# Pharmaceutical Prescription and the Clinical Attributions of the Pharmacist



**Compilation of documents** 

# Pharmaceutical Prescription and the Clinical Attributions of the Pharmacist



**Compilation of documents** 



### **PRESIDENTE**

Walter da Silva Jorge João

### **VICE-PRESIDENTE**

Valmir de Santi

### SECRETÁRIO-GERAL

José Vilmore Silva Lopes Júnior

### **TESOUREIRO**

João Samuel de Morais Meira

### **CONSELHEIROS FEDERAIS EFETIVOS**

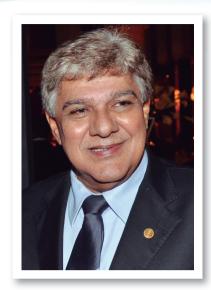
Rossana Santos Freitas Spiguel José Gildo da Silva Karla Regina Lopes Elias Carlos André Oeiras Sena Altamiro José dos Santos Lúcia de Fátima Sales Costa Forland Oliveira Silva Gedavas Medeiros Pedro Jaldo de Souza Santos Fernando Luis Bacelar de Carvalho Lobato Luciano Rena Edson Chiqueru Taki Ângela Cristina Rodrigues Cunha Castro Lopes Walter da Silva Jorge João João Samuel de Morais Meira Carlos Eduardo de Queiroz Lima José Vilmore Silva Lopes Júnior Valmir de Santi Ana Paula de Almeida Queiroz Lenira da Silva Costa Josué Schostack Lérida Maria dos Santos Vieira Erlandson Uchôa Lacerda Paulo Roberto Boff Marcelo Polacow Bisson Vanilda Oliveira de Aguiar

Amilson Álvares

# Table of Contents

Presentation	05
Resolution N° 585	07
Resolution N° 586	18
Open Letter on Pharmaceutical Prescription	32

# Presentation



The Brazilian pharmaceutical field has been taking huge steps towards profound transformation. The Brazilian Pharmacy Federal Council (Conselho Federal de Farmácia – CFF) - one of the 126 members of the International Pharmaceutical Federation – FIP, entity which represents more than three thousand professionals and scientists worldwide - is proud of being on the front line of this movement.

Some strategies have been adopted by the CFF for the accomplishment of the tasks. One of them is pursuing professional recognition by setting up both modern and normative apparatus geared towards the enhancement of the services provided. It is worth mentioning the approval of the Resolution No. 585/2013 which regulates the clinical pharmacist's attributions, along with Resolution No. 586/2013, which regulates pharmaceutical prescription in Brazil.

In this document, the CFF presents the full text on both of these resolutions, which represent an important contribution to the Brazilian Pharmacy scenario as well as public health. Besides promoting the pharmacist' professional recognition, both resolutions constitute an important achievement for the citizens, the Unified Health System (SUS), and the users of private services and health plans.

Besides releasing the abovementioned resolutions, some strategies and partnerships have been implemented, as described below:

- Restructuring the Brazilian Drug for Information Center (Centro Brasileiro de Informação sobre Medicamentos - Cebrim) along with the four-per-year publishing of the phamacotherapeutical report (Boletim Farmacoterapeutico) in order to provide the pharmacists with the necessary support in regard to the practical clinical development(to read the report, access http:// migre.me/kTvtM);
- Development of the Health-Centered Pharmaceutical Care Support Program, which aims
  at instructing the pharmacists about the implementation of pharmaceutical prescription,
  handling of self-limiting health issues, conciliation, pharmacotherapy revision, education
  on health, and pharmaceutical tracking. Through the Internet portal which will hold the
  software for the cited purposes, the professional will have access to online courses on the
  specific subject, clinical practice guidance, bibliographical references and opportunities for
  experience exchange with more professionals.

