmacéutico debe firmar.

Artículo 323. Los productos con contenido de estupefacientes deben ser prescritos en los recetarios oficiales del Ministerio de Salud. Se exceptúan de esta disposición los productos que la Dirección Nacional de Farmacia y Drogas establezca mediante listado en resolución motivada, el cual proporcionará a las farmacias públicas y privadas. Las instituciones de salud estatales son las únicas exentas de utilizar las recetas oficiales del Ministerio de Salud, pero tendrán la obligación de incluir en las que utilicen tanto el color como la información de las reconocidas como oficiales.

Artículo 324. Las prescripciones de sustancias estupefacientes que deban ser aplicados por vía parenteral solo se despacharán para cuarenta y ocho (48) horas. Se exceptúan de esta disposición las recetas de los médicos oncólogos y anestesiólogos que prescriben para pacientes con cáncer, para los cuales se permitirá que la prescripción sea por diez (10) días.

Artículo 325. Las prescripciones de sustancias estupefacientes que deban ser aplicadas por cualquiera vía que no sea la parenteral podrán prescribirse por un total de diez (10) días, a excepción de los médicos oncólogos y anestesiólogos que receten para pacientes con cáncer, que podrán prescribir para un máximo de veinte (20) días.

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Formal Translation

Article 319. Prescriptions for products containing psychotropics and narcotics must meet the general requirements stated in this regulation. Furthermore, the pharmacist dispensing the product is obligated to indicate on the back of the receipt the commercial name of the product dispensed, his or her name and registration number.

Article 320. The name and identification number of the person retrieving the product must appear on the back of all filled prescriptions,

Article 321. No private or state pharmacy will fill prescriptions for products containing psychotropics or narcotics once forty-eight (48) hours have passed since they were prescribed.

Article 322. In the event that the patient cannot purchase the full amount of the medication containing psychotropics or narcotics indicated on the prescription, it is permitted for the pharmacy to partially fill it in accordance with the prescribed dosage. The person retrieving the product must sign the back of the prescription on the instances when he or she takes the product, indicating the identification number, date and amount taken. The pharmacist must sign upon each removal.

Article 323. Products containing narcotics must be prescribed on the official Ministry of Health prescription book forms. Products that the National Pharmacy and Drugs Office establishes by means of a list in a resolution stating its grounds, which it will provide to public and private pharmacies, are excepted from this provision. State health institutions are the only ones exempt from using the official Ministry of Health prescription forms, but they are obligated to include both the officially recognized color and information on the ones that they use.

Article 324. Prescriptions for narcotic substances that should be administered parenterally will only be filled for forty-eight (48) hours. Prescriptions from oncologists and anesthesiologists who are prescribing them for patients with cancer are exempted from this provision; it is permitted for the prescription to be for ten (10) days for these patients.

Article 325. Prescriptions for narcotic substances that should be administered by any route other than parenterally may be prescribed for a total of ten (10) days, with the exception of oncologists and anesthesiologists who are prescribing them for patients with cancer, who may prescribe them for a maximum of twenty (20) days.

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(-) CRITERION C.4: Length of prescription validity is restricted

Comment: Although the limit was increased from 48 hours to 5 days according to Decreto Ejecutivo 320 de 2009, a limit remains.

(+) CRITERION B.8: Other provisions that may enhance pain management

Category C: Issues related to patients

Comment: This provision allows for partial dispensing of prescriptions when the patient cannot afford the full amount of medication, as a means to provide at least partial treatment when the medications are available.

(-) CRITERION C.5: Practitioners are subject to undue prescribing requirements

Category A: Requirement to use special prescription forms

Criterion also identified in:
Ley Numero 23 de 1954, Art. 2 & 3
Decreto Numero 524 de 1956

(-) CRITERION C.3: Restrictions that could limit medical decision-making

Category A: Restrictions based on patient characteristics

Criterion also identified in:
Normativa 22-2001, Art. 4

(+) CRITERION B.8: Other provisions that may enhance pain management

Category A: Issues related to healthcare professionals

Comment: The provision provides an exemption from prescribing limits for certain practitioners. The exemption was increased from a maximum of 20 days to a maximum of 30 days according to Decreto Ejecutivo 320 de 2009, Artículo 3.



Original Policy Language

LEY No. 68 (De 20 de noviembre de 2003)
Que regula los derechos y obligaciones de los pacientes, en materia de información y de decisión libre e informada

LA ASAMBLEA LEGISLATIVA
DECRETA:

Capítulo V
Derecho de los Pacientes en Fase Terminal

Artículo 22. Toda persona que padezca una enfermedad irreversible, incurable y se encuentre en fase terminal, o haya sufrido un accidente que la coloque en igual situación y esté informada de forma clara y confiable de su diagnóstico, su pronóstico y de las alternativas de los tratamientos clínicos y/o quirúrgicos posibles, podrá oponerse a la aplicación de estos, cuando sean extraordinarios o desproporcionados a las perspectivas de mejoría y produzcan dolor y/o sufrimiento.

La información será brindada por el profesional médico, en términos claros y adecuados a su nivel de comprensión y estado psíquico, de acuerdo con la personalidad del paciente, a efecto de que al prestar su consentimiento lo haga debidamente informado. En todos los casos, deberá dejarse constancia por escrito, con las firmas de ambas partes.

Cuando se trate de incapaces o personas imposibilitadas para prestar su consentimiento, se habilitará la vía judicial para que el juez competente, en un término perentorio de 72 horas, verifique o determine la representación legal del enfermo a este solo efecto, siendo quien revista tal carácter quien podrá asumir la decisión de oponerse de acuerdo con lo prescrito en el primer párrafo del presente artículo.

Artículo 23. El equipo de salud actuante de toda unidad hospitalaria deberá mantener aquellas medidas que permitan la mejor calidad de vida posible del paciente, hasta su fallecimiento, para lo cual deberá contar con unidades operativas de cuidados paliativos.

Los centros de atención primaria ofrecerán los cuidados paliativos prolongados, que garanticen la mejor calidad de vida y alivio del dolor mediante la atención del personal médico de que dispongan.

Continued on next page

Formal Translation

LAW No. 68 (From November 20, 2003)
Which regulates the rights and obligations of patients with regard to information and free and informed decision

THE LEGISLATURE
Decreets:

Chapter V
Rights of Patients in Terminal Stage

Article 22. Every person with an irreversible, incurable illness in its terminal phase or had suffered an accident that put in the same situation and be informed in a clear and reliable form regarding his diagnosis, prognosis and possible clinical or surgical treatment alternatives, may oppose the application of these, if they are extraordinary, or disproportionate to the prospects of improvement and cause pain and/or suffering.

The information will be provided by the medical professional, in clear and appropriate terms to their level of understanding and mental state, according to the patient's personality, in order that to give their fully informed consent to do so. In all cases, there must be a recorded constancy in writing, with the signatures of both parties.

In the case of persons unable or incapable to give consent, will enable the legal course to the competent judgment within a fixed period of 72 hours, in order for him to verify or determine the legal representative of the patient in this single effect, being who is invested with such a character who can make the decision to object in accordance with the requirements stated in the first paragraph of this article.

Article 23. The health team acting in every hospital unit must maintain those measures that allow the best quality of life possible for the patient, until his death, so it must have operating units for palliative care.

Primary care centers will offer long-term palliative care, to guarantee the best quality of life and pain relief by means of care from the medical personnel available to them.

Continued on next page

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy issues

Comment: Establishes a mechanism (practitioner obligation to provide information) to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.

