

53rd DIRECTING COUNCIL

66th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

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STRATEGY ON HEALTH-RELATED LAW

Introduction

1. Although the Governing Bodies of the Pan American Health Organization (PAHO) have established diverse technical guidelines and recommendations on the formulation and reform of domestic laws and regulations related to health, it is important to consolidate common and recommended approaches in a Strategy on Health-Related Law and a supporting resolution. The aim of this Strategy is to support Member States that wish to formulate, implement, review, and/or reform their domestic legal frameworks in order to promote, respect, and protect the conditions and rights necessary for achievement of the highest attainable standard of health of their populations.

2. The objectives of this technical document are to: *a)* compile the recommendations of the PAHO Governing Bodies on health-related law; *b)* review basic concepts and links between the law, public health, and health-related human rights; *c)* identify some of the national trends and challenges related to health-related law; and *d)* propose the principles, values, vision, objectives, and lines of action of a Strategy on Health-Related Law (2014-2023) for approval by the Member States of PAHO during the 53rd Directing Council.

Background

3. In 1946, the Member States of the World Health Organization (WHO) agreed on the principle that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition...”¹ This principle, which is generally referred to as “the right to health,” has also been recognized by the United Nations (UN) and regional organizations such as the Organization of American States (OAS) and incorporated into legal instruments, such as treaties, pacts, protocols, and conventions.² Likewise, a number of PAHO Member States have enshrined the right to the enjoyment of the highest attainable standard of health in their national Constitutions.³ Additionally, other international instruments, such as declarations, standards, and technical guidelines,

provide important guidance that States may use to develop and strengthen their national legal frameworks in order to protect the right to the enjoyment of the highest attainable standard of health.⁴

4. The topic of “Health Legislation” was considered by the 18th Pan American Sanitary Conference in 1970. The resulting resolution (CSP18.40) urged Member States to review and modernize their health laws and regulations, and instructed the Director of the Pan American Sanitary Bureau (the Bureau) to support Member States in order to: update their health legislation; sponsor interdisciplinary meetings on legal matters; and promote the unification of basic principles of health legislation, including guidelines on the essential aspects of legislation (1).

5. In 2007, in the Health Agenda for the Americas 2008-2017, PAHO Member States recognized that in order to achieve improvements in the health situation, “the national health authority should have legal frameworks that support, and allow for auditing of, its management”(2). Thereafter, in 2010, the 50th Directing Council urged Member States to “support PAHO’s technical cooperation in the formulation, review and, if necessary, reform of national health plans and legislation, incorporating the applicable international human rights instruments....”(3)

6. Between 2004 and 2013 the Governing Bodies of PAHO adopted numerous resolutions urging Member States to consider the formulation, implementation, review, and/or reform of laws and regulations relating to public health problems in the following areas: *a)* communicable diseases;⁵ *b)* noncommunicable diseases and risk factors;⁶ *c)* health determinants and healthy life course;⁷ and *d)* health systems.⁸

7. Finally, in 2013, the 52nd Directing Council adopted the Strategic Plan of the Pan American Health Organization 2014-2019. The Plan establishes joint responsibilities and commitments of Member States and the Bureau to support a range of interventions required for improving health. These include the formulation, implementation, review, and/or reform of health-related laws and regulations in specific program areas.⁹ However, the Governing Bodies have not indicated how the Bureau should support Member States to implement the recommendations concerning health-related legislation and regulations.

Basic Concepts of Health-Related Law

8. The concept of health-related law is broad and encompasses laws, regulations, decrees, and judicial decisions in all areas where public health, law, and health-related human rights intersect. The right to the enjoyment of the highest attainable standard of health is dependent on other human rights, especially those that affect the underlying determinants of health, such as the right to a safe and adequate supply of food, potable water, adequate housing and sanitation, work and educational opportunities, and civil and political rights such as the right to equality, life, and privacy.

9. Health-related law is essential to strengthen and implement health policies, plans, and programs. Domestic laws establish a framework of minimum legal obligations and duties of States in upholding the right to the enjoyment of the highest attainable standard of health. Moreover, national legal frameworks establish limits, accountability and responsibilities of States and other stakeholders.

Situation Analysis

10. The Governing Bodies of PAHO and the Bureau have observed the following trends and challenges in the Region between 2004 and 2013.¹⁰

Trends

11. During the past ten years some Member States have reformed their Constitutions to guarantee health-related human rights, including a right to “living well” (*el buen vivir*), and rights related to cultural/ethnic/racial diversity, traditional medicine, potable water, sanitation, and nutrition, among others.¹¹

12. At the same time, the Bureau has seen a growing demand for technical cooperation and best practices from national health authorities, legislatures, courts, and national human rights institutions (such as ombudspersons and human rights offices) to formulate, reform, or interpret health-related laws and regulations.¹² As a result, some countries have reformed their domestic laws to ensure access to health services, particularly for specific populations,¹³ as well as access to health insurance and other medical goods and benefits, including vaccines and essential medicines.¹⁴ Other Member States have enacted laws and regulations reforming their national social security systems in areas such as governance and stewardship, for example by creating national health councils.¹⁵ Finally, a large number of Member States have enacted laws that control and regulate tobacco use or create smoke-free spaces, in accordance with the WHO Framework Convention on Tobacco Control (FCTC).¹⁶