- Financing of the Clinical-Pharmaceutical Internet Portal (www.farmaceuticoclinico.com.br), which is presently comprised of over seven thousand registered pharmacists interested in this clinical area.
- Implementation of an agreement with Evidence-Based Health Internet Portal, (*Portal Saúde Baseado em Evidências*) designed by the Health Ministry (http://migre.me/kGa9l), providing access to important sources such as Micromedex, Atheneu Livros Virtuais, Best Practice, Dynamed, Embase, Proguest and Rebrats.
- Foundation of the National Forum for the Fight for the Pharmaceutical Profession Recognition (Fórum Nacional de Luta pela Valorização da Profissão Farmacêutica) - composed by representatives from the CFF, National Federation of Pharmacists (Federação Nacional de Farmaceuticos - Fenafar); Interstate Federation of Pharmacists (Federação interestadual dos Farmacêuticos-Feifar); Brazilian Association of Pharmaceutical Education(Associação Brasileira de Educação Farmacêutica-Abef) and National Executive Committee of Pharmacy Students (Executiva Nacional dos Estudantes de Farmácia (Enefar).
- The Forum has been prioritizing the political work in favor of the assembly of a legal apparatus, which is to lead to the pharmacists' recognition as essential professionals for public health care. Their first battle flag was the approval of the Senate Law Bill (Projeto de Lei do Senado –PLS), the Law Bill 41/93, which changes the Brazilian pharmacies currently known to work under commercial purposes, only into healthcare units.
- The legislation proposed encompasses articles on the clinical performance of the pharmacist, such as the article 13, whose subparagraph **c** makes it paramount that the pharmacist proceed to the patients' pharmacotherapeutical follow-ups, regardless of their being admitted or not, in hospital or ambulatory facilities, being it of public or private nature. The Law Bill-awaits President Dilma Rousseff's sanction. (Ver se retira essa última frase)

The CFF – Brazilian Federal Pharmacy Council – has untiringly fought for the social recognition of the pharmacists as a healthcare professional, not only as medicine-based experts. The expectation is one that pharmacists' expertise be more and more required and recognized. We, as pharmacists, possess both theoretical and practical knowledge along with wide capacity to work on health promotion and recovery, not to mention the prevention against diseases and other health-related issues.

In this sense, it is imperative that the pharmacist-training departments be engaged, via health regulations and professional practice, as well as public health policies, which will establish the suitable ground for the development of pharmaceutical services. We, components of the CFF, have been open to and searching for this engagement. We look forward to doing our part.

May these strategies and tools we have been adopting trigger inspiration for other countries, which, just as Brazil, are in pursuit of a more respected and recognized Pharmacy field.

# Resolution N° 585

OF AUGUST 29, 2013

**Summary:** Regulates the clinical attributions of the pharmacist and gives other measures.

### **PREAMBLE**

This resolution regulates the pharmacist's clinical attributions which, by definition, constitute the rights and responsibilities of this professional regarding his/her field.

Differentiating the meaning of "attributions", described in the scope of this resolution, from "activities" and "services" is necessary.

The activities correspond to the actions of the working process. The activities will be identified at the institutional level, by the patient or by society as "services".

Different pharmaceutical clinical services, for instance, pharmacotherapeutic monitoring, therapeutic conciliation or review of pharmacotherapy, are characterized by a set of specific activities of technical nature. The performance of these activities lies in defining legal foundation of clinical duties of the pharmacist. Thus, a list of duties does not correspond, by definition, to a list of services.

The Clinical Pharmacy, which has begun in hospitals in the United States in the sixties, now incorporates the philosophy of *Pharmaceutical Care*, and, as such, it expands at all levels of health care. This practice can be developed in hospitals, outpatient units, primary health care, community pharmacies, long term care facilities and homes of patients, among others.

The expansion of the pharmacist's clinical activities occurred in part as a response to the phenomenon of demographic and epidemiological transition observed in the society. Increased morbidity and mortality related to disorders and non-communicable diseases as well as pharmacotherapy reflected in health systems and required a new profile of the pharmacist.

In this context, the contemporary pharmacist operates in direct patient care, promotes the rational use of medicines and other health technologies, redefining his/her practice based on the needs of patients, families, caregivers and society.

Finally, we must recognize that the clinical practice of the pharmacist in our country has advanced in recent decades. This is due to the visionary of those who created the first services of Clinical Pharmacy in Brazil, as well as the actions led by professional bodies, academic institutions, international organizations and government initiatives effort.

Different realities and the single health needs of the Brazilian population require a lot of work and unity. The success of the tasks described in this document shall be measured by the effectiveness of the actions proposed and the recognition by society of the role of the pharmacist in the health context.

The Brazilian Federal Pharmacy Council (Conselho Federal de Farmácia - CFF), in the exercise of its powers granted by the Federal Law No 3820 of November 11, 1960, and

considering the provisions of Article 5, item XIII of the Federal Constitution, which grants freedom of exercise, work or profession, observing the qualifications established by the law;

considering that the CFF, in its particular area of expertise and as an entity of profession regulation, performs typical activity of the State, under Article 5, item XIII; Article 21, item XXIV and Article 22, item XVI, all from Federal Constitution;

considering the legal grant to CFF ensuring public health, promoting actions of pharmaceutical assistance at all levels of health care, according to the letter "p", Article 6 of the Federal Law No. 3820, November 11, 1960, amended by Federal Law No. 9120, of October 26, 1995;