(+) CRITERION B.8:
Other provisions that may enhance pain management

Category A: Issues related to healthcare professionals

Comment: Establishes a mechanism (health team) for healthcare facilities to ensure that palliative care (which includes pain management) is an essential part of care for patients with a terminal illness.

(+) CRITERION B.2:
Pain management is recognized as part of general healthcare practice

Comment: Although this provision relates specifically to palliative care, pain management is part of palliative care.

(+) CRITERION B.1:
Patients have a right to pain management

Comment: Although this provision relates specifically to palliative care, pain management is part of palliative care.

Criterion also identified in:
Decreto Ejecutivo 1458 de 2012



Original Policy Language

Continued from previous page

Artículo 24. Para la aplicación del artículo 22, serán necesarios los siguientes requisitos:

1. Que el paciente esté en uso de sus facultades mentales, excepto que se den las situaciones previstas en el último párrafo del artículo 22;
2. Que la oposición se realice mediante un documento escrito donde conste su voluntad;
3. Que la decisión haya sido tomada libremente;
4. Que, agotados los medios conocidos de diagnóstico, se concluya que la enfermedad o accidente que lo haya colocado en igual situación, es irreversible, incurable y se encuentra en fase terminal, conforme al dictamen de una junta médica, integrada por lo menos por dos especialistas en la enfermedad de que se trate.
5. Que un psiquiatra evalúe que se dan las condiciones previstas en los numerales 1 y 3.

Artículo 25. Se considerará enfermedad irreversible, incurable y en fase terminal a la enunciada en el diagnóstico del profesional médico que atienda al paciente, juntamente con el producido por la junta médica de especialistas en la afección que se trata, en el que deberá especificarse que, razonablemente y en condiciones normales, se producirá la muerte del paciente.

Artículo 26. El profesional médico acatará la decisión del paciente a oponerse a los tratamientos médicos o quirúrgicos, cuando sean extraordinarios o desproporcionados a las perspectivas de mejoría y produzcan dolor y/o sufrimiento, previo cumplimiento de las siguientes condiciones:

1. Que le haya informado al paciente o al representante legal, cuando se tratare de incapaces o personas imposibilitadas para prestar su consentimiento, sobre la naturaleza de su enfermedad o características del accidente, y su probable evolución, así como el tratamiento médico aconsejado, incluyendo asesoramiento y apoyo psiquiátrico, y las medidas adecuadas y disponibles para mantenerlo con vida.
2. Que la oposición sea firmada por el interesado o, en caso de imposibilidad física de este, por otra persona que él designe, ante el profesional médico interviniente, junto con dos testigos que no sean parientes del paciente hasta el cuarto grado de consanguinidad, o sus beneficiarios testamentarios o de un seguro de vida.

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Formal Translation

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Article 24. For the application of Article 22 shall need the following requirements:

1. The patient should be in use of his mental faculties, except that the situations provided in the last paragraph of Article 22 are given;
2. That opposition is made by a written document stating their will;
3. That decision has been taken freely;
4. That exhausted the known means of diagnosis, it is concluded that the disease or accident that has placed in the same situation, is irreversible, incurable and terminal in accordance with the opinion of a medical board, consisting of at least two disease specialists concerned.
5. That a psychiatrist evaluates the conditions laid down in paragraphs 1 and 3.

Article 25. Disease is considered irreversible, incurable and terminally ill, those mentioned in the diagnosis of the medical professional providing treatment, together with the proceeds by the medical board of experts in the condition being treated, which must be specified that reasonably and under normal conditions, will result in death of the patient.

Article 26. The medical doctor will accept the decision of the patient to object to medical or surgical treatment, when they are extraordinary or disproportionate to the prospects of improvement and cause pain and/or suffering, subject to fulfillment of the following conditions:

1. It has informed the patient or legal representative, as the case of incapable or persons unable to give consent, on the nature of their accident or disease characteristics, and its likely evolution as well as the recommended medical treatment, including counseling and psychiatric support, and appropriate and available measures to sustain life.
2. That objection is signed by the applicant or, in the case of physical impossibility of him or her, by the person designated by him or her, at the intervening medical professional, along with two witnesses who are not the patient's relatives to the fourth degree of consanguinity, or its beneficiaries of wills or life insurance.

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Original Policy Language

Continued from previous page

En el caso de incapaces o personas imposibilitadas para prestar su consentimiento, la oposición será firmada por sus representantes legales.

3. Cuando resulte necesaria la intervención de un intérprete o traductor para la adecuada firma de la oposición, esta también debe ser suscrita por ellos, con expresa mención de que el paciente ha comprendido correctamente su contenido.

En caso de no existir intérprete o traductor adecuado, se recurrirá a la persona que se considere más idónea para el caso, dándose debida cuenta a la autoridad consular respectiva, cuando ello corresponda.

Artículo 27. El que hubiere intervenido como testigo estando incluido en las limitaciones previstas por el numeral 2 del artículo anterior, será sancionado de conformidad con las normas del Código Penal.

Artículo 28. Firmada la oposición de conformidad a la presente Ley, el profesional médico archivará en el expediente clínico del paciente la siguiente documentación:

1. Diagnóstico de la enfermedad del paciente o accidente sufrido por él;
2. Dictamen establecido en los numerales 4 y 5 del artículo 24;
3. Original del documento escrito donde consta la oposición.

Artículo 29. La oposición podrá ser revocada en cualquier tiempo y en forma fehaciente ante el profesional médico interviniente.

Artículo 30. Los derechos y obligaciones resultantes de hechos y actos existentes con anterioridad a la vigencia de la presente Ley, no estarán condicionados ni limitados por la presentación o revocación de la oposición.

Artículo 31. Ningún profesional interviniente que haya actuado de acuerdo con las disposiciones de la presente Ley, estará sujeto a responsabilidad civil, penal ni administrativa.

Artículo 32. Se prohíbe el ejercicio de la eutanasia.

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Formal Translation

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For people disabled or unable to give consent, the opposition will be signed by their legal representatives.

3. When intervention needed an interpreter or translator for proper firm opposition, this also must be signed by them, specifically mentioning the patient has correctly understood its content.

In the case that there is no adequate interpreter or translator available, the person who is deemed most suitable for the case will be used, giving due consideration to the consular authority respectively, when this is correspond.

Article 27. The witness who had intervened as being included in the limitations provided by paragraph 2 of the preceding article shall be punished in accordance with the rules Penal Code.

Article 28. Signed the opposition pursuant to this Act, the physician will file in the patient's medical record the following documents:

1. Diagnosis of the patient's illness or accident suffered by him;
2. Opinion established in paragraphs 4 and 5 of Article 24;
3. Original written document where the opposition is clear.

Article 29. The opposition may be revoked at any time and in an authentic way in the presence of the intervening medical professional.

Article 30. The rights and obligations arising from existing facts and events prior to the enactment of this Act, shall not be conditioned or limited by the presentation or revocation of the opposition.

Article 31. No professional intervener who has acted in accordance with the provisions of this Act, shall be subject to civil, criminal or administrative responsibility.

Article 32. It prohibits the practice of euthanasia.

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Original Policy Language

REPUBLICA DE PANAMÁ
MINISTERIO DE SALUD
DECRETO EJECUTIVO No.320
(De 17 de junio de 2009)

"Por el cual se modifican los artículos 321, 324 y 325, del Decreto Ejecutivo 178 de 12 de julio de 2001, referentes a las recetas de sustancias controladas"

EL PRESIDENTE DE LA REPUBLICA,

en uso de sus facultades constitucionales y legales,

CONSIDERANDO:

Que el numeral 14 del artículo 184 de la Constitución Política preceptúa que es atribución del Presidente de la República con la participación del Ministro respectivo, reglamentar las leyes que lo requieran para su mejor cumplimiento, sin apartarse en ningún caso de su texto ni de su espíritu.