Most Significant Challenges

13. Despite these positive trends, some Member States still face significant challenges in the formulation, implementation, review, and/or reform of health-related laws and regulations. For example, some Member States need to promote broader dissemination of health-related technical standards and guidelines to ministries of health and the legislative and judicial branches.¹⁷ Other Member States should promote better coordination between the legislative branch (e.g. health commissions) and the health authority (e.g. governance and stewardship units),¹⁸ while some Member States should consider taking better advantage of their tax-related legislative and regulatory powers in order to protect and promote the health of their populations.¹⁹

14. Additionally, while some Member States have incorporated the right to health in their Constitutions, and/or have ratified international legal instruments related to health and human rights, some of them still need to adopt domestic legislative and/or regulatory

frameworks to implement these instruments.²⁰ For example, some Member States still need to align their domestic laws and regulations with the IHR and other applicable international instruments, such as the FCTC.²¹

15. Finally, some Member States should consider adopting or reviewing domestic laws and regulations that impact noncommunicable diseases and determinants of health,²² while others should consider reforming domestic laws (civil and criminal codes) that may negatively impact health throughout the life course.²³

Proposed Strategy on Health-Related Law

16. The proposed Strategy on Health-Related Law envisions a broader advisory and coordination role for the Bureau in response to technical cooperation requests from PAHO Member States (including subcomponents, branches of government, or national human rights institutions, as appropriate) and other relevant actors.

Vision of the Strategy

17. The vision is to support and build technical capacity in Member States that wish to formulate, implement, review, and/or reform their domestic legal and regulatory frameworks in order to promote, protect, and respect the conditions and rights necessary for achievement of the highest attainable standard of health, as may be applicable within the national context.

Objective of the Strategy

18. The objective is to promote, as appropriate to the respective national context:

- a) Greater coordination between the health authority and the legislative and other branches of government in the formulation, implementation, review, and/or reform of health-related laws and regulations, and;
- b) To promote the adoption and implementation of legislative and regulatory measures that effectively protect health and reduce risk factors, including all sectors that impact health.

19. The Strategy also seeks to harmonize, unify, and implement, in a more strategic manner, the recommendations of PAHO's Governing Bodies related to the formulation implementation, review, and/or reform of health-related laws and regulations.

Principles and Values of the Strategy

20. This Strategy will emphasize the following principles and values:

- a) Promotion of, respect for, and protection of the conditions and rights necessary for achievement of the highest attainable standard of health.
- b) Nondiscrimination.

- c) Equity.
- d) Promotion and protection of the economic, social, and cultural determinants of health.
- e) Integration of other cross-cutting issues (such as gender and ethnic/racial equality) into health-related laws and regulations.

Strategic Lines of Action

21. The strategic lines and their specific objectives will guide the Bureau's technical cooperation in health-related law over a period of 10 years (2014–2023).

Strategic Line of Action 1: Interventions for the promotion of healthy lifestyles and the reduction of risk factors.

Objectives:

- 1.1 To promote the formulation, implementation, review, and/or reform of laws and regulations that utilize a life-course approach, with special attention to maternal and neonatal health, sexual and reproductive health, and the health of children, adolescents, and older persons (including prevention of violence).
- 1.2 To promote the formulation, implementation, review, and/or reform of laws and regulations that reduce the use of products that are harmful to health. These measures should include a system of prices, taxes, incentives, disincentives, or other fiscal measures applicable to such products.
- 1.3 To promote the formulation, implementation, review, and/or reform of laws and regulations that promote a healthy diet and well-being. These may include measures aimed at reducing consumption of saturated fats and salt, reducing promotion to children of foods and beverages with high saturated fat and sugar content, and promoting active and healthy communities.
- 1.4 To promote the formulation, implementation, review, and/or reform of laws and regulations that impact individual behavior, such as road safety measures, among others, in order to reduce morbidity, mortality, and disability.

Strategic Line of Action 2: Interventions for the dissemination of strategic information on health with the support of various sectors.

Objectives:

- 2.1 To promote best practices on health-related legislative and regulatory reform, and disseminate the recommendations, resolutions, strategies, technical guidelines, learning tools, and legal instruments (such as the IHR and FCTC) approved by PAHO and WHO that may be useful in the formulation and interpretation of health-related laws, decrees, rules, and regulations.

- 2.2 To develop tools, such as manuals and model legislation, based on PAHO and WHO technical recommendations and guidelines, and such international legal instruments as may be applicable within the national context. This includes developing a database on health-related laws and international health-related instruments that Member States may use and adapt to their own national realities.
- 2.3 To facilitate and encourage collaboration and research on health-related law with academic entities, civil society, and other non-State actors, as appropriate.
- 2.4 To promote broader engagement between the health authority, the legislative branch, and other relevant sectors—such as civil society, consumer organizations, and the private sector, as appropriate—in the formulation and adoption of laws and regulations related to false, misleading, deceptive, or ambiguous information on packaging, labeling, and advertising of food, beverages, and other products, and which promote inclusion of health warnings on packaging.
- 2.5 To strengthen and expand PAHO’s technical collaboration on health-related law with international and regional partners, such as the World Bank, OAS, Inter-American Development Bank, specialized agencies of the UN, and committees, organs, and special rapporteurs of the UN and inter-American systems.

