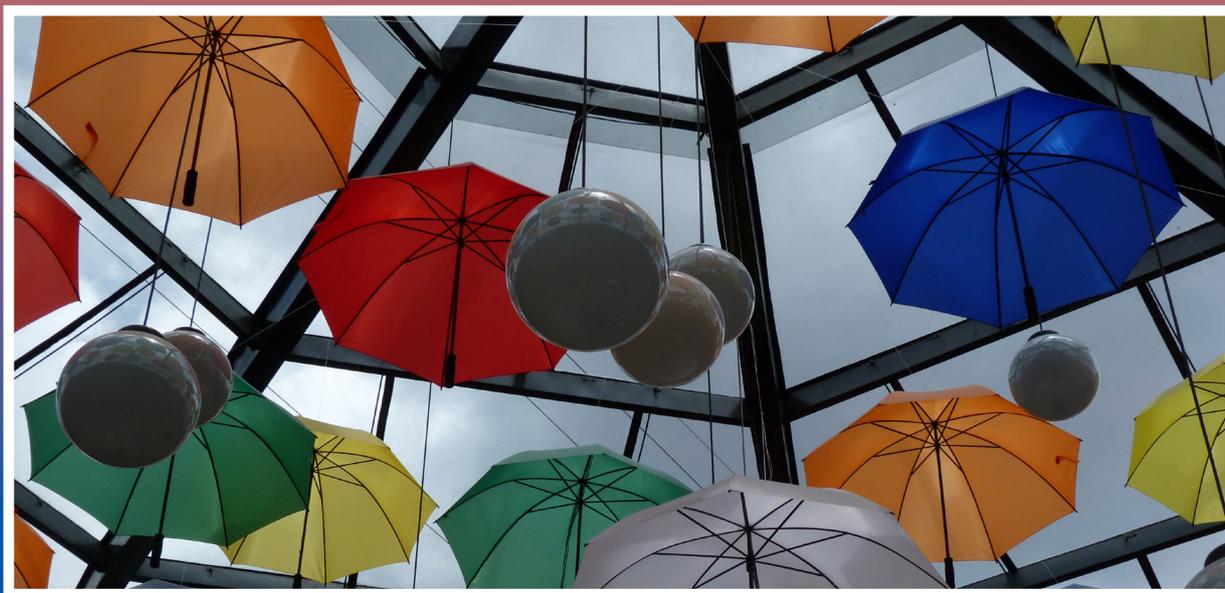


STRATEGY ON HEALTH-RELATED LAW



Pan American
Health
Organization



World Health
Organization

REGIONAL OFFICE FOR THE Americas



Kite painting by David Goldstein

STRATEGY ON HEALTH-RELATED LAW

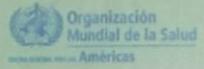
54th DIRECTING COUNCIL

67th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 28 September-2 October 2015

*CD54/14, Rev. 1
30 September 2015*

Fecha: 1 y 2 de abril de 2014
Lugar: Congreso de la República
(Palacio Legislativo del Perú)



Avanzando las Iniciativas Legislativas Relacionadas con la Salud en Sudamérica

Fecha: 1 y 2 de abril de 2014
Lugar: Congreso de la República
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Introduction

1. The Governing Bodies of the Pan American Health Organization (PAHO) have adopted various technical directives and recommendations on the formulation of health-related law that are important to consolidate in a strategy on the topic.
2. This technical document has the following objectives:
 - a) to compile the recommendations of the Governing Bodies of PAHO with regard to health-related law;
 - b) to review the basic concepts and links between law, public health, and health-related human rights;
 - c) to determine certain national trends and challenges with respect to health-related law; and
 - d) to state the principles, values, vision, objectives, and lines of action of a strategy on health-related law (2015-2023) for approval by the Member States during the 54th Directing Council.



Background

3. In 1946, the Member States of the World Health Organization (WHO) agreed on the principle whereby “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 The right to the enjoyment of the highest attainable standard of health has also been recognized by the United Nations and regional organizations such as the Organization of American States (OAS), and addressed in legally binding international instruments such as the International Health Regulations (IHR 2005) and the WHO Framework Convention on Tobacco Control (FCTC).² Furthermore, several PAHO Member States have strengthened their health systems including based on the perspective of the right to health where nationally recognized and promoting the right to the enjoyment of the highest attainable standard of health.³ Moreover, other international instruments such as declarations, standards, and technical guidelines, provide important guidance that Member States may use to develop and strengthen their national legal frameworks in order to promote the right to the enjoyment of the highest attainable standard of health.⁴

4. The subject of health legislation was considered by the 18th Pan American Sanitary Conference in 1970. The adopted resolution (CSP18.R40) urged Member States to promote the review and updating of their legal provisions on health and requested the Director of the Pan American Sanitary Bureau (the Bureau) to continue providing technical assistance to countries that request it for the review and modernization of health legislation, and to promote meetings of multidisciplinary working groups to discuss legal issues and the unification of basic principles of health legislation, including the study of the essential aspects that should be incorporated in order for the countries to have guidance they can use in accordance with their characteristics and needs (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). Then, 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).