Que la Ley 1 de 10 de enero de 2001 "Sobre Medicamentos y otros Productos para la Salud Humana", en su artículo 8 establece que su interpretación y reglamentación deberá efectuarse necesariamente en estricta concordancia con los objetivos y principios enunciados en ella.

Que la Organización Mundial de la Salud (OMS) y la Junta Internacional de Fiscalización de Estupefacientes (JIFE) continúan instando a los gobiernos del mundo a modificar las normativas relacionadas a prescripción y dispensación de opioides de forma que exista un balance entre el acceso a estos medicamentos, considerados esenciales, y las medidas de control para evitar el abuso de las mismas.

Que según las estadísticas de la Junta Internacional de Fiscalización de Estupefacientes (JIFE) de los últimos años la cuota internacional de Panamá de consumo de opioides es inferior a la cuota mundial.

Que el dolor de moderado a severo que requiere para su alivio de morfina y otros opioides clasificados como estupefacientes, está presente en distintas condiciones médicas incluyendo el cáncer.

Que según el Registro Nacional del Cáncer, de los años 2003, 2004 y 2005, reflejan una tendencia de casi 5 mil casos nuevos de cáncer cada año.

Que anualmente se registran, en todo el territorio nacional, un incremento de nuevos casos de pacientes afectados de otras condiciones médicas que requieren del uso de opioides.

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Formal Translation

REPUBLIC OF PANAMA
MINISTRY OF HEALTH
EXECUTIVE DECREE No. 320
(from June 17, 2009)

"By which Articles 321, 324, and 325 of Executive Decree 178 from July 12, 2001, regarding prescriptions for controlled substances, are amended."

THE PRESIDENT OF THE REPUBLIC,

in exercise of his constitutional and legal powers,

CONSIDERING:

That numeral 14 of Article 184 of the Political Constitution establishes that it is the responsibility of President of the Republic, with the participation of the respective Ministry, to regulate the laws that require it for their better fulfillment, without deviating in any case from their text or spirit.

That Law 1 from January 10, 2001, "Concerning Medications and other Products for Human Health", in Article 8, establishes that its interpretation and regulation must necessarily be carried out in strict adherence to the objectives and principles stated therein.

That the World Health Organization (WHO) and the International Narcotics Control Board (INCB) continue to urge the governments of the world to amend the regulations related to the prescription and dispensation of opioids so that there is a balance between access to these medications, which are considered essential, and control measures to prevent their abuse.

That according to statistics from the International Narcotics Control Board (INCB) from the last few years, Panama's international quota for opioid consumption is lower than the global quota.

That moderate to severe pain that requires morphine and other opioids classified as narcotics for its relief is present in various medical conditions, including cancer.

That according to the National Cancer Registry for the years of 2003, 2004, and 2005, there is a trend of almost 5 thousand new cases of cancer every year.

That every year an increase in new cases of patients within the entire national territory who are affected by other medical conditions that require the use of opioids is recorded.

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(-) CRITERION A.4:
Recognizes the medical use of controlled substances as indispensable for the relief of pain and suffering, including being necessary for the public health



Original Policy Language

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Que la Ley 68 de 20 de noviembre de 2003, "Que regula los Derechos y Obligaciones de los Pacientes en Materia de Información y de Decisión Libre e Informada", en el Capítulo V "Derechos de los Pacientes en Fase Terminal", artículo 23, señala que el equipo de salud de toda unidad hospitalaria deberá mantener aquellas medidas que permitan la mayor calidad de vida posible del paciente, hasta su fallecimiento, para lo cual deberá contar con unidades operativas de cuidados paliativos y que los centros de atención primaria ofrecerán los cuidados paliativos prolongados, que garanticen la mejor calidad de vida y alivio del dolor mediante la atención del personal médico de que dispongan.

Que la única Unidad de Cuidados Paliativos que a la fecha existe como tal se ubica en el Instituto Oncológico Nacional.

Que no solo los anestesiólogos y oncólogos prescriben opioides para aliviar dolor por cáncer o dolor producido en enfermedades fuera de tratamiento curativo.

Que el Decreto 178 de 12 de julio de 2001, que reglamenta la Ley 1 de 10 de enero de 2001, establece en su artículo 321, un período para la dispensación de productos con contenido de psicotrópicos y estupefacientes de solo cuarenta y ocho (48) horas, término que resulta insuficiente para que el paciente pueda obtener los señalados medicamentos.

Que el artículo 324 del referido Decreto Ejecutivo, dispone que las prescripciones de sustancias estupefacientes quedaban ser aplicadas por vía parenteral solo se despacharán para cuarenta y ocho (48) horas y que se exceptúan de esta disposición las recetas de los médicos oncólogos y anestesiólogos que prescriben para pacientes con cáncer, para los cuales se permitirá que la prescripción sea por diez (10) días.

Que el término de cuarenta y ocho (48) horas señalado en el artículo 324, resulta insuficiente para el manejo de dolor por vía oral y que otros profesionales de la medicina proveen servicios vinculados al manejo del dolor a nivel nacional.

Que el término de diez (10) días señalado en el artículo 324, es inferior a la frecuencia quincenal de pagos de salarios y por lo tanto establece una limitación en el acceso a los estupefacientes utilizados en el manejo de dolor crónico.

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Formal Translation

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That Law 68 from November 20, 2003, "Which Regulates the Rights and Obligations of Patients with Regard to Information and Free and Informed Decision," in Chapter V, "Rights of Patients in Terminal Phase," Article 23 indicates that the health team in every hospital unit must maintain those measures that allow for the best quality of life possible for the patient, until their death, so it must have operating units for palliative care and that primary care centers will offer long-term palliative care, to guarantee the best quality of life and pain relief by means of care from the medical personnel available to them.

That the only Palliative Care Unit that currently exists as such is located in the National Oncological Institute.

That not only anesthesiologists and oncologists prescribe opioids to relieve pain caused by cancer or pain caused by incurable diseases.

That Decree 178 from July 12, 2001, which regulates Law 1 from January 10, 2001, establishes in Article 321 a period for the dispensation of products containing psychotropics and narcotics of only forty-eight (48) hours, a period that is insufficient for the patient to be able to obtain the indicated medications.

That Article 324 of the aforementioned Executive Decree establishes that prescriptions for narcotic substances that must be administered parenterally will only be filled for up to forty-eight (48) hours and that prescriptions from oncologists and anesthesiologists prescribing them to patients with cancer are exempted from this provision, for whom it is permitted for the prescription to be for ten (10) days.

That the forty-eight (48) hour period mentioned in Article 324 is insufficient for pain management by this route and that other medical professionals provide services connected to pain management at a national level.

That the ten (10) day period indicated in Article 324 is less than the two-weekly frequency of salary payment and therefore establishes a limitation in access to the narcotics used in the management of chronic pain.

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy issues

Comment: These provisions acknowledge potential treatment barriers contained in other laws.



Original Policy Language

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Que el Decreto Ejecutivo 178 de 12 de julio de 2001, establece en su artículo 325 que las prescripciones de substancias estupefacientes que deban ser aplicadas por cualquiera vía que no sea la parenteral, podrán prescribirse por un total de diez (10) días y que se exceptúan de esta disposición las recetas de los oncólogos y anesthesiólogos, que receten para pacientes por cáncer, los cuales podrán prescribir por un máximo de veinte (20) días.