Strategic Line of Action 3: Interventions to favorably influence socioeconomic and cultural environments.

Objectives:

- 3.1 To promote the formulation, implementation, review, and/or reform of laws and regulations that address the social and economic determinants of health. Such determinants include access to potable water, adequate sanitary conditions, wholesome food and adequate nutrition, decent housing, healthy working conditions, protection of the environment, healthy communities, and access to health education and information.
- 3.2 To promote the formulation, implementation, review, and/or reform of laws and regulations that establish joint responsibilities between the health authority and other relevant public sectors involved in the promotion and protection of the social and economic determinants of health.
- 3.3 To promote subregional and regional consultations between the health authority, the legislative branch, and organizations of indigenous and Afro-descendant populations, among others, to formulate, implement, review, and/or reform legislative and regulatory frameworks, as appropriate, that incorporate ethnic/racial variables into health information systems; include indigenous practitioners in health systems; and train health human resources in traditional medicine and ethnic/racial/intercultural approaches to health, among others.

Strategic Line of Action 4: Interventions to enhance access to quality health facilities, goods, and services.

Objectives:

- 4.1 To promote the formulation, implementation, review, and/or reform of laws, executive decrees, rules, and regulations aimed at achieving universal health coverage and measures related to social protection in health, in accordance with the respective national legal frameworks and international instruments that may be applicable within the national context.
- 4.2 To strengthen the stewardship and governance role of the health authority in the formulation, implementation, review, and/or reform of laws, executive decrees, rules, and regulations that are consistent with the technical norms, standards, and guidelines recommended by PAHO and WHO, and with such international legal instruments as may be applicable within the national context.
- 4.3 To promote and strengthen the technical capacity of health workers in collaboration with other governmental sectors, such as the legislative and judicial branches and national human rights institutions, to better monitor and evaluate the implementation of domestic laws and regulations applicable to the health services, particularly in relation to services provided to rural and/or vulnerable populations.
- 4.4 To promote the formulation, implementation, review, and/or reform of laws and regulations that ensure access to quality, safe, and affordable essential medicines and technologies for the prevention, control, and elimination of diseases.
- 4.5 To promote the formulation, implementation, review, and/or reform of laws and regulations that make full use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in accordance with the Doha Declaration and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in order to improve access to medicines (4).
- 4.6 To promote the formulation, implementation, review, and/or reform of laws and regulations that ensure health services—including mental health services—for persons with disabilities and users of psychoactive substances, in the community and at the primary care level.

Strategic Line of Action 5: Interventions to promote coordination between the health authority and the legislative branch.

Objectives:

- 5.1 To promote and strengthen coordination between the legislative branch (e.g. health commissions) and the health authority (e.g. stewardship and

- governance units) in the formulation, adoption, and implementation of health-related executive orders, decrees, and regulations, ensuring their complementarity with existing laws.
- 5.2 To strengthen the technical capacity of the health authority to collaborate with national legislatures and regional parliamentary bodies, in coordination with other sectors (such as agriculture, trade, education, labor, development, environment, transportation, and national human rights institutions, as appropriate).
- 5.3 To promote the formulation, implementation, review, and/or reform of laws and regulations in accordance with the IHR and other international legal instruments that may be applicable within the national context borders.

Strategic Line of Action 6: Interventions for the elimination of health-related legislative barriers.

Objectives:

- 6.1 To promote the review and, when necessary, reform of laws (civil and criminal codes) that may negatively impact health. Special attention should be paid to laws regarding the exercise of reproductive rights, legal capacity of adolescents and persons with disabilities, and laws that may pose barriers to access to health services, care, and information (e.g., laws regarding autonomy, consent, privacy, gender expression, sexual orientation, or ethnicity).
- 6.2 To promote the formulation, implementation, review, and/or reform of laws and regulations related to the use of psychoactive substances in a manner consistent with the international instruments on drug control and human rights that may be applicable within the national context.
- 6.3 To promote coordination between the health authority, the legislative and judicial branches, and the correctional system, as appropriate, to evaluate the impact of criminal laws on health protection and access to health services for members of certain population groups.

Action by the Directing Council

22. The Directing Council is invited to examine and analyze this document concerning health-related law and to consider adopting the proposed resolution contained in Annex A.