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 (1996) 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 20 of 35 Constitutions of PAHO Member States (Bolivia, Brazil, Chile, Colombia, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, Uruguay, and Venezuela).

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.”

6. Between 2004 and 2014, the Governing Bodies of PAHO adopted numerous resolutions urging Member States to consider the formulation, implementation, review, or modification of legislative and regulatory frameworks related to public health issues in the following areas:
 - a) communicable diseases;⁵
 - b) non-communicable diseases and risk factors;⁶
 - c) health determinants and health promotion throughout the entire 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 lays out the joint responsibilities and commitments of the Member States and the Bureau to support a range of interventions aimed at improving health. These include considering the formulation, implementation, or review of health-related legislative and regulatory frameworks in specific program areas.⁹

⁵ For example, in the area of communicable diseases, PAHO's Governing Bodies have adopted several resolutions which include recommendations regarding health-related law in the context of plans of action and/or strategies related to HIV/AIDS (2006-2015), STIs (2005), integrated vector management and vector-borne diseases (2008) and immunization in the Americas (2006).

⁶ For example, in the area of non-communicable diseases and risk factors, PAHO's Governing Bodies have adopted several resolutions which include recommendations regarding health-related legislation in the context of plans of action and strategies related to chronic kidney disease in agricultural communities in Central America (2013), control of non-communicable diseases (2013), harmful use of alcohol (2011), psychoactive substance use (2011), road safety (2011), strengthening the capacity of Member States to implement the provisions and guidelines of the WHO Framework Convention on Tobacco Control (2010), mental health (2009), diabetes and obesity (2008) and disability (2006).

⁷ For example, in the area of determinants of health and healthy life course, PAHO's Governing Bodies have adopted several resolutions which include recommendations regarding health-related legislation in the context of plans of actions and strategies related to health in all policies (2014), health service access and utilization for Lesbian, Gay, Bisexual and Trans (LGBT) Persons (2013), child health (2012), maternal mortality and severe maternal morbidity (2011), active and healthy aging (2009), gender equality (2009), adolescent and youth health (2008), neonatal health within the continuum of maternal, newborn, and child care (2008) and health of the indigenous peoples (2006).



⁸ For example, in the area of health systems, PAHO's Governing Bodies have adopted several resolutions which include recommendations regarding health-related legislation in the context of plans of actions and strategies related to universal access to health and universal health coverage (2014), social protection in health (2013), human organ donation and transplantation (2009) and health research 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, or reform health-related legislation in the following areas: a) non-communicable 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) (4).

Basic Concepts of Health-related Law

8. Health-related law frames health-related policies, plans, and programs. Domestic laws are an important instrument to establish a framework to promote health including based on the perspective of the right to health where nationally recognized and promoting the right to the enjoyment of the highest attainable standard of health. Moreover, legal and regulatory frameworks can be used to establish limits, accountability, and responsibilities of States and other stakeholders.
9. The concept of health-related law is broad and encompasses a wide spectrum of legal standards and guidelines related to health issues. These legal and regulatory frameworks lay the foundation for the promotion and protection of the right to health where it is nationally recognized and the enjoyment of the highest attainable standard of health. This right is related to other human rights, in particular those that affect the underlying determinants of health.



Situation Analysis

10. The Governing Bodies of PAHO and the Bureau have observed the following challenges and trends in the Region, between 2004 and 2014.¹⁰

Trends

11. In the past ten years, some Member States have reformed their Constitutions to include health-related rights and human rights, including the right to “living well”; cultural, ethnic, and racial diversity; traditional medicine, potable water, sanitation, and nutrition, among others (5).
12. At the same time, the Bureau receives an ever-growing number of requests 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, review, or interpret health-related

law (3, 6). For example, with the support of the Bureau, some countries have modified their domestic laws to ensure access to health services, in particular for specific populations¹¹, as well as access to health insurance and other medical goods and benefits such as vaccines and essential medicines (6). Other Member States have enacted laws and regulations reforming their national health system in areas such as governance and stewardship, for example through the creation of national health councils (7). Finally, a large number of Member States have enacted laws to control and regulate tobacco use or create smoke-free spaces, in accordance with the WHO FCTC (8).

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; 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 sub-regional 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.

