

Pharmaceutical services as shared responsibility in SUS: a logical framework proposal

Assistência farmacêutica como responsabilidade compartilhada no SUS: uma proposta de modelo lógico

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Abstract: *Objectives:* To present a Logical Framework (LF) of Pharmaceutical Services (PS) in Unified Health System (SUS, Brazil). *Methods:* The LF results from the legislation synthesis and experts' consultation. Delphi methodology was used to create and quantify consensus between specialists. *Results:* Legislation selected (n= 183) were published mostly by Federal Level (88%), between 2010 and 2015 (91%). The legislation contained 304 sections that addressed inter-federal responsibilities, contemplating eight components of PS (selection, financing, programming and acquisition, logistics, use, management, education and research), and an array of 54 responsibilities and 73 products in charge of Federal, State and Municipal Governments, which support PS three main pillars: access to essential drugs, rational use of medicines and structuring of PS. *Conclusions:* PS is under shared responsibility by the three levels of government, thus, the successful implementation of this public policy depends on the joint effort. The LF allows a broader understanding of the role of SUS managers, can be useful to define strategies to implement PS in Health Care Networks, and above all provides a reference for the construction of theoretical evaluation models addressing PS as a shared responsibility in SUS.

Keywords: Pharmaceutical Services; Unified Health System; Health Policy

Resumo: *Objetivos:* Apresentar um modelo lógico (ML) da assistência farmacêutica (AF) no Sistema Único de Saúde (SUS, Brasil). *Métodos:* O ML foi resultante da síntese de legislações e da consulta a especialistas. A metodologia Delphi foi empregada para criação e quantificação do consenso entre especialistas. *Resultados:* As legislações selecionadas (n= 183) foram publicadas principalmente pelo nível federal (88%), entre 2010 e 2015 (91%). As legislações continham 304 trechos relacionados a responsabilidades interfederativas, contemplando oito componentes da AF (seleção, financiamento, programação e aquisição, logística, utilização, gestão, educação e pesquisa), e uma matriz de 54 responsabilidades e 73 produtos a cargo dos Governos Federal, Estadual e Municipais, os quais suportam os três principais pilares da AF: acesso a medicamentos essenciais, uso racional de medicamentos e estruturação da AF. *Conclusões:* AF é uma responsabilidade compartilhada pelos três entes federativos, assim, o sucesso na implementação desta política pública depende do esforço conjunto. O ML contribui para o entendimento do papel dos gestores do sistema de saúde de forma abrangente, podendo ser útil para definição de estratégias para implementação da AF nas Redes de Atenção à Saúde, e sobretudo fornece uma referência para a construção de modelos teóricos de avaliação da AF como responsabilidade compartilhada no SUS.

Palavras-chave: Assistência Farmacêutica; Sistema Único de Saúde; Política de Saúde

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Introduction

The Federal Constitution (1998) inserted health in the role of Brazilian citizens' social rights, establishing co-responsibility and co-operative action among the three levels of government as a prerequisite for the implementation of the health policy¹. The Organic Health Law, on the other hand, specified the public national health system (SUS) attributions and organization and delimited competencies of the three levels of government, basing its implementation at national level². Thus, SUS implementation, based on universality, equity and integrality principles, requires inter-operative articulation, consensual management mechanisms and health responsibilities well defined^{2,3,4}.

In SUS legislation, responsibility refers to the functions that each level of government should play, the division of competences between Federal, State and Municipal Governments^{2,5,6}.

For analytical and management purposes, health responsibility may be classified in micro and macro-health responsibility. Micro-health responsibility depends on work organization at all health-care levels and aims the constitution of solid therapeutic linkages between health professionals and patients and their families. In this perspective, it's up to health teams the comprehensive approach of each case on their level of competence. On the other hand, macro-health responsibility turns to SUS regionalization, seeking of "what is in charge of who", clarifying each entity role. Within states and municipalities, defining activities under responsibility of health-care facilities, and responsibility delimitation as basis for financing agreements and for access management too⁵. The Health Pact (2006) set up macro-health responsibilities, defining individual and shared responsibilities by the three levels of government⁶.

Pharmaceutical services (PS) comprises a set of activities designed to complement and support health care actions at all complexity levels^{2,7,8}. It's one of the key elements for structuring health care networks, contributing to increase the solvability of the health system and legitimize the lines of care⁹.

Under shared responsibility in SUS⁶, the coordination of PS in networks implies the development

of structuring actions. Access to medicine must take place with strategies for rational use in order to provide the best therapeutic response for patients at the lowest cost to health system. One should seek to improve service quality and management processes. Ultimately, there must be synergy between management levels' actions to achieve concrete results and to improve population's quality of life^{8,10,11}.

Assessment practices add to strengthen PS management, providing useful information to answer to problems faced by managers and to support public policy formulation, implementation and reorientation processes¹².

The evaluation of PS in Brazil is a priority in health research¹³, and the construction of instruments that consider it a shared responsibility in SUS, as the Health Pact determines, is needed¹⁴.