Annexes

Endnotes

- ¹ Constitution of the World Health Organization, adopted by the International Health Conference, New York, signed on 22 July 1946 by 61 Member States and subsequently ratified by 194 Member States.
- ² For example, the International Covenant on Economic, Social and Cultural Rights (1966) protects “the right of everyone to the enjoyment of the highest attainable standard of...health” (Article 12), and the Protocol of San Salvador (1969) (OAS) protects “the right to health” (Article 10).
- ³ The right to health is enshrined in 19 of 35 Constitutions of PAHO Member States (Bolivia, Brazil, Chile, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, and Uruguay).
- ⁴ For example, the Universal Declaration of Human Rights states that “everyone has the right to a standard of living adequate for the health and well-being of himself and of his family,” and the American Declaration on the Rights and Duties of Man provides for the “right to the preservation of health and to well-being.”
- ⁵ For example, in the area of communicable diseases, PAHOs Governing bodies have adopted the following resolutions which include recommendations regarding health-related law:
- [CD46.R15](#) - Regional Strategic Plan for HIV/AIDS/STI (2005).
 - [CD48.R8](#) - Integrated Vector Management: A Comprehensive Response to Vector-borne Diseases (2008).
 - [CD47.R10](#) - Regional Strategy for Sustaining National Immunization Programs in the Americas (2006).
- ⁶ For example, in the area of noncommunicable diseases and risk factors, PAHOs Governing bodies have adopted the following resolutions which include recommendations regarding health-related law:
- [CD52.R10](#) - Chronic Kidney Disease in Agricultural Communities in Central America (2013).
 - [CD52.R9](#) - Plan of Action for the Prevention and Control of Noncommunicable Diseases (2013).
 - [CD51.R14](#) - Plan of Action to Reduce the Harmful Use of Alcohol (2011).
 - [CD51.R7](#) - Plan of Action on Psychoactive Substance Use and Public Health (2011).
 - [CD51.R6](#) - Plan of Action on Road Safety (2011).
 - [CD50.R6](#) - Strengthening the Capacity of Member States to Implement the Provisions and Guidelines of the WHO Framework Convention on Tobacco Control (2010).
 - [CD49.R17](#) - Strategy and Plan of Action on Mental Health (2009).
 - [CD48.R9](#) - Population-based and Individual Approaches to the Prevention and Management of Diabetes and Obesity (2008).
 - [CD47.R1](#) - Disability: Prevention and Rehabilitation in the Context of the Right to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health and Other Related Rights (2006).
- ⁷ For example, in the area of determinants of health and healthy life course, PAHOs Governing bodies have adopted the following resolutions which include recommendations regarding health-related law:
- [CD52.R6](#) - Addressing the Causes of Disparities in Health Service Access and Utilization for Lesbian, Gay, Bisexual and Trans (LGBT) Persons (2013).
 - [CSP28.R20](#) - Strategy and Plan of Action for Integrated Child Health (2012).
 - [CD51.R12](#) - Plan of Action to Accelerate the Reduction in Maternal Mortality and Severe Maternal Morbidity (2011).
 - [CD49.R15](#) - Plan of Action on the Health of Older Persons, Including Active and Healthy Aging (2009)
 - [CD49.R12](#) - Plan of Action for Implementing the Gender Equality Policy (2009)
 - [CD48.R5](#) - Regional Strategy for Improving Adolescent and Youth Health (2008).
 - [CD48.R4](#) - Regional Strategy and Plan of Action for Neonatal Health within the Continuum of Maternal, Newborn, and Child Care (2008).
 - [CD47.R18](#) - Health of the Indigenous Peoples in the Americas (2006).
- ⁸ For example, in the area of health systems, PAHOs Governing bodies have adopted the following resolutions which include recommendations regarding health-related law:

- [CD52.R11](#) - Social Protection in Health (2013).
 - [CD49.R18](#) -Policy Framework for Human Organ Donation and Transplantation (2009).
 - [CD47.R7](#) - Public Health, Health Research, Production, and Access to Essential Medicines (2006).
- ⁹ The PAHO Strategic Plan 2014-2019 establishes six categories and 30 program areas. Among the strategies recommended, the Plan identifies the need to formulate, implement, review, and/or reform health-related law in the following areas: *a*) noncommunicable diseases and risk factors (Category 2); *b*) determinants of health and promoting health throughout the life course (Category 3); *c*) health systems (Category 4); and *d*) preparedness, surveillance, and response, especially through implementation of the International Health Regulations (IHR) (Category 5). See, Pan American Health Organization. [Strategic Plan 2014-2019](#) (Official Document 345), 2013.
- ¹⁰ The trends and challenges identified by the Governing Bodies of PAHO between 2004 and 2013 are compiled in the annual reports of the Director of the Bureau; in the [Strategic Plan 2014-2019](#), *Idem*; in Scientific and Technical Publication No. 622, [Health in the Americas 2007](#); and in Scientific and Technical Publication No. 636, [Health in the Americas 2012](#). This section also includes trends and challenges identified by the PAHO Office of the Legal Counsel during a regional technical meeting held at PAHO Headquarters in Washington, DC, in 2013, and in three subregional technical meetings on health-related legislative initiatives held in 2014 in El Salvador (for Central America and the Spanish-speaking Caribbean), Peru (for South America), and Barbados (for the Caribbean). At these meetings—which were supported by the PAHO/WHO Representative Offices and national health authorities, and financed by Norway, the Spanish Agency for International Development Cooperation, and the Nordic Trust Fund of the World Bank—input was collected from 160 participants representing ministries of health, legislative and judicial branches, national human rights institutions, academia, international and regional organizations, and civil society organizations, among others.
- ¹¹ See, Annual Report of the Director, “[Advancing toward ‘Health for All’: Progress in Primary Health Care in the Americas](#)”, Doc. CD49/3, Rev. 1, Sept 2009.
- ¹² This trend was also identified between 2004 and 2010 in “[Health and Human Rights](#),” 50th Directing Council of PAHO, 62nd Session of the Regional Committee of WHO for the Americas; 27 Sept - 1 Oct 2010; Washington (DC), Doc. CD50/12. Also, [Health in the Americas 2007, Vol. I](#), which analyzes the technical collaboration provided by the Bureau to ministries of health and other actors in the formulation or reform of laws, decrees, rules, and regulations (pp. 325–326).
- ¹³ *Idem*. Doc.CD50/12, “[Health and Human Rights](#),” noted legislative reforms relating to vulnerable groups. Also, legislative trends on HIV, mental health, maternal health, disability, and adolescent and child health are noted between 2001- 2013, in PAHO publication [Supporting the Implementation of Mental Health Policies in the Americas: A Human Rights Law-Based Approach. Findings, Trends, and Targets for Public Health Action](#); and in [The Right of Young People to Health and Gender Identities](#).
- ¹⁴ *Supra* note 12.
- ¹⁵ *Supra* note 11. See also, [Quinquennial Report 2008-2012 of the Director of the Pan American Sanitary Bureau: 110 Years of Pan American Progress in Health](#), Official Doc.343, 2012.
- ¹⁶ [Tobacco Control Report for the Region of the Americas](#), PAHO, 2013.
- ¹⁷ *Supra* note 12. This risk was also identified under category 3 of the [Strategic Plan 2014–2019](#) (pp. 85–86), *supra* note 9.
- ¹⁸ The 27th Pan American Sanitary Conference noted insufficient interaction among the various actors engaged in formulating health-related laws and regulations, see Pan American Health Organization, [Strategic Plan 2008–2012](#), (Official Document 328), 2007 (Strategic Objective 11, p. 89).
- ¹⁹ Several experts in global health law have noted the challenge of incorporating into national laws and regulations the taxing powers of States with respect to health protection. See <https://www.law.georgetown.edu/oneillinstitute/about/index.cfm>.
- ²⁰ *Supra* note 12; Also Category 4 of the [Strategic Plan 2014–2019](#) (pp. 89–100), *supra* note 9.
- ²¹ *Supra* note 10 and note 12.
- ²² *Supra* note 6, CD52.R9 -[Plan of Action for the Prevention and Control of Noncommunicable Diseases](#).
- ²³ *Supra* note 12. Also in Category 3 of the [Strategic Plan 2014–2019](#) (pp. 74–88), *supra* note 9.

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1. Pan American Health Organization. [Health legislation](#) [Internet]. XVIII Pan American Sanitary Conference of PAHO, XXII Meeting of the Regional Committee of WHO for the Americas, 1970 Sep 28-Oct 8; Washington, (DC), US. Washington (DC): PAHO; 1970 (Document CSP18/21 and Addendum I) [cited 2014 Apr 28].
2. Pan American Health Organization. [Health Agenda for the Americas 2008-2017](#) [Internet].]. Washington (DC): PAHO; 2007 (presented by the ministers of health of the Americas in Panama City, 2007 Jun) [cited 2014 Apr 28].
3. Pan American Health Organization. [Health and human rights \(concept paper\)](#) [Internet]. 50th Directing Council of PAHO, 62nd Session of the Regional Committee of WHO for the Americas; 2010 Sep 27-Oct 1; Washington (DC), US. Washington (DC): PAHO; 2010 (Document CD50/12) [cited 2014 Apr 27].
4. World Health Organization. [Global strategy and plan of action on public health, innovation and intellectual property](#) [Internet]. 61st World Health Assembly; 2008 May 19-24; Geneva (Switzerland). Geneva: WHO; 2008 (Resolution WHA61.21) [2014 Jul 15].

53rd DIRECTING COUNCIL

66th SESSION OF THE REGIONAL COMMITTEE FOR WHO FOR THE AMERICAS

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PROPOSED RESOLUTION

STRATEGY ON HEALTH-RELATED LAW

THE 53rd DIRECTING COUNCIL,

Having reviewed the *Strategy on Health-related Law* (Document CD53/13);

Taking into account that the Constitution of the World Health Organization (WHO) establishes as one of its basic principles that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition...”;

Aware that the Strategic Plan of the Pan American Health Organization (PAHO) 2014-2019 establishes various categories, program areas, outputs, outcomes, and indicators relating to the formulation, implementation, review, and/or reform of domestic health-related laws, regulatory frameworks, and regulations in relation to *a*) noncommunicable diseases and risk factors (Category 2); *b*) determinants of health and promoting health throughout the life course (Category 3); *c*) health systems (Category 4); and *d*) preparedness, surveillance, and response (Category 5);

Recalling that the Directing Council of PAHO in Resolution CD50.R8 (2010), “Health and Human Rights,” called on the PAHO Member States to “support PAHO’s technical cooperation in the formulation, review and, if necessary, reform of national health legislation, incorporating the applicable international human rights instruments...”;