Que el término de diez (10) días señalado en el artículo 325, resulta insuficiente para el manejo de dolor por cualquiera otra vía que no sea la parenteral y que otros profesionales de la medicina proveen servicios vinculados al manejo del dolor a nivel nacional.

Que el término de veinte (20) días señalado en el artículo 325, es inferior a la frecuencia quincenal de pagos de salarios y por lo tanto establece una limitación en el acceso a los estupefacientes utilizados en el manejo de dolor crónico.

Que el Gobierno de Panamá ha demostrado su interés en seguir las indicaciones de la Organización Mundial de la Salud (OMS) y la Junta Internacional de Fiscalización de Estupefacientes (JIFE) con las modificaciones realizadas a la normativa que regulaba hasta el año 2001, la prescripción y dispensación de opioides, las mismas fueron plasmadas en los artículos 321, 324 y 325 del Decreto 178 de 12 de julio de 2001.

Que es necesario realizar una nueva modificación, en los tiempos señalados, para la prescripción y dispensación de opioides y facultar a otros profesionales de la medicina para que puedan prescribir estupefacientes por quince (15) días cuando se trate de la vía parenteral y por treinta (30) días para estupefacientes administrados por cualquiera otra vía.

DECRETA:

Artículo 1. El artículo 321 del Decreto Ejecutivo 178 de 12 de julio de 2001, queda así:

Artículo 321. Ninguna farmacia privada o estatal dispensará las recetas de productos con contenido de psicotrópicos y estupefacientes indicada en la receta después de pasados cinco (5) días de su prescripción.

Artículo 2. El artículo 324 del Decreto Ejecutivo 178 de 12 de julio de 2001, queda así:

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Formal Translation

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That Executive Decree 178 from July 12, 2001 establishes in Article 325 that prescriptions for narcotic substances that should be administered by any route other than parenterally may be prescribed for a total of ten (10) days and that prescriptions by oncologists and anesthesiologists prescribing them to cancer patients are exempted from this provision, being able to prescribe for a maximum of twenty (20) days.

That the ten (10) day period mentioned in Article 325 is insufficient for pain management by any other route and that other medical professionals provide services connected to pain management at a national level.

That the twenty (20) day period indicated in Article 325 is less than the two-weekly frequency of salary payment and therefore establishes a limitation in access to the narcotics used in the management of chronic pain.

That the Government of Panama has demonstrated its interest in following the instructions of the World Health Organization (WHO) and the International Narcotics Control Board (INCB) with the amendments made to the regulations that were in force until the year 2001, prescription and dispensation of opioids, which were given in Articles 321, 324, and 325 of Decree 178 from July 12, 2001.

That it is necessary to make a new amendment to the times indicated for the prescription and dispensation of opioids, and to authorize other medical professionals so that they may prescribe narcotics for fifteen (15) days when for parenteral administration and for thirty (30) days for narcotics administered by any other route.

DECREES:

Article 1. Article 321 of Executive Decree 178 from July 12, 2001, is as follows:

Article 321. No private or state pharmacy will fill prescriptions for products containing psychotropics or narcotics indicated on the prescription once five (5) days have passed since they were prescribed.

Article 2. Article 324 of Executive Decree 178 from July 12, 2001, is as follows:

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(+) CRITERION B.8:
Other provisions that may enhance pain management

Category C: Other regulatory or policy issues

Comment: These provisions acknowledge potential treatment barriers contained in other laws.

(-) CRITERION C.4:
Length of prescription validity is restricted

Comment: Although this limit was increased from 48 hours (in Decreto Ejecutivo 178 de 2001) to 5 days, a limit remains.



Original Policy Language

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Artículo 324. Las prescripciones de sustancias estupefacientes que deban ser aplicadas por vía parenteral solo sedespacharán para cinco (5) días. Se exceptúan de esta disposición las recetas de los médicos anesthesiólogos, oncólogos o Master en dolor y aquellos médicos que proveen cuidados paliativos, para los cuales se permitirá que estas prescripciones sean para un máximo de quince (15) días.

Artículo 3. El artículo 325 del Decreto Ejecutivo 178 de 12 de julio de 2001, queda así:

Artículo 325. Las prescripciones de sustancias estupefacientes que deban ser aplicadas por cualquiera vía que no sea laparenteral, podrán prescribirse por un total de quince (15) días. Se exceptúan de esta disposición las recetas de los médicos anesthesiólogos, oncólogos, ortopedas o master en dolor y aquellos médicos que proveen cuidados paliativos, para los cuales se permitirá que estas prescripciones sean para un máximo de treinta (30) días.

Artículo 4. El presente Decreto Ejecutivo modifica los artículos 321, 324 y 325 del Decreto Ejecutivo 178 de 12 de Julio de 2001.

Artículo 5. El presente Decreto Ejecutivo entrará en vigencia a partir de su promulgación en la Gaceta Oficial.

Dado en la Ciudad de Panamá, a los 17 días del mes de junio del año dos mil nueve (2009).

Formal Translation

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Article 324. Prescriptions for narcotic substances that should be administered parenterally will only be filled for five (5) days. Exempt from this provision are prescriptions from anesthesiologists, oncologists or pain specialists and physicians who provide palliative care, who are permitted to prescribe for a maximum of fifteen (15) days.

Article 3. Article 325 of Executive Decree 178 from July 12, 2001, is as follows:

Article 325. Prescriptions for narcotic substances that must be administered by any route other than parenterally may be prescribed for a total of fifteen (15) days. Exempt from this provision are prescriptions by anesthesiologists, oncologists, orthopedists or pain specialists and physicians who provide palliative care, who are permitted to prescribe for a maximum of thirty (30) days.

Article 4. This Executive Decree amends Articles 321, 324 and 325 of Executive Decree 178 from July 12, 2001.

Article 5. This Executive Decree will go into effect upon being published in the Official Gazette.

Issued in Panama City on the 17th of the month of June in the year two thousand nine (2009).

(-) CRITERION C.3: Restrictions that could limit medical decision-making

Category C: Restrictions regarding quantity prescribed or dispensed

Comment: Although this limit was increased from 10 days (in Decreto Ejecutivo 178 de 2001, Artículo 3) to 15 days, a limit remains.

(+) CRITERION B.8: Other provisions that may enhance pain management

Category A: Issues related to healthcare professionals

Comment: The provision provides an exemption from prescribing limits for certain practitioners. The exemption was increased from a maximum of 20 days (in Decreto Ejecutivo 178 de 2001, Artículo 3) to a maximum of 30 days.



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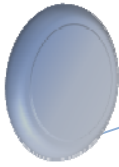
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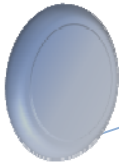
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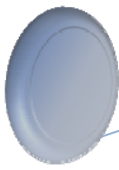
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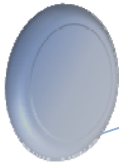
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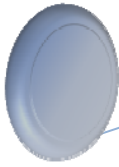
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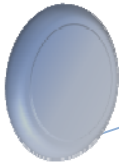
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APPENDIX A: ENSURING MEDICATIONS FOR LEGITIMATE PURPOSES SHOULD NOT ESCALATE DIVERSION

The principal aim of the Single Convention of Narcotic Drugs of 1961 is reducing drug abuse, which is accomplished largely by limiting the trade in and use of controlled drugs exclusively to medical and scientific purposes (United Nations, 1961). Also inherent in this international treaty is the clear recognition about the indispensability of medications for the relief of pain and suffering, and that medications should be available for such purposes. As a result, since the time of its promulgation there has been increasing acknowledgement of what has been characterized as the dual purposes of the Single Convention: To achieve effective drug control while promoting safe and appropriate medical and scientific use of medications (United Nations Commission on Narcotic Drugs, 2011b). In the late 1990s, Hamid Ghodse, then President of the INCB, gave voice to the importance of achieving both objectives – accomplishing one at the expense of the other creates an inequitable situation.