A fundamental step in evaluation models design is the development of logical frameworks (LF)¹⁵. A LF is a schematic representation or a visual scheme, which presents a policy or a program (main components and objectives) and their expected results (products and impact) in a given political and organizational context¹⁶. Based on literature review, Escher *et al* (2011) infers that the use of LF is relatively simple and can be a helpful tool for evaluation, allowing the program or policy to be treated in depth, valuing its plurality, and explicitly specifying its effects¹⁵. Some authors have already used LF to build PS evaluation models in Brazil. Despite the differences in the evaluation process focus, the studies emphasize on specific programs¹⁷⁻²¹ or processes²², at state or municipal levels²³⁻²⁵.

The purpose of this article is to present a LF of PS in SUS, clarifying technical components, purposes, inter-federal responsibilities, and expected products required for achieving the main goals of the public policy, in a comprehensive manner.

Methods

It was conducted a search of legislation database (*Informe Eletrônico de Legislação em Saúde*), published by São Paulo State Health Department to explore inter-federal responsibilities related to PS in SUS.

It was selected current legislation, from Federal and São Paulo State Governments, disposing about

the structure of health system, processes relating to drugs and PS, pharmacist's role in SUS, and treatment guidelines, which support activities organization at all levels and guide PS in Brazil. In addition, Brazilian health policies and other publication on PS from national and international organizations were also collected.

São Paulo is the most populous state in Brazil and 55.5% of its population is SUS dependent for

medical and pharmaceutical care; economically, it's responsible for the largest federal spending on drugs. It has also been pioneer in the development of state-level drug policies. Therefore, the inclusion of SP legislation was strategic to understand how regional publications influence PS Policy.

The LF was prepared considering six elements, adapted from Cosendey, Hartz and Bermudez (2003)¹⁸, as shown in Chart 1.

Chart 1. Logical framework elements: what and how.

<i>Logical Framework elements</i>	<i>What (Definition)</i>	<i>How?</i>
Component(s)	Essential aspects of pharmaceutical services in Unified Health System.	From the complete reading of the selected legislation, it was identified the sections related to inter-federal responsibilities regarding Pharmaceutical Services in Unified Health System. The categorization of these sections according to PS cycle resulted in the components of the Logical Framework.
Objective(s)	Purposes of each component	Legislation and literature from World Health Organization, Pan American Health Organization, Ministry of Health, Federal Council of Pharmacy and National School of Public Health supported the definition of components' purposes.
Individual or shared responsibilities	List of responsibilities in charge of each level of government, expressed in current legislation	Construction of an array of inter-federal responsibilities for Pharmaceutical Services in Unified Health System, by the synthesis of legislation sections, with the identification of health responsibilities, related management level and outputs. Similar responsibilities and products were clustered for the representation in the Logical Framework.
Level in charge	Related management level (Federal, State and/or Municipal)	
Product(s)	Good or service offered as a result of the individual and / or shared responsibilities	
Impact	Expected comprehensive result of the levels of government joint effort in the implementation Pharmaceutical Services in SUS	Based on the agreement on health responsibilities in Unified Health System ¹¹ .

A specialist panel, composed of seven pharmacists, enrolled in education, management or health care, and with previous experience in SUS (federal, state or municipal levels), validated the LF drafted by the researchers. Delphi methodology was used to create and quantify consensus between the specialists.

An online structured questionnaire, designed with Google Forms®, was used to collect data. In the evaluation of each element of the LF with a Likert scale, the specialists could (1) strongly disagree, (2) disagree, (3) agree, or (4) fully agree with researcher's proposal. They could also comment and suggest text modification, when options (1) or (2) were chosen. The results were evaluated by the degree of consensus. The elements that resulted in at least 60% of the answers (3) and (4) were considered approved by experts. Specialists' comments and suggestions were analyzed from a reflexive perspective and based the reformulation of LF elements.

The development of this study was within Research Program for SUS (PPSUS), with the partnership of the Coordination of Science, Technology and Strategic Inputs, São Paulo Health Department. The results presented here also composed a PhD Thesis presented to School of Public Health, Universidade de São Paulo (FSP/USP), in March 2018^{31,32}.

Ethics Committee of School of Public Health, Universidade de São Paulo (FSP/USP), approval CAAE number was 48473915.3.0000.5421, on September 23, 2015.

Results and discussion

According to Dallari (2003), social activity expresses in official documents what government must do²⁶. Drug National Policy (1998) was the first publication to systematize individual responsibilities related to PS⁷. PS National Policy (2004) included as a strategic axis the delimitation of inter-federal responsibilities, in order to overcome PS fragmentation⁸. The Health Pact (2006) strengthened PS as shared responsibility in SUS⁶.

After Health Pact, the Ministry of Health, State and Municipal Health Secretaries have published thousands of legislation every year in order to structure SUS, give transparency to public health actions and clarify the role of each level of government. Consequently, to comprehend macro-health responsibilities, one should look for many official documents, available at different data sources.