considering CFF's attribution to issue resolutions for effectiveness of the Federal Law No. 3820, of November 11, 1960, and, also, it is responsible for setting or modify the competence of Pharmacy professionals in its scope, according to Article 6, letters "q" and "m";

considering the provisions of Federal Law No. 8078, of September 11, 1990, establishing the Consumer Defense Code:

considering that Federal Law No. 8080, of September 19, 1990, in Article 6, letter "d", includes in the field of action of the Unified Health System (SUS) the integrated therapy care, including pharmaceutical;

considering the Federal Decree No. 20377, of September 8, 1931, that approves the regulation of pharmacy profession in Brazil;

considering the Federal Decree No. 85878, of April 7, 1981 that establishes rules for the implementation of the Federal Law No. 3820, of November 11, 1960, that disposes about the exercise of the pharmacy profession, and give other provisions;

considering the Ordinance MS / SNVS No. 272, of April 8, 1998, that approves the technical regulation of the minimum requirements for parenteral nutrition therapy;

considering the Ordinance MS/GM No. 2612, of May 12, 1998, that establishes guidelines and standards for prevention and control of hospital infection;

considering the Ordinance MS/GM No. 3916, of October 30, 1998, that approves the National Drug Policy;

considering the Ordinance MS/GM No. 687, of March 30, 2006, which adopted the Policy on Health Promotion;

considering the Ordinance MS/GM No. 4283, of December 30, 2010, that approves the guidelines and strategies for the organization, strengthening and improvement of actions and pharmacy services within the hospitals, especially the chapter 4.2, letter "d";

considering the Ordinance MS/GM No. 3124, of December 28, 2012, which redefines the parameters of binding Centers of Support for Family Health (NASF) Types 1 and 2 to the Family Health Teams and/or Primary Care Teams to specific populations, creates the NASF mode 3, and gives other provisions;

considering the Ordinance MS/GM No. 529 of April 1, 2013, that establishes the National Patient Safety Program (PNSP);

considering the Resolution MS/CNS No. 338, of May 6, 2004, that approves the National Policy on Pharmaceutical Assistance:

considering the provisions of the Resolution No. 2, of February 19, 2002, from the National Council on Education, that establishes the National Curriculum Guidelines for Pharmacy Degree;

considering the Ordinance from the Ministry of Labor and Employment No. 397, of October 9, 2002, that establishes the Brazilian Occupation Classification - CBO (updated on January 31, 2013), which deals with the occupation in labor market for classification purposes with the administrative and household records;

considering the Resolution/CFF No. 160, of April 23, 1982, that disposes about pharmacy professional activity;

considering the Resolution/CFF No. 357, of April 27, 2001 that approves the technical regulation for Good Pharmacy Practices;

considering the Resolution/CFF No. 386, of November 12, 2002, that disposes about the pharmacist's duties within the home care in multidisciplinary teams;

considering the Resolution/CFF No. 486, of September 23, 2008, that disposes about the pharmacist in the area of radiopharmacy and gives other measures;

considering the Resolution/CFF No. 492, of November 26, 2008, which regulates the professional practice in pre-hospital care services, in hospital pharmacy and in other health services, public or private, as amended by Resolution/CFF No. 568, of December 6, 2012;

considering the Resolution/CFF No. 499, of December 17, 2008, that disposes about pharmaceutical services in pharmacies and drugstores, and gives other measures, modified by the Resolution/CFF No. 505, of July 23, 2009;

considering the Resolution/CFF No. 500, of January 19, 2009, that disposes about pharmacists' attributions under dialysis services, being public or private;

considering the Resolution/CFF No. 509, of July 29, 2009, that regulates the work of the pharmacist in centers of clinical research, representative organizations of clinical research, industry or other institutions that perform clinical research;

considering the Resolution/CFF No. 546, of July 21, 2011, that disposes about pharmaceutical indication of nonprescription herbal medicines and medicinal plants and their documentation;

considering the Resolution/CFF No. 555, of November 30, 2011, that regulates the record, keeping and handling of information resulting from the practice of pharmaceutical care in health services;

considering the RDC Anvisa No. 220, of September 21, 2004, that regulates the operation of antineoplastic therapy services and establishes that the multidisciplinary team in antineoplastic therapy (EMTA) shall have in its composition a pharmacist;

considering the RDC Anvisa No. 7 of February 24, 2010, which in Section IV, article 18, establishes the need of pharmaceutical care in bedside in Intensive Care Unit, and in its article 23, establishes that the pharmaceutical care must integrate the multidisciplinary team, **DECIDES:** 

**Article 1** - Regulating pharmacist's clinical attributions under this resolution.

**Sole paragraph** - Clinical attributions ruled by this resolution constitute prerogative of legally qualified pharmacist registered in the Regional Pharmacy Council of his/her jurisdiction.