“There are two other elements in the 1972 Protocol which should be mentioned: (a) The 1961 Convention was amended by demand reduction provisions which were patterned after the respective provisions of the 1971 Convention; (b) The provisions of the 1961 Convention, intended to limit the availability of narcotic drugs to medical and scientific purposes, were supplemented by the obligation of parties to ensure the availability of those drugs for such purposes. Both amendments are very important. First, because they reflect the realization that without the reduction of illicit demand, supply reduction measures will bring temporary results only, and, second, one of the basic principles of international drug control is that reduction in the availability of drugs for non-medical purposes should not affect and limit their therapeutic use.” (Bayer & Ghodse, 1999, p. 12)

Importantly, this was not the first time that the INCB addressed the conceptual framework intrinsic to the Single Convention. The INCB (International Narcotics Control Board, 1996) earlier established the context for Bayer and Ghodse’ statement, to support the principle of sufficiently achieving these dual purposes:

“The Board is responsible for ensuring that the supply of narcotic drugs for licit purposes is limited exclusively to the amount needed for medical and scientific needs. To prevent and detect diversion of narcotic drugs from licit to illicit channels, the Board monitors the cultivation, manufacture, import, export and consumption of such drugs in the world. If the treaty requirements for drug control are implemented consistently, the potential for diverting narcotic drugs to illicit channels is reduced to a minimum without interfering in their availability for medical treatment of patients who need them. The international system to prevent diversion of narcotic drugs is working well. The number of incidents involving diversion of narcotic drugs is small considering the large number of transactions at the international and national levels.” (¶12)

“The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes. A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licenses, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (¶148)



APPENDIX A: ENSURING MEDICATIONS FOR LEGITIMATE PURPOSES SHOULD NOT ESCALATE DIVERSION

Numerous times the INCB has substantiated the general effectiveness, globally, of countries' drug control activities. A 2008 statement (International Narcotics Control Board, 2009) is provided as an example:

"The system of control measures laid down in the 1961 Convention provides effective protection of international trade in narcotic drugs against attempts at their diversion into illicit channels. In 2008, as in recent years, no cases of diversion of narcotic drugs from licit international trade into the illicit traffic were detected." (¶69)

In 2010, the INCB was invited by the Commission on Narcotic Drugs (CND) to report on the availability of internationally-controlled substances for medical requirements. To meet that request, the INCB, in addition to its 2010 annual report, issued a supplemental report with the goal to improve availability of internationally-controlled medications for medical and scientific purposes (International Narcotics Control Board, 2011). Even with the objective of issuing recommendations that continue to promote a balance between ensuring medication availability and preventing their abuse and diversion, the report focused on instances where this balance has been unsuccessful – specifically, when *excessive availability* has led to controlled medications being diverted into illicit channels, which can contribute directly to non-medical use, adverse events, and overdose deaths.

"Data collected by Governments suggest that abuse patterns are related to excessive overall availability of the pharmaceutical preparations containing these substances. In particular, countries with already elevated levels of consumption of narcotic drugs and psychotropic substances that experience further significant increases should be vigilant to determine whether these increases are related to actual medical requirements or to their misuse and abuse..." (¶108)

"Abuse of prescription drugs can be as dangerous as abuse of illicit drugs...Since excessive availability is often the first step towards increasing abuse of prescription drugs, drug control regulators need to be vigilant with regard to high consumption levels of narcotic drugs and psychotropic substances." (¶110)

"The channels of supply of abused prescription drugs vary, but, in principle, once they have left the officially controlled supply channels they are to be found in a "parallel market" of sometimes significant dimensions. In many countries, unregulated drug markets called "street markets" operate in parallel to or often in the absence of licensed pharmacies. The reasons for purchasing medications on such street markets are often related to economic factors or to an insufficient supply through official channels. Illegally operating Internet pharmacies are another kind of parallel market. As in street markets, customers can obtain internationally controlled drugs such as benzodiazepines, opioids, stimulants and barbiturates without a prescription. The supplies for these markets are often diverted or stolen products, or unregistered, substandard or counterfeit medications." (¶117)

"The Board has always emphasized that the efforts to limit the use of narcotic drugs and psychotropic substances to medical and scientific purposes must not adversely affect their availability for such purposes. On the other hand, increasing the use of certain controlled drugs for legitimate medical purposes needs thorough monitoring. Careful attention has to be given to ensuring the legitimate absorption capacity of countries and the proper functioning of safeguard mechanisms in order to minimize misuse and leaks in the system..." (¶131)



APPENDIX A: ENSURING MEDICATIONS FOR LEGITIMATE PURPOSES SHOULD NOT ESCALATE DIVERSION

The INCB Supplemental Report included an entire section delineating recommendations. The series of recommendations outlined ways to improve the legitimate availability of opioids, to ensure the safe and appropriate use of these medications, and to enhance the effectiveness of national drug control systems, as well as to continue the INCB's efforts in monitoring its responses to these recommendations. Importantly, the INCB also provided the following separate list of methods for Governments to prevent diversion and abuse (International Narcotics Control Board, 2011):

(v) Governments should enforce existing legislation to ensure that narcotic drugs and psychotropic substances are not illegally manufactured, imported or exported and are not diverted to the unregulated market;

(w) Governments should collect data on the abuse of prescription drugs in a more systematic manner and include in their national surveys on drug abuse, as far as possible, pharmaceuticals containing narcotic drugs and psychotropic substances, by including either specific groups of substances or specific narcotic drugs and psychotropic substances, as required;

(x) Considering the international nature of the problem and to complement the efforts of law enforcement in individual countries in the above-mentioned areas, Governments, as well as regional and international organizations, should develop intergovernmental agreements for effective joint operations and arrangements and standards to be applied at the regional level;

(y) Governments should take prompt and effective action to implement previous recommendations of the Board on Internet trading and on the misuse of the mail for smuggling of internationally controlled substances. (¶132)

At the same time as the INCB's governmental call to action, a 2010 resolution from the UN Economic and Social Council (ECOSOC) echoed similar messages within a context of "promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse" (United Nations Economic and Social Council, 2010), p. 1):

"Acknowledging that an increase in the licit supply of internationally controlled substances may raise the diversion and abuse of those substances and that in its annual reports for 2008 and 2009, the International Narcotics Control Board encouraged Governments to increase their vigilance regarding trafficking in and abuse of prescription drugs containing internationally controlled substances and consider enacting enhanced laws to counter trafficking in such prescription drugs," (p. 2)

"Noting the medical and scientific needs for internationally controlled substances worldwide to be met within a regulatory and legal framework that prevents their diversion and abuse, (p. 2)

"Encourages Member States to regularly examine, and report to the International Narcotics Control Board for inclusion in its annual report, trends in their countries on the use of internationally controlled licit substances for medical and scientific purposes, as well as trends in the diversion of, trafficking in and abuse of those substances and to take appropriate action, if necessary;" (p. 3)



APPENDIX A: ENSURING MEDICATIONS FOR LEGITIMATE PURPOSES SHOULD NOT ESCALATE DIVERSION

The year after the ECOSOC resolution, a Discussion Paper prepared for the 54th session of the CND offered clear support for a country needing both to establish effective drug control measures and also to maintain legitimate medication availability (United Nations Commission on Narcotic Drugs, 2011a). Such efforts conform to the Single Convention, which allows Governments considerable flexibility in developing appropriate control mechanisms that provide the best balance between medication access and control.