Aiming to implement health policies, a broader understanding of SUS managers' role is the basis for an efficient organization of the work process. Therefore, this article answers to the need to systematize fragmented legislation, regarding inter-federal responsibilities and PS in SUS.

In the legislation database consulted, 2.311 electronic reports were available, containing 38.514 legislation from May/2006 to November/2015. Considering the including criteria, 178 current legislation were selected. With the addition of health policies before 2006, the study sample resulted in 183 documents (Table 1).

Table 1. Distribution of legislation about pharmaceutical services, according to origin and year of publication.

Origin	Legislation Number								Total
	Year (*)								
	Before 2006	2006 - 2008	2010	2011	2012	2013	2014	2015	
Federal legislation	4	7	27	11	20	43	27	22	161
SP legislation	1	5	2	2	1	1	1	9	22
Total	5	12	29	13	21	44	28	31	183

(*) Column "Before 2006" includes legislation published in 1990 (Lei nº 8.080 - Health Organic Law), 1998 (Portaria nº 3.916 - Drug National Policy), 2001 (Lei nº 10.938 - Drug State Policy/São Paulo), e 2004 (Resolução nº 338 - PS National Policy) and May 3th, 2006 (Portaria nº 971 - National Policy of Integrative and Complementary Practices). Columns "2006" to "2015" includes legislation published from May 16, 2006 to November 30, 2015.

The legislation that based LF construction were normative documents, as laws, ordinances, resolutions, deliberations and technical standards, published mostly by the Federal Level (88%), between 2010 and 2015 (91%). Highlights that selected legislation are concentrated in the last five years of data collection period. Then, the 10-year period that based data collection was enough to understand the development process and conformation of PS in SUS.

Regarding the central issue, legislation distribution was as follows: treatment guidelines (n=109), processes relating to drugs and PS (n=56), structure of health system (n=10), pharmacist's role in SUS (n=3), and health policies before 2006 (n=5).

Moreover, 304 sections addressed shared responsibilities in SUS, contemplating eight main components of PS: selection, financing, programming and acquisition, logistics, use, management, education and research (Table 2). The legislation usually covers more than one component of PS in their different sections.

The synthesis of these sections resulted in an array of 54 responsibilities and 73 products of PS, in charge of the Federal, State and Municipal Governments. Responsibilities relating to drug use (prescribing, dispensing and use) were the most

common, followed by management and activities to promote drugs availability (programming, acquisition and logistics). Research and education were the least frequent issues addressed in government publications.

With respect to the origin, shared responsibilities on PS in SUS were mostly defined in Federal legislation, suggesting that the Ministry of Health has been the main inducer of PS reorientation in Brazil in the past ten years.

It was expected that São Paulo State legislation would bring up regional specificities related to stakeholder's decisions on public health services management, often different from those adopted elsewhere in the country. They were focused, however, on strategies to implement and operationalize PS at state level, based on federal guidelines, Brazilian health policies and nationwide inter-federal agreements.

State legislation were available in smaller number and less significant to LF development, since they do not modify government responsibilities previously defined in federal documents, but add regional characteristics. Therefore, despite the LF has been based on PS in SUS/SP, the tool may be applicable nationwide.

Table 2. Distribution of legislation sections according to origin and related components of pharmaceutical services.

<i>Components of Pharmaceutical Services</i>	<i>Legislation section number</i>		
	<i>Origin</i>		<i>Total</i>
	<i>Federal Legislation</i>	<i>São Paulo State Legislation</i>	
Selection	9	3	12
Financing	11	3	14
Programming and acquisition	45	8	53
Logistics	27	1	28
Use	105	4	109
Management	73	5	78
Education	2	3	5
Research	3	2	5
<i>Total</i>	<i>275</i>	<i>29</i>	<i>304</i>

This study did not consider municipal legislation because of methodological reasons and document characteristics. Regarding methodological limitations, although São Paulo State has 645 municipalities, with political and administrative autonomy, the database includes only legislation published by São Paulo Municipal Health Department. Concerning document characteristics, municipal legislation consider the principle of local interest predominance, that is, the peculiarities and the immediate needs of the municipality. Thus, the consideration of municipal legislation to LF development could limit its use by different stakeholders.

It's worth to mention that operational, financial and administrative aspects of SUS shared manage-

ment are agreed under Tripartite (CIT) and Bipartite (CIB) Commissions composed, respectively by municipal, state and federal, or municipal and state representatives. Inter-federal agreements are published as state and federal official documents¹⁰, thus their presence minimize the impact of municipal legislation absence.

Relative to the validation process with Delphi methodology, the rates of answers (3) and (4) ranged from 71 to 100% in the first round of questions, reaching the degree of consensus for all LF elements. Experts' comments and suggestions were helpful to improve the proposal in six aspects – two objectives, two outputs and two individual or shared responsibilities (Table 3).

Table 3. Results of the validation process of the logical framework of pharmaceutical services in Unified Health System, Brazil, with Delphi methodology.