**Article 2** - The pharmacist's clinical attributions aim at promotion, protection and recovery of health as well as prevention of diseases and other health problems.

**Sole paragraph** - The pharmacist's clinical attributions intend to provide healthcare to the patient, family and community in order to promote rational use of medicines and optimize pharmacotherapy to achieve defined outcomes that improve the patients` quality of life.

- **Article 3** Within the scope of his/her duties, the pharmacist provides health care everywhere and in all levels of attention, even for private or public services.
- **Article 4** The pharmacist performs his/her activities autonomously, based on bioethics and professional principles and values through work processes with established standards and management models of practice.
- **Article 5** The pharmacist's clinical attributions established in this resolution address the needs of the patient health, family, caregivers and society, and are performed in accordance with the policies of health, considering the health standards and the institution with the pharmacist is related.
- **Article 6** The pharmacist, in the exercise of his/her clinical attributions, has the duty to contribute to the generation, dissemination and application of new knowledge to promote health and well-being of the patient, family and community.

### CHAPTER I - REGARDING THE PHARMACIST'S CLINICAL ATTRIBUTIONS

**Article 7** - There are the pharmacist's clinical attributions related to the healthcare of the individual and collective spheres:

- I. Establishing and conducting a care relation centered in the patient;
- II. Developing in collaboration with other members of the healthcare team actions for promotion, protection and health recovery and the prevention of diseases and other health problems;
- III. Participating in the planning and evaluation of pharmacotherapy, so the patient make a safe use of medicines that he/she needs regarding doses, frequency, schedules, routes of administration and appropriate duration, contributing to his/her conditions to perform the treatment and achieve therapeutic goals;
- IV. Analyzing medicine prescription in relation to legal and technical aspects;
- V. Performing pharmaceutical interventions and emit opinion to the other members of the health team with the purpose of assisting in selection, addiction, replacement, adjustment or discontinuation of pharmacotherapy of the patient;
- VI. Participating and promoting discussions on clinical cases in an integrated manner with other members of the health team;
- VII. Providing pharmaceutical consultation in a pharmaceutical office or in an appropriate environment which ensures privacy;
- VIII. Performing pharmaceutical anamnesis as well as check signs and symptoms with the purpose of providing patient care;

- IX. Accessing and identifying information in patient records;
- X. Organizing, interpreting and summarizing, if necessary, patient's data in order to proceed to the pharmaceutical assessment;
- XI. Requesting laboratory tests as part of his/her professional competence in order to monitor the results of pharmacotherapy;
- XII. Evaluating results of clinical and laboratory tests of the patient as a tool for individualization of pharmacotherapy;
- XIII. Monitoring therapeutic levels of drugs, through clinical pharmacokinetic data;
- XIV. Determining biochemical and physiological parameters of the patient to follow the pharmacotherapy and health tracking;
- XV. To prevent, identify, evaluate and intervene in incidents related to medicines and other problems associated with pharmacotherapy;
- XVI. To identify, assess and intervene in unwanted and clinically significant drug interactions;
- XVII. Developing the pharmaceutical care plan of the patient;
- XVIII. Planning with the patient and, if necessary, with other health professionals the actions of the pharmacist's care plan.
- XIX. Performing and record pharmaceutical intervention with the patient, family, caregivers and society;
- XX. Periodically evaluate results of pharmaceutical interventions building indicators of quality of the offered clinical services;
- XXI. Performing, as part of professional competence, medication administration of the patient;
- XXII. Advising and assisting patients, caregivers and health professionals regarding the administration of pharmaceutical dosage formulas, recording these actions, if necessary;
- XXIII. Performing the pharmaceutical development and register it in the patient's medical record;
- XXIV. Elaborating an updated and reconciled list of medicines taken by the patient during the admission process, transference and discharge between services and levels of health care;
- XXV. Providing support to patients, caregivers, families and the community toward the self-care process, including the management of self-limiting health problems;
- XXVI. Prescribing according to specific law as part of professional competence;
- XXVII. Evaluating and monitor patients' adherence to treatment, and take actions to promote it;
- XXVIII. Performing tracking actions in healthcare, based on technical and scientific evidence and in line with current health policies.
- Art. 8° There are duties of the pharmacist related to communication and health education:
- I. Establishing an appropriate process of communication with patients, caregivers, family, health team and society, including the use of mass communication;

- II. Providing information on medicines to the health team;
- III . To inform, guide and educate patients, families, caregivers and society on issues related to health, rational use of medicines and other health technologies;
- IV. Developing and participating in educational teams for groups of patients;
- V. Developing educational materials for the promotion, protection and restoration of health and prevention of diseases and other related problems;
- VI. Acting in training and professional development of pharmacists;
- VII. Developing and participating in training and continuing education of human resources in health programs.