“While the rational use of opioids is essential to health, they can produce negative health consequences and secondary effects that can be particularly serious in cases of misuse and abuse, such as sleep apnoea, constipation, decreased sexual hormone levels leading to osteoporosis, sedation (car and workplace accidents), nausea, loss of judgement and sometimes fatal overdose (respiratory depression and death). Health professionals must monitor adverse effects and indications of misuse especially amongst patients with history of misuse.” (¶11)

“The reason that opioids are controlled under the international drug control Conventions is the harm associated with misuse and abuse. As the Commission affirmed in Resolution 53/4, the Conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse. Both sides of this balance — ensuring availability and preventing diversion and abuse — are concerned with the protection and promotion of health and public safety. As the World Health Organization (WHO) states, the public health outcome is “at its maximum” when “the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use.” (¶13)

“This recognition of the international drug control Conventions as concerned primarily with health was articulated by the former Executive Director of the United Nations Office on Drugs and Crime (UNODC), in his report to the review of the twentieth special session of the General Assembly, in which he said ‘we must bring public health — the first principle of drug control — back to centre stage’ and ‘drug control, and the implementation of the drug Conventions, must proceed with due regard to health and human rights.” (¶14)

“The control provisions of the Conventions are designed 1) to ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and 2) to combat illicit manufacture, trade and distribution. They are designed to serve what the INCB has described as the overall goal of a “well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances” namely “to provide relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, to prevent the diversion of drugs for the purpose of abuse.” (¶32)



APPENDIX A: ENSURING MEDICATIONS FOR LEGITIMATE PURPOSES SHOULD NOT ESCALATE DIVERSION

In addition, the CND-related Discussion Paper proffered a list of recommendations designed to help bring into alignment the dual purposes of preventing opioid diversion and abuse while maintaining or enhancing legitimate availability, which is outlined below. Many of these recommendations extend beyond merely the identification and modification of legislative and regulatory policy, to include promoting inter-agency cooperation, providing education for healthcare professionals, providing technical assistance to countries, and strengthening activities meant to reduce prescription medication diversion (United Nations Commission on Narcotic Drugs, 2011a):

- “(b) Review and revise national legislation, regulation and policies, in order to ensure that they reflect a balance between ensuring availability and preventing diversion and abuse, including by identifying and removing overly restrictive provisions which unnecessarily impede availability;
- (d) Stimulate inter-agency coordination and cooperation between relevant government ministries and agencies, including health, drug regulation, law enforcement, justice and customs, to facilitate the sharing of information and to ensure the implementation of balanced laws, regulations, policies and programmes;
- (e) Establish national committees and workshops on pain treatment and palliative care that bring together relevant government personnel, medical and pharmaceutical stakeholders, and patients’ and families’ representatives, to facilitate the sharing of information and better coordination of regulatory, medical and pharmaceutical practices affecting access to and control of opioid analgesics;
- (f) Provide training to medical doctors, nurses, pharmacists and health-care professionals concerning the treatment of pain, methods to prevent the misuse of opioid analgesics, the balance between ensuring availability and preventing diversion and abuse, and the most common misunderstandings about the use of opioid analgesics. Such training should be included in both health-care professional university curricula and ongoing professional education;
- (i) Provide Member States, particularly low- and middle-income countries, with the necessary technical assistance, and the necessary instruments including model laws, to facilitate the implementation of a better balance between ensuring availability of opioid analgesics and preventing diversion and abuse;
- (j) Reinforce existing monitoring mechanisms, and assist low- and middle income countries to develop systematic supervision systems — including electronic monitoring systems — enabling the detection of illegal manufacture, overprescription, unjustified sale or supply, and diversion;
- (l) Increase the monitoring of internet trading and delivery of controlled medications by mail and dismantle illegal delivery channels;
- (m) Engage civil society and relevant nongovernmental organizations, as appropriate, in activities designed to enhance availability of opioid analgesics and prevent their diversion and abuse.” (¶47)

These suggested actions, as well as the above historical statements from the INCB and other ECOSOC resources, reaffirm the importance of both maintaining efforts to reduce abuse and diversion, while at the same time assuring adequate access to medications for medical and scientific purposes. Reducing effective drug control as a means to enhance medication availability should be considered as unbalanced as achieving drug control by severely restricting legitimate availability. Clearly, governments recently have been urged to sustain focus on, and commit resources to, these two objectives through a variety of means. Ensuring this dual obligation, which corresponds to what the WHO terms a “quadruple imperative, which is based on legal, political, public health and moral grounds” (World Health Organization, 2011, p. 11), represents a means of conforming to international drug control conventions.



APPENDIX A: ENSURING MEDICATIONS FOR LEGITIMATE PURPOSES SHOULD NOT ESCALATE DIVERSION

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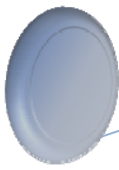
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The Morphine Manifesto

A call for affordable access to immediate release oral morphine.

On the Occasion of World Cancer Day 2012

Pallium India,

International Association for Hospice & Palliative Care (IAHPC),
Pain & Policy Studies Group, Univ of Wisconsin / WHO Collaborating
Center for Pain Policy and Palliative Care (PPSG),

African Palliative Care Association (APCA),
American Cancer Society (ACS),

Argentine Program of Palliative Medicine - Foundation FEMEBBA (PAMP-FF),
Asia Pacific Hospice Palliative Care Network (APHN),
Association for Palliative Medicine of Great Britain and Ireland (APM),

Cairdeas International Palliative Care Trust,
Centre for Palliative Care, Australia,
Centre for Palliative Care, Nigeria,

Danish Association for Palliative Medicine (DSPaM),
Eastern and Central Europe Palliative Care Task Force (ECEPT),
European Association for Palliative Care (EAPC)
(representing 48 national associations from 29 European countries),
European Society for Medical Oncology (ESMO),

Foundation for Hospices in Sub-Saharan Africa (FHSSA),
French Society of Palliative Care (SFAP),
German Association for Palliative Medicine,

Hellenic Society for Palliative and Symptomatic Care for Cancer
and Non Cancer Patients (HSPSCCNCP),
Help the Hospices (HtH),

Hong Kong Society for Palliative Medicine (HKSPM),
Hospice and Palliative Care Association of Nigeria (HPCAN),
Hospice of the Good Shepherd,

Hospice Palliative Care Association of South Africa (HPCA),
Hospice Unit, University College Hospital, Nigeria,
Human Rights Watch (HRW),

Hungarian Hospice Palliative Association (HHPA),
Indian Association for Palliative Care (IAPC),

Institute for Palliative Medicine at San Diego Hospice,
International Association for the Study of Pain (IASP),

International Children's Palliative Care Network (ICPCN),
International Network for Cancer Treatment and Research (INCTR),

International Observatory on End of Life Care (IOELC),
International Society of Nurses in Cancer Care (ISNCC),

Irish Association for Palliative Care (IAPC Irl), Italian Society of Palliative Care (SICP),
Kenya Hospices and Palliative Care Association (KEHPCA),

Latin America Association for Palliative Care (ALCP),
Latvian Palliative Care Association (PALL),

Lien Foundation,
LIVESTRONG,

Moroccan Society of Palliative Care,
Mozambique Palliative Care Association (MOPCA),
Norwegian Palliative Association (NPA),