Elements of the logical framework	Evaluation of the logical framework model: % of the answers (3) agree and (4) fully agree								Changes due to comments and suggestions
	Selection	Financing	Programming and acquisition	Logistics	Use	Management	Education	Research	
Components	100%	86%	71%	100%	86%	100%	100%	100%	—
Objectives	100%	100%	100%	100%	100%	100%	100%	100%	<ul style="list-style-type: none"> • Text Improvement in financing and use objectives
Products (Outputs)	71 a 100%	86 a 100%	71 a 100%	100%	86 a 100%	71 a 100%	71%	86 a 100%	<ul style="list-style-type: none"> • Change in one output from the component use (from “pharmacotherapeutic follow-up” to “pharmaceutical care” • Detail of one output from the component management (Technical standards and guidelines)
Individual or Shared Responsibilities (**)	Not rated								<ul style="list-style-type: none"> • Update in one itens from the component programming and acquisition, due to legislation repeal during data collection and • Redundancy eliminated in one item of the component use (exclusion of the phrase “for free”, since Unified Health System is an universal system).
Responsible (**)	Not rated								—
Impact (***)	Not rated								—

(**) Already defined on legislation.

(***) Based on the agreement on health responsibilities in SUS, between three federal levels.

Chart 2 shows the LF of PS in SUS. This proposal is the first to explore federal, state and municipal responsibilities and to represent the rationale behind PS Policy in a comprehensive manner.

Chart 2. Logical framework of pharmaceutical services in Unified Health System, Brazil.

<i>Components</i>	<i>Individual or Shared Responsibilities</i>	<i>Level in Charge</i>	<i>Products (Outputs)</i>
Selection	To develop and update essential medicines lists.	F	National Essential Medicines List (RENAME) National Medicinal Plants and Herbal Medicines List (RENAFITO) National Medicines List for Indigenous Health Health Technology Assessment processes finished on time
		S	State Essential Medicines List (RESME)
		M	Municipal Essential Medicines List (REMUME)
	To develop and update Clinical Guidelines and the Therapeutic Formulary	F	Clinical Guidelines Therapeutic Formulary (FTN)
Financing	To finance essential medicines and supplies, by fund to fund transfer: CBAF – per capita/year	F, S	Financial resources to acquire medicines and supplies
	To finance essential medicines, by fund to fund transfer: CEAF – according to SUS Procedures Table	F	
	To finance medicines, additional to RENAME, according to CIB and Municipal Council of Health definition	S, M	
	To finance procedures involving medicines, by fund to fund transfer: Home ambulatory and hospital care – according to SUS Procedures Table	F	Financial resources to offer procedures
	To finance the qualification of Pharmaceutical Services, by fund to fund transfer: Structuring of warehouses and pharmacies and education	F	Financial resources to qualify Pharmaceutical Services
	To finance the implementation of Health Policies related to medicines	F, S, M	Financial resources to implement National Policies related to medicines
Programming and acquisition	To regulate drug prices.	F	Medicines Price List – CMED (Drug Market Regulation Chamber)
	To manage the System of Drug Prices Registration.	S	Drug Prices Registration available at municipal level and health-care facilities.
	To purchase and provide essential medicines to State and Municipal Health Secretaries: CBAF – insulin, contraceptives, National Medicines List for Indigenous Health; CESAF – epidemic diseases control, antiretroviral drugs, blood products, vaccines, sera and immunoglobulin CEAF – Group 1 Anti-neoplastic medicines	F	Availability of medicines at State and Municipal Warehouses, Special Indigenous Health Districts, and health-care facilities.
	To purchase and provide essential medicines to Municipal Health Secretaries and Health Facilities: CBAF – RESME and State Medicines List to Prison HealthCare CEAF – Group 1	S	
	To purchase and provide essential medicines to Health Facilities: CBAF	M	
	To purchase and provide medicines, additional to RENAME, according to CIB and Municipal Council of Health definition	S, M	
Logistics	To receive, store and distribute medicines purchased by the Ministry of Health to Municipal Health Secretaries and Health Facilities.	S	Availability of medicines at Municipal Warehouses and health-care facilities.
	To receive, store and distribute medicines received from the State Health Secretary to Health Facilities.	M	Availability of medicines at health-care facilities.

Chart 2. Logical framework of pharmaceutical services in Unified Health System, Brazil (cont.).