Noting that the Pan American Sanitary Conference and the Directing Council have recommended that Member States formulate, adopt, strengthen, and reform domestic laws and regulations on access to care for people living with HIV (CD45.R10, 2004); prevention and control of noncommunicable diseases (CD52.R9, 2013); harmful use of alcohol (CD51.R14, 2011); access to medicines (CD45.R7, 2004); road safety (CD51.R6, 2011); prevention and management of diabetes and obesity (CD48.R9, 2008); mental health (CD49.R17, 2009); psychoactive substance use disorders (CD51.R7,

2011); disability and rehabilitation (CD47.R1, 2006); reduction in maternal mortality and morbidity (CD51.R12, 2011); child health (CSP28.R20, 2012); adolescent and youth health (CD48.R5, 2008); active and healthy aging (CD49.R15, 2009); disparities in health service access for lesbian, gay, bisexual, and trans persons (CD52.R6, 2013); social protection in health (CD52.R11, 2013); and health of indigenous peoples (CD47.R18, 2006), among others;

Aware that domestic health-related laws and regulations are essential in order to strengthen and complement the implementation of health-related policies, plans, and programs and are useful to clarify accountability, responsibilities, and limits that States may establish in the promotion and protection of public health;

Affirming that States should respect, protect, and promote human rights; and

Recognizing that in some PAHO Member States health-related matters may fall under different jurisdictions,

RESOLVES:

1. To adopt the *Strategy on Health-related Law* (Document CD53/13) in order to respond effectively and efficiently to current and emerging public health needs in the Region.
2. To urge the Member States, as appropriate, taking into account their national contexts, priorities, financial and budgetary capacities, and laws currently in force, to:
 - a) promote and strengthen collaboration between the competent health authorities and the legislative branch in the formulation, implementation, review, and/or reform of domestic health-related laws and regulations, incorporating, as appropriate, all the elements necessary to respect, protect, and promote health and human rights;
 - b) promote the formulation, implementation, review, and/or reform of domestic health-related laws and regulations, as appropriate, with a view to reducing the use of harmful products, creating healthy spaces, promoting a healthy diet, and protecting the well-being of the population;
 - c) strengthen, as appropriate, the technical capacity of the health authority, the tax authority, and the legislative branch to formulate, implement, review, and/or reform domestic laws and regulations which establish a system of prices, taxes, incentives, disincentives, subsidies, or other fiscal measures to reduce the use of products that are harmful to health and to promote healthy habits, thereby reducing the risk factors associated with noncommunicable diseases, among others;
 - d) strengthen the technical capacity of the health authority to collaborate with national legislatures and regional parliamentary bodies, in coordination with other

- sectors, in order to promote the integration, as appropriate, of the technical norms, standards, and guidelines recommended by PAHO and WHO, and other health-related international instruments that may be applicable within national legal frameworks;
- e) promote and support broader engagement between the health authority, the legislative branch, and other relevant sectors, as appropriate, in efforts to reduce risk factors and promote healthy environments through the formulation, implementation, review, and/or reform of domestic health-related laws and regulations related to false, misleading, deceptive, or ambiguous information in packaging, labeling, and advertising of products with respect to their effects on consumers' health, among others;
 - f) consider the review and, if necessary, reform of domestic laws in order to make full use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in accordance with the Doha Declaration and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, in order to improve access to medicines;
 - g) promote and support the formulation, implementation, review, and/or reform of domestic laws and regulations that establish joint responsibilities between the health authority and other public sectors concerned with the promotion and protection of the social and economic determinants of health, in accordance with the technical norms, standards, and guidelines recommended by PAHO and WHO, and with applicable international human rights instruments, as appropriate;
 - h) promote and support the review and, if necessary, reform of domestic laws that may negatively influence physical, mental, sexual, and reproductive health during the life course, especially those laws that represent barriers to access to health services, care, and information;
 - i) promote and strengthen the technical capacity of health workers in collaboration with other relevant government entities, such as the legislative and judicial branches and national human rights institutions, as appropriate, to better monitor and evaluate the implementation of domestic laws and regulations in the health services;
 - j) promote the formulation, implementation, review, and/or reform of domestic laws and regulations aimed at achieving universal health coverage and measures related to social protection in health, as appropriate;
 - k) strengthen the technical capacity of the health authority to formulate, implement, review, and/or reform domestic laws and regulations in accordance with the International Health Regulations, the Framework Convention on Tobacco Control, and other health-related international instruments, as appropriate.
3. To request the Director, within the financial possibilities of the Organization and as requested by Member States, to:

- a) implement the *Strategy on Health-related Law*;
- b) support national, subregional, and regional consultations with relevant sectors, always in coordination and consultation with the national health authority;
- c) promote and encourage initiatives for training on and dissemination of the *Strategy on Health-related Law*;
- d) promote the sharing of best practices and successful experiences with regard to domestic health-related legislative reforms and regulatory frameworks among PAHO Member States;
- e) facilitate and encourage collaboration and research on health-related law with academic entities, civil society, and other non-State actors, as appropriate;
- f) develop a database on health-related laws and international health-related instruments that Member States can use and adapt to their own national realities;
- g) collect evidence of best practices on how health-related laws can contribute to improvements in access, equity, and quality of care;
- h) harmonize, unify, and implement more strategically the recommendations of PAHO's Governing Bodies in relation to the drafting and revision of health-related domestic laws and regulations.



Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. Agenda item: 4.11- Strategy on Health-related Law

2. Linkage to Program and Budget 2014-2015:

a) Categories:

Category 2 (Noncommunicable Diseases); Category 3 (Determinants of Health and Promoting Health throughout the Life Course); Category 4 (Health Systems); Category 5 (Preparedness, Surveillance, and Response).

b) Program areas and outcomes:

Noncommunicable Diseases and Risk Factors

Outcome: 2.1. Increased access to interventions to prevent and manage noncommunicable diseases and their risk factors

Mental Health and Psychoactive Substance Use Disorders

Outcome 2.2. Increased service coverage for mental health and psychoactive substance use disorders

Disabilities and Rehabilitation

Outcome 2.4. Increased access to social and health services for people with disabilities, including prevention

Women, Maternal, Newborn, Child, Adolescent, and Adult Health, and Sexual and Reproductive Health

Outcome 3.1. Increased access to interventions to improve the health of women, newborns, children, adolescents, and adults

Aging and Health

Outcome 3.2. Increased access to interventions for older adults to maintain an independent life

Gender, Equity, Human Rights, and Ethnicity

Outcome 3.3. Increased country capacity to integrate gender, equity, human rights, and ethnicity in health

Health Governance and Financing; National Health Policies, Strategies, and Plans

Outcome 4.1. Increased national capacity for achieving universal health coverage

Alert and Response Capacities (for IHR)

Outcome 5.1. All countries have the minimum core capacities required by the International Health Regulations (2005) for all-hazard alert and response

3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US\$ 10,000, including staff and activities):

The planned lifecycle of the Strategy is 10 years (2014–2023). Its annual estimated implementation cost is USD \$850,000. These costs are already included in those estimated for the implementation of the 2014-2019 PAHO Strategic Plan.

b) Estimated cost for the 2014–2015 biennium (estimated to the nearest US\$ 10,000, including staff and activities):

The 2014-2015 budget for the Office of the Legal Counsel (LEG) is USD \$4,725,800, including all sources of funding. This amount includes, in addition to other program activities under the responsibility of LEG, the annual estimated cost of USD \$850,000 (stated above) for the implementation of the Strategy on Health-related Law. Funding gaps are expected to be covered through resource mobilization actions which are currently in progress.

c) Of the estimated cost noted in b), what can be subsumed under existing programmed activities?

The technical cooperation activities for the implementation of the Strategy will be integrated into the already programmed activities of LEG, prioritizing the activities and maximizing efficiencies.

4. Administrative implications

a) Indicate the levels of the Organization at which the work will be undertaken:

Regional, subregional, and country.

b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):

Not applicable.

c) Time frames (indicate broad time frames for the implementation and evaluation):

2014-2023.



ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.11 - Strategy on Health-related Law

2. Responsible unit: Office of the Legal Counsel (LEG)

3. Preparing officer: Dr. Heidi V. Jiménez, Legal Counsel (LEG)

4. List of collaborating centers and national institutions linked to this agenda item:

- Organization of American States (OAS)
- O'Neill Institute for National and Global Health Law, Georgetown University Law Center (Washington D.C.)
- Andean Parliament
- Central American Parliament (PARLACEN)
- Parliamentary Confederation of the Americas (COPA)
- Inter-Parliamentary Union (IPU)
- Hemispheric Network of Legislators and Former Legislators for Early Childhood
- Inter-American Commission on Human Rights (IACHR)
- Swedish International Development Cooperation Agency (SIDA)
- Spanish Agency for International Development Cooperation (AECID)
- Tobacco Free Kids Initiative
- World Bank Nordic Trust Fund
- University of Southern California, Program on Global Health and Human Rights
- Washington College of Law, American University (Washington D.C.)
- International Development Law Organization (IDLO)
- World Bank Institute
- International Monetary Fund
- Ibero-American Network on Health Law
- Center for Studies and Research on Health Law (CEPEDISA), University of São Paulo

- Center for Study and Research on Health Law and Biolaw (CEDSABIO)
- International Health Central American Institute
- The NCD Alliance
- European Commission
- United Nations Office of the High Commissioner for Human Rights
- United Nations Committee on Economic, Social and Cultural Rights (CESCR)
- United Nations Committee on the Rights of Persons with Disabilities (CRPD)
- Committee for the Elimination of All Forms of Discrimination against Women (CEDAW)
- Inter-American Institute of Human Rights
- United Nations Economic Commission for Latin America and the Caribbean (ECLAC)
- Latin American and Caribbean Demographic Centre (CELADE)
- PAHO/WHO Collaborating Centre for Addiction and Mental Health at the University of Toronto
- Center for Reproductive Rights (CRR)
- HelpAge International
- United Nations Educational, Scientific and Cultural Organization (UNESCO)
- United Nations Environment Programme (UNEP)
- Disability Rights International (MDRI)
- United Nations Population Fund (UNFPA)
- United Nations Children’s Fund (UNICEF)
- United Nations Development Programme (UNDP)
- Joint United Nations Programme on HIV/AIDS (UNAIDS)
- The New York Academy of Medicine
- International Planned Parenthood Federation (IPPF)
- Global Action on Aging, Centre for Human Rights, University of Essex
- School of Law of the University of Texas
- San Carlos University (Guatemala)
- University of the West Indies
- University of Pune (India)