Pain Relief and Palliative Care Society - Hyderabad (PRPCS),
Palliative Care Association of Malawi, Palliative Care Association of Uganda,
Palliative Care Australia, Polish Society of Palliative Medicine (PTMP),

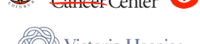
Portuguese Association for Palliative Care (APCP),
Qualy Observatory, WHO Collaborating Centre for Public Health Palliative Care Programs,
Catalan Institute of Oncology,

Romanian Palliative Care Association (ANIP),
Sobell House Hospice Charity, WHO Collaborating Centre for Palliative Care, Oxford,
Swedish Association of Palliative Medicine,

Swiss Association for Palliative Care, Tanzania Palliative Care Association,
Ukrainian League of Palliative and Hospice Care Development (LHPCDU),
Union for International Cancer Control (UICC) and,

University of Edinburgh - College of Medicine,
University of Texas M.D. Anderson Cancer Center,
University of Utah Pain Management Center,

Victoria Hospice and
Worldwide Palliative Care Alliance (WPCA),



The Morphine Manifesto

A call for affordable access to immediate release oral morphine.

Considering that the 2011 United Nations political declaration on non-communicable diseases calls for member states to promote the use of affordable medicines, including generics, for palliative care;¹

Considering the World Health Organization's recommendation that essential medicines should be available to patients at all times and at a price the individual and the community can afford;²

Recognizing that morphine is the only strong opioid analgesic included in the WHO Model List of Essential Medicines;³

In the light of the available scientific evidence that immediate release oral morphine is both safe and effective as first-line treatment for severe pain;^{4;5}

Finding that immediate release oral morphine is less expensive for patients than sustained release morphine and most other strong opioid formulations;⁶

Aware that in many institutions, particularly in low and low-middle income countries, immediate release oral morphine is not available, while opioid formulations that are more expensive (or more difficult to use, such as injectable morphine) are available;

Considering that the high cost of opioids hinders access to treatment to the vast majority of patients in many low and low-middle income countries, resulting in millions of patients suffering needlessly with untreated pain;

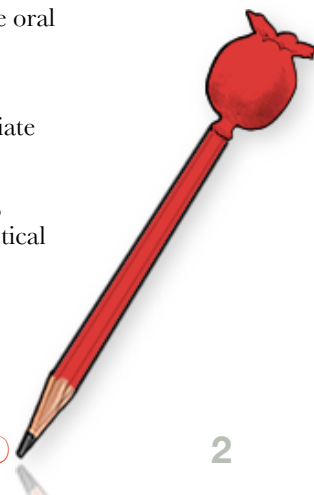
Recognizing that the low profit margin typically realized from selling immediate release oral morphine is often made worse by the additional costs of unnecessarily burdensome regulatory requirements, which may further deter the pharmaceutical industry from supplying immediate release morphine,

DECLARE that denial of adequate pain treatment to significant numbers of patients violates the right to the highest attainable standard of physical and mental health, as articulated in article 12 of the International Covenant on Economic, Social and Cultural Rights,⁷ and may violate the prohibition of cruel, inhuman, or degrading treatment⁸ as articulated in article 7 of the International Covenant on Civil and Political Rights;⁹ and

DECLARE that the exclusive availability of sustained release morphine and other expensive or injectable opioid formulations hinders access to an essential health service, leading to poor clinical and public health practice.

WE CALL UPON GOVERNMENTS, PHARMACEUTICAL INDUSTRY AND HEALTH CARE INSTITUTIONS to guarantee the accessibility of immediate release oral morphine to patients in need at a cost that the individual and community can afford. In particular:

- Governments should ensure that immediate release oral morphine is always available in public healthcare institutions before other more expensive opioid formulations become available. Where more expensive or injectable opioid formulations are already available and immediate release oral morphine is not, they should take immediate steps to ensure that it becomes available.
- Governments should work collaboratively with private healthcare institutions and the pharmaceutical industry to ensure the widest possible availability and accessibility of immediate release oral morphine in the private healthcare system.
- Governments should minimize the impact of regulatory requirements on the manufacturing, importation, exportation and distribution of opioid analgesics and work with the pharmaceutical industry to facilitate the availability of immediate release oral morphine.



The Morphine Manifesto

A call for affordable access to immediate release oral morphine.

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READ & SIGN THE MORPHINE MANIFESTO ONLINE AT

palliumindia.org/manifesto





APPENDIX D: INTERNATIONAL AUTHORITATIVE SOURCES FOR THE CENTRAL PRINCIPAL OF BALANCE

United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol¹

“the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...adequate provision must be made [by governments] to ensure the availability of narcotic drugs for such purposes” (Preamble).

“The Parties [national governments] shall take such legislative and administrative measures as may be necessary...to limit exclusively to medical and scientific purposes the production, manufacture...distribution... and possession of drugs” (Article 4(c)).

“The Board, in co-operation with Governments, and subject to the terms of this Convention, shall endeavour to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes, to ensure their availability for such purposes and to prevent illicit cultivation, production and manufacture of, and illicit trafficking in and use of, drugs.” (Article 9(4))

International Narcotics Control Board

“One of the objectives of the Single Convention on Narcotic Drugs, 1961, and of that Convention as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961, is to ensure the availability of opiates, such as codeine and morphine, that are indispensable for the relief of pain and suffering, while minimizing the possibility of their abuse or diversion.” (¶1)²

“...[the Board], in conjunction with WHO, undertook to identify possible medical needs for opiates which were currently not being met for a variety of reasons. Information was gathered from various sources, including drug regulators, health system managers, medical specialists, pharmacists and specialized units within WHO, to determine how countries are assessing their medical needs for opiates, the extent to which those needs are being met, what impediments have arisen, and what short-, medium- and long-term strategies may be deployed to overcome those impediments.” (¶5)²

“International drug control treaties not only recognize the dangers associated with abuse of and trafficking in narcotic drugs, but they also recognize that they are indispensable for the relief of pain and suffering...The [INCB], in cooperation with Governments, endeavours to ensure that there is an adequate supply of narcotic drugs for medical and scientific purposes and to limit their production and use only to such purposes in order to prevent illicit narcotic drug production, trafficking and use.” (Summary, p. iii)³

“The Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol establishes a dual drug control obligation for Governments: to ensure adequate availability of narcotic drugs, including opiates, for medical and scientific purposes, while at the same time preventing the illicit production of, trafficking in and use of such drugs.” (¶1)³

“The Board believes that an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes...Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.” (¶48)³



APPENDIX D: INTERNATIONAL AUTHORITATIVE SOURCES FOR THE CENTRAL PRINCIPAL OF BALANCE

“The International Narcotics Control Board is the successor to drug control bodies the first of which was established by international treaty over sixty years ago. A series of treaties confer on the Board specific responsibilities. The Board ‘shall endeavor to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes’ and ‘to ensure their availability for such purposes’.”(Forward, p. iii)⁴

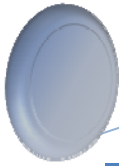
“The principal objective of the Single Convention on Narcotic Drugs of 1961 and previous international conventions to limit the use of narcotic drugs to legitimate medical and scientific purposes reflects the consensus among all Governments that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...Adequate availability and limitation were considered by the State parties to the 1961 Convention...as two complementary, not mutually exclusive, aims and were thus incorporated in the control provisions of those Conventions. In adopting such aims, Governments were motivated by two complimentary humanitarian considerations, namely the need to provide optimal help and relief for pain and suffering and the need to protect the individual and society from drug dependence and its detrimental consequences.” (¶1)⁵