<i>Components</i>	<i>Individual or Shared Responsibilities</i>	<i>Level in charge</i>	<i>Products (Outputs)</i>
Use	To prescribe, dispense and support quality use of medicines, according to Clinical Guidelines and meeting sanitary standards.	F, S, M	Access to medicines Education initiatives for patients and health professionals Pharmaceutical care
	To execute CEAF: request, dispensing and treatment renewal.	S, M	
	To offer procedures involving medicines, at all levels of care, according to SUS Procedures Table.	F, S, M	Access to medicines Procedure codification, authorization and registration, according to SUS Procedures Table.
	To execute CEAF: evaluation and authorization steps	S	
	To provide medicines and supplies to patient through "Farmácia Popular do Brasil" Program.	F	Access to medicines, at low cost (co-payment scheme) or free of charge
Management	To develop Drug Policies	F, S	National and State Drug Policies
	To implement Drug, Pharmaceutical Services and other Health Policies	F, S	Technical cooperation to State and Municipal Governments
		F, S, M	Health Policies implemented
	To coordinate PS at national, state or municipal level.	F, S, M	Technical standards and guidelines Warehouses and pharmacies implemented Health Policies implemented
	To participate in the development and monitoring of SUS management tools: PlanejaSUS; plurianual plans and budget legislation; SISPACTO and COAP	F, S, M	PS integrated in SUS management tools Essential medicines lists and shared and individual responsibilities related to PS defined in COAP
	To join Inter-Federative Commissions.	F, S, M	Agreement for the provision of PS: access criteria, reference services, patient care flows, shared and individual responsibilities
	To ensure the availability of incorporated medicines.	F, S, M	Incorporated medicines available for dispensing in 180 days.
	To implement Drug Traceability, meeting sanitary standards.	F, S, M	Drug Traceability
	To transmit information to National Database of Pharmaceutical Services and Actions in SUS.	S, M	Agreed information on essential medicines transmitted regularly to the National Database.
	To monitor and evaluate Pharmaceutical Services.	F, S, M	Pharmaceutical Services performance indicators Drug use indicators
Education	To define and implement guidelines and strategies to provide education and training in Pharmaceutical Services.	F, S, M	Trained health professionals
Research	To promote research in Pharmaceutical Services.	F, S, M	Research lines and studies in Pharmaceutical Services Dissemination of experiences and technical information
<i>Impact</i>			
To promote the structuring of Pharmaceutical Services, free access and the rational use of essential medicines, in accordance with sanitary standards and existing agreements.			

SUS – Unified Health System

F – Federal Government; S – State Government; M – Municipal Government

CBAF: Basic Component of PS; CEAF: Specialized Component of PS; CESAF: Strategic Component of PS

CIB: Comissão Intergestores Bipartite or Bipartite Commission

PlanejaSUS: System Health Plans, Annual Health Program, Annual Management Report; PPA: Mutiannual Plan; Budget Legislation: Budget Guidelines Law - LDO and Annual Budget Law - LOA; SISPACTO: instrument for filling in and recording the agreement of priorities, objectives, goals and indicators of the Health Pact; COAP: Organizational Contract of Public Action.

The LF of PS in SUS proposes eight components – selection, financing, programming and acquisition, logistics, use, management, education and research and its purposes; individual and shared responsibilities by Federal, State and Municipal Governments, and related expected products.

Cosendey, Hartz and Bermudez (2003)¹⁸, Oliveira *et al.* (2002)¹⁹ and Luiza (2003)²³ represented similarly pharmacist's activities focused on quality and access to medicines, including the components selection, programming and acquisition and logistics in the LF. The use of medicines was also considered a key component of PS by Oliveira *et al.* (2002)¹⁹, Osorio-de-Castro *et al.* (2009)²¹ and Luiza (2003)²³, entitled “use control”, “prescription, dispensing and adherence”, and “dispensation and promotion of Rational Use of Medicines (RUM)”, respectively. Cosendey, Hartz and Bermudez (2003)¹⁸ and Luiza (2003)²³ were the only authors to consider, respectively, management or education as a component of PS. Financing and research we never mentioned in literature, although they are essential to structure PS in SUS^{15, 17-25}.

SUS management levels have independent operating structures, with relative autonomy, and their coordinated action depends on the development of agreed and relayed activities, but not necessarily simultaneous and coincident. Thus, the review of PS tasks included the identification of individual responsibilities of each entity and shared responsibilities by the levels of government.

The LF presented focus on the understanding of PS in a comprehensive manner. Activity flows, resources (inputs) and connections among activities, resources (inputs) and products (outputs) were not included, because at first they are not necessary to understand macro-health responsibilities in SUS.

The three main pillars of PS in SUS were understood as the comprehensive result of all components (impact) in the LF. They are free access to essential medicines, promotion of RUM and structuring of PS¹¹.

Access to essential medicines is the “relationship between the need for drugs and the supply of the same (...)”²³. Ensuring access to essential medicines requires a coordinated set of actions, including rational selection and use (...), sustainable financing sys-

tems and reliable health and supply of medicines²⁶. Therefore, selection, financing, programming and acquisition, and logistics are the components that enable access to medicines in SUS.

The selection of safe and effective drugs for priority diseases is essential to PS Policy implementation, once access to medicines with these characteristics helps to improve therapeutic resolution and to promote RUM²⁸.

The National Essential Medicines Lists (RENAME) comprises the selection of medicines for health-care in SUS, including medicines for outpatient and hospital care, as well as plants and herbal medicines^{9,10}. It's a guiding tool for the definition of State and Municipal Essential Medicines Lists and, the National Medicines List for Indigenous Health^{9, 28}.