Most Significant Challenges

13. In addition to the positive trends, some Member States still face considerable challenges in the formulation, implementation, or review of health-related law. For example, some Member States may wish to promote broader dissemination of health related technical standards and guidelines within ministries of health and legislative and judicial authorities.¹² Other Member States may wish to promote better coordination between the legislative branch (e.g., health commissions) and the health authority (e.g., governance and stewardship units),¹³ while other Member States may consider how to take better advantage of their tax-related legislative and regulatory powers in order to protect and promote the health of their populations.¹⁴
14. Furthermore, while some Member States have incorporated a right to health or to the enjoyment of the highest attainable standard of health into their constitutions or have ratified international legal instruments related to health and human rights, some have not yet implemented applicable instruments domestically.¹⁵ For example, Member States may need to comply with international legally binding instruments to which they are State parties including the WHO FCTC, as well as other applicable international instruments, as needed¹⁶ such as the IHR 2005 (3, 6).
15. Some Member States still face challenges in reviewing their legal and regulatory frameworks that may have negative effects on health throughout the life course (3, 6).¹⁷

11 Health and Human Rights (Concept Document. CD50/12) noted legislative reforms relating to vulnerable groups. Also, legislative trends (2001–2013) in HIV, mental health, maternal health, disability, and adolescent and child health are noted 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 http://www2.paho.org/hq/dmdocuments/2010/Tends_HR_Eng.pdf; and in *The Right of Young People to Health and Gender Identities*: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=16022&Itemid

12 This risk was also identified in the context of category 3 of the PAHO Strategic Plan 2014–2019.

13 This risk was also identified in the context of objective 11 of the PAHO Strategic Plan 2008–2013 (9).

14 Several experts in global health-related legislation have noted the challenge of incorporating the taxing powers of States into domestic laws and regulations on health protection. See <https://www.law.georgetown.edu/oneillinstitute/about/index.cfm>.

15 See also Category 4 of the PAHO Strategic Plan 2014–2019 (3).

16 See note 10 above.

17 See also Category 3 of the PAHO Strategic Plan 2014–2019.





Proposed Strategy on Health-related Law

16. The Strategy on Health-related Law envisions that the Bureau, in response to the requests of the Member States and in coordination and consultation with the national health authority, will strengthen its advisory services, technical cooperation, and coordination efforts to provide greater coherence to the implementation of the highest technical standards and guidelines.

Vision of the Strategy

17. The vision of this strategy is that Member States will have adequate and strengthened legal and regulatory frameworks to promote health including based on the perspective of the right to health where nationally recognized and promoting the right to the enjoyment of the highest attainable standard of health.

Objectives of the Strategy

- 18.** To provide guidance that the Member States can consider and use, as appropriate based on the respective national context, in order to strengthen:
- a)** greater coordination between the health authority, the legislative branch of government and other State authorities, and other stakeholders as appropriate, in the formulation, implementation, or review of health-related law;
 - b)** legislative and regulatory measures to protect health and address the determinants of health;
 - c)** the harmonization or implementation of the recommendations of the Governing Bodies of PAHO/WHO related to the formulation, implementation, or review of health-related law, taking into account national contexts and priorities.

Principles and values of the Strategy

- 19.** The Strategy will take into consideration the following principles and values:
- a)** respect for the sovereignty of each Member State to design, implement, revise or reform its legal and regulatory frameworks, within its national context and financial and budgetary possibilities, as appropriate;
 - b)** implementation in coordination and consultation with the national health authority, as appropriate;
 - c)** promotion of, respect for, and protection of human rights;
 - d)** solidarity and nondiscrimination in health;
 - e)** equity;
 - f)** consideration of responses to the social, economic, environmental, and behavioral determinants that have an impact on health;
 - g)** integration of cross-cutting principles and values, such as gender equality and ethnic or racial equality, into health-related law.

Strategic Lines of Action

20. The strategic lines of action and their specific objectives will guide the Bureau's technical cooperation in health-related law for those Member States that expressly request the Bureau's support.

Strategic Line of Action 1: Actions for health determinants

Objective 1.1: Promote the formulation, implementation, or review of legal and regulatory frameworks, as appropriate, that:

- a) address health determinants, health promotion through a life-course, the reduction of risk factors, and the prevention of disease, through a multisectoral approach, as appropriate (3, 6, 10, 11);
- b) consider the strengthening of a comprehensive primary health care approach through participatory processes with the communities.

Strategic Line of Action 2: Actions for the promotion, dissemination, and exchange of strategic information on health related law

Objectives:

- 2.1 Promote the exchange of best practices between Member States on health-related law, as well as relevant judicial decisions with an impact on health, and applicable national and international legal instruments, through tools such as manuals, model legislation, databases,¹⁸ among others.
- 2.2 Promote and facilitate collaboration on research on health-related law with Member States and non-State actors, as appropriate.¹⁹
- 2.3 Strengthen the collaboration between PAHO and Member States to facilitate the exchange of strategic information on health-related law with international, regional, and subregional organizations, committees, organs, and special rapporteurs of the United Nations and Inter-American systems.