5. Link between agenda item and Health Agenda for the Americas 2008-2017

- Declaration of the Ministers and Secretaries of Health
- Statement of Intent: paragraphs 2 and 3
- Principles and Values: paragraphs 9, 11 and 12

6. Link between agenda item and the PAHO Strategic Plan 2014-2019:

a) Categories:

Category 2 (Noncommunicable Diseases); Category 3 (Determinants of Health and Promoting Health throughout the Life Course); Category 4 (Health Systems); Category 5 (Preparedness, Surveillance, and Response)

b) Program areas and outcomes:

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Outcome 4.1. Increased national capacity for achieving universal health coverage

Alert and Response Capacities (for IHR)

Outcome 5.1. All countries have the minimum core capacities required by the International Health Regulations (2005) for all-hazard alert and response

7. Best practices in this area and examples from countries within the Region of the Americas:

In 2013 and 2014, the PAHO Office of the Legal Counsel (LEG) organized a regional technical meeting (held at PAHO Headquarters in Washington D.C.) and three subregional technical meetings on health-related legislative initiatives, with the support of the PAHO/WHO Representative Offices and national health authorities of Central America (El Salvador), South America (Peru), and the Caribbean subregion (Barbados). At these meetings, which were supported financially by the Spanish Agency for International Development Cooperation, Norway, Canada, and the Nordic Trust Fund of the World Bank, input was collected from a total of 150 participants representing ministries of health, legislative and judicial branches, human rights defenders, academia, international and regional organizations, and civil society organizations, among others.

For more information on the regional and subregional meetings, please see:

- Regional Technical Meeting, Washington D.C.
http://www.paho.org/hq/index.php?option=com_content&view=article&id=9238%3Alegal-experts-define-strategies-to-use-legislation-to-promote-the-right-to-health-in-the-americas&catid=1443%3Anews-front-page-items&Itemid=1&lang=en
- Technical Meeting for South America, Peru
<http://www.paho.org/nutricionydesarrollo/?p=4312>
- Technical Meeting for Central America and the Spanish-speaking Caribbean, El Salvador
http://www.paho.org/els/index.php?option=com_content&view=article&id=890:expertos-definen-estrategias-para-utilizar-la-legislacion-como-herramienta-para-promover-el-derecho-a-la-salud-y-otros-derechos-humanos-relacionados-en-centroamerica-y-el-caribe-hispano&catid=671:els.-noticias-de-el-salvador&Itemid=291
- Technical Meeting for the Caribbean subregion, Barbados
http://www.paho.org/ecc/index.php?option=com_content&view=article&id=278:experts-propose-strategies-to-utilize-legislative-tools-to-promote-the-right-to-health-and-other-related-human-rights-in-the-caribbean-sub-region&catid=297:events

In addition, LEG, in close collaboration with Family, Gender, and Life Course (FGL), Communicable Diseases and Health Analysis (CHA), Noncommunicable Diseases and Mental Health (NMH), and Health Systems and Services (HSS), has carried out the following technical collaboration activities between 2010 and 2014, which have led to the formulation and/or reform of health-related legislation in 23 countries of the Region:

- Dissemination of international human right instruments in 23 countries in the context of health of persons with mental disorders, older persons, persons with disabilities, women, and adolescents (sexual/reproductive health), persons living with HIV and indigenous peoples. This dissemination of instruments has been carried out through training workshops and technical consultations that have included ministries of health, ministries of education, ministries of labor, courts of law, human rights defenders, lawmakers, police, correctional systems, universities, and civil society organizations and the Inter-American Commission on Human Rights (*including* organizations of health service users and their family members).
- In coordination with FGL, trainings have been offered for lawmakers in the legislatures of Brazil, the Dominican Republic, El Salvador, and Paraguay.
- Collaboration with Member States to incorporate international human rights norms and standards into draft legislation on mental health (Argentina, Barbados, Belize, El Salvador, Grenada, Paraguay, Saint Kitts and Nevis, Saint Lucia, Trinidad and Tobago, and Venezuela); disability (Chile and Guyana); health of older persons (Belize); HIV (Guatemala); and reproductive health (Honduras and Peru).
- Technical collaboration with the Inter-American Commission on Human Rights (IACHR) of the OAS and with Member States of PAHO in the implementation of interim or emergency relief measures to protect the health and other related human rights of 450 people interned in mental health facilities (Paraguay) and on the repair of

the hyperbaric chambers and rehabilitation services for the Miskito indigenous population (Nicaragua and Honduras), which have facilitated the reform of mental health law in Paraguay.

- Currently, LEG in collaboration with the aforementioned technical units is working with some Member States on the reform of legislation on mental health, disability, HIV, foods, maternal health, adolescent health, sexual/reproductive health, tobacco control, human resources for health, health systems and services, and health information.

8. Financial implications of this agenda item:

Its annual estimated implementation cost is USD \$850,000. These costs are already included in those estimated for the implementation of the 2014-2019 PAHO Strategic Plan.