Therapeutic formularies and clinical guidelines are complementary instruments to support prescription, dispensing and use of medicines at all health-care levels, and should be considered by SUS managers to implement the lines of care^{9,28}. They are the cornerstone of rational drug therapy.

The Ministry of Health is responsible for RENAME and clinical guidelines nationwide, assisted by the National Committee for Health Technology Incorporation (CONITEC). Administrative procedures for incorporation and exclusion of medicines in RENAME must finish within 180 days, and figures as one expected product of the component selection².

SUS financing is a shared responsibility by the three levels of government^{2, 10, 11}. The financial responsibility for the delivery of medicines or procedures are defined in CIT and CIB⁹.

Federal funds for health are organized in funding blocks. PS block comprises resources for drug supply, especially to outpatient. The financing of medicines for hospital care or antineoplastic treatment are integrated into procedures costs, according to SUS Procedures Table. SUS Management Financing block contains resources for PS qualification. State and Municipal Governments are also involved with the financing of medicine and actions to strengthen PS in SUS⁹.

Due to the increasing technological innovation and health care situation profile, characterized by

aging, the increase of life expectation and an epidemiological transition, with the existence of a triple burden of diseases (infectious diseases, external causes and chronic diseases), the representativeness of medicines in government spending tend to growth²⁹. Undoubtedly, it's necessary a major concern and to monitor PS financing, due to its impact to public budget.

In reference to the implementation of PS health policies, it's stressed the need for tripartite composition of funding, but the responsibilities are not clearly defined in the legislation.

Programming, acquisition and logistics give concreteness to the availability of selected drugs at municipal level and health-care facilities. The main goal of these components is to ensure continuous supply of drugs, in adequate quantities and quality, timely, compatible with available resources, to meet needs of the population^{9,28}.

Since these are competences of the three levels of government, according to the type of medicines, the synergy between management levels' is a key point to ensure continuous drug supply in SUS.

RUM requires patients to receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community²⁸. Thus, it's a process comprising appropriate prescription; correct dispensation, including information on prescribed medicines; adherence by patient; and monitoring drug therapy^{9,28,29}.

In fact, the eight components of PS in SUS contribute to RUM, but the main importance of component "use" rests on the interaction of the three key players of medication process: prescribers, dispensers and patients²⁸. Furthermore, its products are directly related to the provision of comprehensive care, as defined in Organic Health Law: (1) the dispensation of medicines, attending to prescriptions in accordance with Essential Medicines Lists and clinical guidelines, and (2) the provision of therapeutic procedures – home, ambulatory and hospital care – according to SUS Procedures Table^{2,9,28}.

In addition, given the PS National Policy priorities and considering Brazilian health care situation, it's worth highlighting the need to support RUM

with the integration of pharmaceutical care into healthcare process^{8,9,29}.

The third pillar of PS in SUS is the structuring of PS as a qualification strategy to access to drugs and RUM⁹. Twenty-five years after SUS construction, it remains a challenge for federative entities, and management, continuing education and research can help face it.

Management is the activity and the responsibility for running a health system through the coordination, articulation, negotiation, planning, monitoring, control, evaluation and audit⁹. The management of PS is the ability to formulate, articulate and create conditions for implementation and sustainability of PS, in a decentralized and shared manner at federal, state and municipal levels³⁰.

Drug and PS National Policies (1998 and 2004) establish the guidelines for the structuring of PS in SUS, defining inter-federal responsibilities^{7,8}.

Aiming to make health policies come true, from an analysis of health situation, available resources, priorities and strategies of a particular management level, government commitments and initiatives to improve PS can be defined. They are expressed in SUS management tools, an important product of the component management^{8,9,28}.

The structuring of health care networks demands the integration of actions and services at the three levels to ensure comprehensive care^{10,29}. Thus, a regional list of medicines, access criteria to PS, reference services and patient care flows are part of inter-federative negotiation within Inter-Regional Commissions (CIR) and CIB. Recent regulation of technology incorporation process in SUS, which states a maximum of 180 days to make available incorporated medicines⁹, also implies the need for strengthening inter-federative bonds.

The structuring of warehouses and pharmacies is another key management intervention. It's necessary to have appropriate physical area, equipment, furniture and human resources, ensuring physical-chemical integrity of medicines and an appropriate environment to the development of PS. Seen pharmacies as health-care facilities, conditions to welcome patients with dignity, respect and humanization and to enable the dialogue between pharmacists and patients are essential too^{9,28}.

Aiming to gather information for monitoring and evaluation Drug and PS policies and to promote patient safety, some initiatives related to the formulation and implementation of technological innovation focused on PS management have been instituted in SUS.

In 2013, the Ministry of Health created the National Database of PS in SUS to the transmission of data related to medicine inputs, outputs and dispensations carried out by state and municipal health-care facilities. That same year, Brazilian Health Surveillance Agency (ANVISA) set out mechanisms to drug traceability. Both initiatives are in legislation, but concrete implementation is medium to long-term.

It's also a shared responsibility the promotion of education and research.