“If the underlying principles of the international drug control treaties are correctly and fully implemented, they can provide the necessary international basis for Governments to guarantee the availability of narcotic drugs and psychotropic substances with accepted medical use to all those who need them. Those principles can also provide the necessary mechanism for preventing the inappropriate use and abuse of those narcotic drugs and psychotropic substances. The correct interpretation of the two complementary aims, namely ensuring and at the same time limiting the availability of those controlled drugs which are essential for medical purposes, is gaining wider acceptance.” (¶38)⁵

“A well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances has to fulfill, inter alia, the following functions: To provide for relief from pain and suffering by ensuring the safe delivery of the best affordable drugs to those patients who need them and, at the same time, preventing the diversion of drugs for the purpose of abuse;” (¶41(a))⁵

“The Single Convention is the result of the recognition by the United Nations of the fact that the adequate provision of narcotic drugs for medical purposes is indispensable for the welfare of mankind, as well as of the fact that drug addiction is a worldwide social and economic threat...Therefore, the Single Convention aims to restrict the use of narcotic drugs to medical and scientific purposes and to prevent their diversion and abuse, while at the same time ensuring their availability for legitimate purposes. It includes control measures over the cultivation of plants that serve as sources of raw material of narcotic drugs, provisions regarding the obligations of national authorities in the application of control measures over the production, manufacture, trade, and distribution of narcotic drugs, as well as provisions for the medical treatment and rehabilitation of addicts.”(¶2)⁶

“Another objective of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical treatment and to promote the rational use of controlled drugs.” (¶649)⁷



APPENDIX D: INTERNATIONAL AUTHORITATIVE SOURCES FOR THE CENTRAL PRINCIPAL OF BALANCE

“The primary objective of the 1961 and 1971 Conventions is to ensure the availability of controlled drugs for medical and scientific purposes and to prevent the non-medical use of those drugs.” (¶20)⁸

“One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote the rational use of narcotic drugs and psychotropic substances.” (¶770)⁸

“Ensuring the availability of internationally controlled substances for treatment in accordance with article 9 of the Single Convention on Narcotics Drugs of 1961 (1961 Convention), as amended by the 1972 Protocol, and the preamble of the 1971 Convention on Psychotropic Substances (1971 Convention) is a mandate of the International Narcotics Control Board.” (¶1)⁹

“The conventions established a control regime to serve a dual purpose: to ensure the availability of controlled substances for medical and scientific ends while preventing the illicit production of, trafficking in and abuse of such substances. The 1961 Convention, while recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to humankind, affirms that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...The implementation of the international drug control treaties by parties is monitored by the Board, whose responsibilities under article 9 of the 1961 Convention expressly include the responsibility to ensure the availability of narcotic drugs for medical and scientific purposes.” (¶3)⁹

“The international drug control treaties recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. However, despite numerous efforts by the Board and the World Health Organization (WHO), as well as non-governmental organizations, their availability in much of the world remains very limited, depriving many patients of essential medicines. The Board continues to monitor the worldwide availability of narcotic drugs and psychotropic substances and has made their availability one of the main topics of its dialogue with Governments on adequate treaty implementation.” (¶4)⁹

“By becoming parties to these conventions, States accept the obligation to implement in their national legislation the provisions of the [international drug control] conventions...(¶1)...The international drug control conventions were elaborated in recognition of the fact that certain substances, while being of great benefit to mankind, also had the potential to cause harm, such as dependence syndrome. Therefore, the conventions established a control regime that would ensure the availability of controlled substances for medical and scientific purposes while preventing their illicit production, trafficking and abuse...(¶2)...WHO also provides guidance to Governments on policies and legislation on the availability, accessibility, affordability and control of medicines made from controlled substances.” (¶4)¹⁰

World Health Organization

“Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation.” (p. 58)¹¹

“those [drugs] that satisfy the health care needs of the majority of the population; they should



APPENDIX D: INTERNATIONAL AUTHORITATIVE SOURCES FOR THE CENTRAL PRINCIPLE OF BALANCE

therefore be available at all times in adequate amounts and in the appropriate dosage forms...” (1998, p. 2)¹²

“...access to pain relief and palliative care services is often limited, even in high-resource settings, because of...excessive regulation of opioids...[and] urges Member States...to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Control Board.” (pp. 3-6)¹³

“During the discussions, factors limiting the availability of drugs for medical use were identified, including barriers inadvertently created by the application of laws and regulations. There are countries where stricter measures are applied than are required by the Conventions. This is permissible, as the requirements of the Conventions are minimum requirements. However, the aims of the Conventions are to ensure availability for medical use as well as the prevention of abuse. It should be noted therefore that the Conventions do not require the parties to implement specific licensing for prescribing and dispensing controlled substances for medical use, nor require permits for receiving these substances therapeutically. Applying stricter measures than those required by the Conventions may hamper rational use of medicines. The appropriate national authorities should carefully consider whether any such measure currently in force could be modified to permit access for patients in need...The Committee requested the WHO Secretariat to suggest including on the proposed agenda of the next Committee meeting, a discussion of the impact of scheduling on the balance between medical availability of controlled substances and the prevention of their abuse.” (pp. 20-21)¹⁴

“The central principle of ‘balance’ represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meeting those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care.” (p. 11)¹⁵

United Nations Commission on Narcotic Drugs

“Opioid analgesics are essential for sufficient pain management, but should never be the only available substance type for the treatment of pain, particularly for the treatment of mild to moderate pain. Both opioid and non-opioid analgesics should be made available for appropriate pain management and their rational use should follow an appropriate clinical assessment, criteria for proportional interventions and pharmacological rules for the integration in a complex therapeutics approach. If appropriately used, opioid medicines are safe and the patients rarely become dependent on opioid analgesia.” (¶23)¹⁶

United Nations Economic and Social

“Recognizes the importance of improving the treatment of pain, including by the use of opioid analgesics, as advocated by the World Health Organization, especially in developing countries, and calls upon Member States to remove barriers to the medical use of such analgesics, taking fully into account the need to prevent their diversion for illicit use.” (p. 2)¹⁷



APPENDIX D: INTERNATIONAL AUTHORITATIVE SOURCES FOR THE CENTRAL PRINCIPAL OF BALANCE

"...Recognize[s] that the medical use of narcotic drugs, including opiates, is indispensable for the relief of pain and suffering [and]...the need to balance the global licit supply of opiates against the legitimate demand for opiates used to meet medical and scientific needs is central to the international strategy and policy of drug control." (p. 1)¹⁸

"Affirming that the international drug control conventions seek to achieve a balance between ensuring the availability of narcotic drugs and psychotropic substances under international control for medical and scientific purposes and preventing their diversion and abuse." (p. 1)¹⁹

"Noting the medical and scientific needs for internationally controlled substances worldwide to be met within a regulatory and legal framework that prevents their diversion and abuse." (p. 2)¹⁹

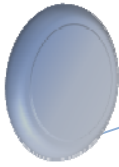
"Invites Member States to ensure that the International Narcotics Control Board and the United Nations Office on Drugs and Crime are funded adequately, as appropriate, to support their activities to ensure adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes, including the development and implementation of guidelines to assist Governments in estimating their requirements for internationally controlled substances and to address the risk of the diversion and abuse of those substances." (pp. 5-6)¹⁹

World Health Assembly

"to ensure the medical availability of opioid analgesics according to international treaties and recommendations of WHO and the International Narcotics Control Board and subject to an efficient monitoring and control system." (p. 3)²⁰

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