Strategic Line of Action 3: Actions for universal access to health and universal health coverage

Objective 3.1: Promote the formulation, implementation, or review of legal and regulatory frameworks:

- a) to facilitate universal access to health and universal health coverage;
- b) to support Member States in strengthening the stewardship and governance function of the health authority;
- c) to move toward achieving universal access to quality, safe, effective, and affordable medicines and health technologies (12);²⁰
- d) to strengthen technical capacities of Member States' human resources in health with a view to improve access and quality of health services with special emphasis on groups in situation of vulnerability.

¹⁸ The databases will be developed in coordination as closely as possible with WHO.

¹⁹ In accordance with applicable PAHO/WHO policies.

²⁰ In accordance with the directives of the Doha Declaration on Public Health, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, among others.





*Strategic Line of Action 4:
Actions to strengthen the
coordination between the health
authority and the legislative branch
and other sectors*

Objective 4.1 Strengthen the technical capacity of Member States' health authority to facilitate coordination and collaboration with the legislative branch and other sectors, as appropriate, including in identifying and addressing legal gaps and contradictions.

Annexes

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RESOLUTION

STRATEGY ON HEALTH-RELATED LAW

54th DIRECTING COUNCIL

67th SESSION OF THE REGIONAL COMMITTEE OF WHO FOR THE AMERICAS

Washington, D.C., USA, 28 September-2 October 2015

CD54.R9

30 September 2015

The 54th Directing Council

Having considered the Strategy on Health-related Law (Document CD54/14,Rev. 1);

Considering 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 2014-2019, in accordance with the Twelfth General Program of Work of WHO, establishes different categories, program areas, outputs and outcomes, and indicators;

Recalling that the issue of health law was considered by the 18th Pan American Sanitary Conference in Resolution CSP18.R40 (1970) and that the Directing Council of PAHO, through Resolution CD50.R8 (2010) (Health and Human Rights), urged the 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;”

Noting that the Directing Council approved the Plan of Action on Health in All Policies (Resolution CD53.R2 [2014]) and the Strategy for Universal Access to Health and Universal Health Coverage (Resolution CD53.R14 [2014]);

Recognizing that adequate, strengthened legal and regulatory frameworks can promote and protect health including from the perspective of the right to health where nationally recognized, and promoting the right to the enjoyment of the highest attainable standard of health;

Affirming the commitment of the Member States to respect, protect, and promote human rights;

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



Resolves:

1. To adopt the Strategy on Health-related Law (Document CD54/14, Rev. 1) 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, and financial and budgetary capacities, to:
 - a) promote the formulation, implementation, or review of their legal and regulatory frameworks, policies, and other legal provisions, as appropriate, taking a multisectoral approach to addressing health determinants, health promotion throughout the life course, the reduction of risk factors, and disease prevention, as well as the primary health care approach, through participatory processes with the communities;
 - b) promote and facilitate the exchange of strategic information, such as best practices and judicial decisions, among Member States and with international organizations; and collaboration on health-related law research with other Member States and other non-State actors;
 - c) promote the formulation, implementation, or review of their legal and regulatory frameworks to facilitate universal access to health and universal health coverage; the strengthening of the stewardship and governance role of the health authority to move toward achieving universal access to quality, safe, effective, and affordable medicines and health technologies; and the strengthening of the technical capacities of health workers with a view to improving access and quality in health services, with emphasis on groups in situations of vulnerability;
 - d) strengthen the technical capability of the health authority to facilitate coordination and collaboration with the legislative branch and other sectors, as appropriate, including the identification and review of legal gaps and conflicts.
3. To request the Director, within the Organization's financial capacities, upon the request of Member States, and in coordination, consultation, and jointly with their national health authority, to:
 - a) promote the implementation of the Strategy on Health-related Law and with it, to strengthen advisory and technical cooperation to Member States for the formulation, implementation, or review of health-related legal and regulatory frameworks;
 - b) provide the technical collaboration that the Member States request to implement the

Strategy, which may include training and dissemination to support mechanisms of technical cooperation, in relation to their legal and regulatory frameworks;

- c) support the Member States in the formulation, implementation, or review of their legal and regulatory frameworks, policies, and other provisions, as appropriate, taking a multisectoral approach to addressing health determinants, health promotion throughout the life course, the reduction of risk factors, and disease prevention, as well as the primary health care approach, through participatory processes with the communities;
- d) develop actions and tools to promote, among the Member States and international organizations, the exchange of best practices, successful experiences and strategic information in health-related law that Member States can use and adapt to their national reality;
- e) facilitate collaboration in research on health-related law with Member States and non-State actors;
- f) harmonize, unify and implement in a strategic way the recommendations of the Governing Bodies of PAHO with respect to the drafting and review of health-related law.







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