PS management is guided by the need for professionals' technical training, together with the development of strategic and political skills. Continuing education is essential to qualify professional practices and figures as one driver to public policies implementation⁷⁻⁹. That is why the LF proposes education as one component of PS in SUS.

Research is another strategic ally to management. It's advisable the use of scientific knowledge in policy formulation and decision-making in health. Thereby, PS is one of the priorities sub-agendas of health research in Brazil, and two major areas are stressed: development and evaluation of medicines; and evaluation of policies, programs and services¹³.

In conclusion, the LF of PS in SUS is a useful tool to clarify technical components and its purposes, inter-federal responsibilities and expected products required for achieving the main goals of this public policy.

Selection, financing, programming and acquisition, logistics, use, management, education and research are PS components under shared responsibilities by the three levels of government. These components support the three main pillars of PS in SUS: free access to essential drugs, RUM and structuring of PS.

Resulting from legislation synthesis and experts' consultation, the LF allows a broader understanding of SUS managers' role, in a comprehensive manner. Since it clarifies inter-federal responsibilities and

related expected products of their actions, it can be useful for the definition of strategies to implement and operationalize PS in the context of health care networks.

The successful implementation of PS as a public policy depends on the joint effort of SUS managers, driven by health standards and existing inter-federative agreements. Therefore, inter-federal cooperation is a premise to achieve the common purpose to qualify and overcome PS challenges in SUS.

Finally, highlight that the LF also provides a reference for the construction of theoretical evaluation models addressing PS as a shared responsibility in SUS.

References

1. Constituição da República Federativa do Brasil (1988). [on line] [Available from: http://www.planalto.gov.br/ccivil_03/Constituicao/Constituicao.htm. Cited 20 oct. 2017].
2. Lei n° 8.080, de 19 de setembro de 1990. Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências. Diário Oficial da União 1990. [on line] [Available from: http://www.planalto.gov.br/ccivil_03/Leis/L8080.htm Cited 20 oct. 2017].
3. Paim J, Travassos C, Almeida C, Bahia L, Macinko J. O sistema de saúde brasileiro: história, avanços e desafios. Lancet. (Internet) 2011; Série no Brasil 1:11-31.
4. Santos LS. Regionalizando a descentralização: região de saúde como imposição constitucional ou como ato de vontade dos entes federativos? In: Oliveira NA (org.). Direto Sanitário. Oportuna discussão via coletânea de textos do 'blog Direito Sanitário: Saúde e Cidadania'. Brasília: ANVISA, CONASEMS, CONASS, 2012. p. 289-290.
5. Campos, GWS. Reforma política e sanitária: a sustentabilidade do SUS em questão? Ciência & Saúde Coletiva 2007; 12(2):301-306.
6. Portaria GM/MS n° 399, de 22 de fevereiro de 2006. Divulga o Pacto pela Saúde 2006 – Consolidação do SUS e aprova as diretrizes operacionais

- do referido pacto. Diário Oficial da União 2006. [on line] [Disponível em: http://bvsmms.saude.gov.br/bvs/publicacoes/prtGM399_20060222.pdf Cited 20 oct. 2017].
7. Ministério da Saúde. Política Nacional de Medicamentos. Série C. Projetos, Programas e Relatórios. Brasília: Ministério da Saúde, 2001.
 8. Conselho Nacional de Saúde. Resolução n° 338, de 6 de maio de 2004. Aprova a Política Nacional de Assistência Farmacêutica. Diário Oficial da União 2004. [on line] [Disponível em: http://bvsmms.saude.gov.br/bvs/saudelegis/cns/2004/res0338_06_05_2004.html Cited 20 oct. 2017].
 9. Conselho Federal de Farmácia (CFF). O farmacêutico na assistência farmacêutica do SUS: diretrizes para ação. Brasília: CFF; 2015.
 10. Decreto n° 7.508, de 28 de junho de 2011. Regulamenta a Lei n° 8.080, de 19 de setembro de 1990, para dispor sobre a organização do SUS, o planejamento da saúde, a assistência à saúde e a articulação interfederativa, e dá outras providências. Diário Oficial da União 2011. [Disponível em: http://www.planalto.gov.br/ccivil_03/_Ato2011-2014/2011/Decreto/D7508.htm Cited 20 Oct. 2019].
 11. Comissão Intergestores Tripartite. Resolução n° 4, de 19 de julho de 2012. Dispõe sobre a pactuação tripartite acerca das responsabilidades sanitárias no âmbito do SUS, para fins da transição entre o Pacto pela Saúde e a sistemática do COAP. Diário Oficial da União 2012. [Disponível em: http://bvsmms.saude.gov.br/bvs/saudelegis/cit/2012/res0004_19_07_2012.html Cited 20 Oct. 2019].
 12. Tamaki EM, Tanaka OY, Felisberto E, Alves CKA, Drumond Jr Mr, Bezerra LCA, Calvo MCM, Miranda AS. Metodologia de construção de um painel de indicadores para o monitoramento e a avaliação da gestão do SUS. Ciênc. Saúde Colet., 2012;17(4):839-49.
 13. Ministério da Saúde. Agenda Nacional de Prioridades de Pesquisa em Saúde. 2. ed. Série B. Textos Básicos em Saúde. Brasília: Ministério da Saúde, 2011.
 14. Medeiros AL, Romano-Lieber N, Tanaka OY. Produção científica relacionada à avaliação de políticas e serviços de Assistência Farmacêutica no Brasil. J. Bras. Econ. Saúde, 2015;7(Suppl 2):46-47.
 15. Esher A, Santos EM, Azeredo TB, Luiza VL, Osorio-de-Castro CGS, Oliveira MA. Logic models from an evaluability assessment of pharmaceutical services for people living with HIV/AIDS. Ciênc. Saúde Colet., 2011;16(12):4833-4844.
 16. Medina, MG *et al.* Uso de modelos teóricos na avaliação em saúde: aspectos conceituais e operacionais. In: Hartz, Z. M. A.; Vieira-da-Silva, L. M. (org.). Avaliação em saúde, dos modelos teóricos à prática na avaliação de programas e sistemas de saúde. Salvador: EDUFBA; Rio de Janeiro: FIOCRUZ, 2005. p. 41-64.
 17. Pimenta-de-Souza P, Miranda ES, Osorio-de-Castro CGS. Preparação da assistência farmacêutica para desastres: um estudo em cinco municípios brasileiros. Ciênc. Saúde Colet., 2014; 19(9):3731-3742.
 18. Cosendey MAE, Hartz ZMA, Bermudez JAZ. Validation of a tool for assessing the quality of pharmaceutical services. Cad. Saúde Pública, 2003;19(2):395-406.
 19. Oliveira MA, Esher AFSC, Santos EM, Cosendey MAE, Luiza VL, Bermudez JAZ. Avaliação da assistência farmacêutica às pessoas vivendo com HIV/AIDS no Município do Rio de Janeiro. Cad. Saúde Pública, 2002;18(5):1429-1439.
 20. Rover, MRM.; Vargas-Pelaez, CM; Manzini, F; Mendes, SJ; Farias, MR; Leilte, SN. Modelo teórico e lógico para avaliação da capacidade de gestão do Componente Especializado da Assistência Farmacêutica. Revista Eletrônica Gestão & Saúde, 2016; 7(1):191-210.
 21. Osorio-de-Castro CGS, Chaves GC, Ruiz AM, Miranda ES, Campos MR, Suárez-Múrtis MC *et al.* A proposal for an evaluation model of pharmaceutical services for malaria. Cad. Saúde Pública, 2009;25(9):2075-2082.
 22. Sartor V, Freitas S. Modelo para avaliação do serviço de dispensação de medicamentos na atenção básica à saúde. Rev. Saúde Pública, 2014;48(5):827-836.
 23. Luiza VL. Acesso a medicamentos essenciais no Rio de Janeiro (phD thesis). Escola Nacional de Saúde Pública Sergio Arouca, Rio de Janeiro, Brazil, 2003.

24. Fraga FNR. A utilização de um modelo lógico para a reorientação dos serviços farmacêuticos no âmbito municipal (dissertation). Universidade Federal do Rio Grande do Sul, Porto Alegre, RS, Brazil, 2005.
25. Pereira N, Luiza VL, Cruz MM. Serviços farmacêuticos na atenção primária no município do Rio de Janeiro: um estudo de avaliabilidade. *Saúde em Debate*, 2015;39(105):451-468.
26. Dallari, SG. Direito Sanitário. *In*: Direito sanitário e saúde pública: coletânea de textos, 1. Brasília: Ministério da Saúde; 2003. p. 39-58.
27. World Health Organization (WHO). WHO Medicines Strategy-countries the core: 2004-2007. Geneva: WHO, 2004.
28. Marin N, Luiza VL, Osorio-de-Castro CGS, Machado-dos-Santos S (ed.) Assistência farmacêutica para gerentes municipais. Rio de Janeiro: Organização Pan-americana de Saúde, 2006.
29. Mendes, EV. As redes de atenção à saúde. Brasília: Organização Pan-Americana da Saúde, Organização Mundial da Saúde e Conselho Nacional de Secretários de Saúde, 2011.
30. Barreto JL, Guimarães MCL. Avaliação da gestão descentralizada da assistência farmacêutica básica em municípios baianos, Brazil. *Cad. Saúde Pública*, 2010;26(6):1207-20.
31. Medeiros AL. Assistência farmacêutica no Sistema Único de Saúde: responsabilidade compartilhada por União, Estado e Municípios. Tese (Doutorado) – Faculdade de Saúde Pública, Universidade de São Paulo, 2018.
32. Medeiros, AL; Romano-Lieber NS; Tanaka, OY. Assistência farmacêutica no Estado de São Paulo: responsabilidade dos três entes federativos do SUS. São Paulo: Edição do Autor, 2017. [online] [Disponível em: <http://ses.sp.bvs.br/vhl/outras-fontes-de-informacao/biblioalerta-saude/centro-de-documentacao/>]

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