**Article 9** - There are pharmacists' attributions related to practice management, production and application of knowledge:

- I. Participating in the coordination, supervision, assessment, accreditation and certification programs and services within the pharmacist's clinical activities;
- II. Performing management processes and projects, through tools and indicators of quality of the clinical services provided;
- III. Searching, selecting, organizing, interpreting and disseminating information to guide decision-making based on evidence in the health care process;
- IV. Interpreting and integrating data from different sources of information in evaluation of health technologies process;
- V. Participating in the development, implementation and update of forms and therapeutic clinical protocols for the use of medicines and other health technologies;
- VI. Participating in the development of service protocols and other regulation involving clinical activities;
- VII. Developing actions for prevention, identification and notification of incident and technical complain related to medicines and other technologies in health;
- VIII. Participating in commissions and committees within institutions and health services, aimed at promoting rational use of medicines and patient safety;
- IX. Participating in the planning, coordination and execution of epidemiologic studies and other investigations of technical and scientific nature in health;
- X. Integrating research ethics committees;
- XI. Documenting the entire work process of the pharmacist;

### **CHAPTER II - FINAL PROVISIONS**

**Article 10** - Attributions provided by this resolution correspond to the rights, responsibilities and skills of the pharmacist in the development of clinical activities and the provision of pharmaceutical services.

Article 11 - For the purposes of this resolution there are considered the definition of terms (glossary) and references in Annex

Article 12 - This Resolution shall come into force on this date, and any provisions in contrary are revoked.

# WALTER DA SILVA JORGE JOÃO President - CFF

### ANNEX

### **GLOSSARY**

**Pharmaceutical anamnesis:** procedure of data collection on patient, performed by the pharmacist through interview in order to know the patient's health background, developing pharmacotherapeutic profile and identifying his/her needs related to health.

**Bioethics:** ethics applied specifically to the field of medical and biological sciences. It represents the systematic study of human behavior in health care in the light of principle and moral values. It covers ethical and deontological dilemmas related to medical and pharmaceutical ethics, including health care, biomedical research on humans and the humanities and social issues such as access and the right to health, resources and public policy for health care. Bioethics is based on principles, values and virtues such as justice, beneficence, non-maleficence, fairness, autonomy, which assumes responsibility in human relationships, free will, consciousness, and the moral decision respect for human dignity in care, research and social interaction.

**Pharmaceutical consultation:** assistance provided by the pharmacist to the patient, respecting ethical and professional principles in order to get the best results with pharmacotherapy and promote rational use of medicines and other health technologies.

**Pharmaceutical office:** pharmaceutical workplace to assist patients, families and caregivers, where it is held privately pharmaceutical consultation. It can operate autonomously or as reliance on hospitals, clinics, community pharmacies, multidisciplinary units of health care, long term care institutions and other health services in the public and private spheres.

**Patient-centered care:** humanized relationship that involves respect for the beliefs, expectations, experiences, attitudes and concerns of the patient or caregivers about their health conditions and the use of medication, in which pharmacists and patients share decision making and responsibility for health outcomes achieved.

**Caregiver:** a person who plays the role of providing care for patients with a dependency in a relationship of physical and emotional closeness. The caregiver can be a relative, who assumes the role from a family relationship, or a professional, specially trained for this purpose.

**Pharmaceutical evolution:** register made by the pharmacist in the patient's record in order to document the health care provided, allowing communication between the various members of the healthcare team.

**Clinical Pharmacy:** field of pharmacy focused on science and practice of the rational use of medicines, where pharmacists take care of the patient to optimize the pharmacotherapy, promote health and wellness and prevent diseases.

**Pharmacotherapy:** treatment of diseases and other health conditions through the use of medicines.

**Incident:** an event or circumstance that could have resulted in unnecessary harm to the patient.

**Pharmaceutical intervention:** professional action planned, documented and performed by the pharmacist for the purpose of optimization of pharmacotherapy, promotion, protection and recovery of health, prevention of diseases and other health problems.

**Patient's medication list:** complete and updated list of medicines taken by the patient, including prescription and non-prescription drugs, medicinal herbs, supplements and other products for therapeutic purposes.

**Optimization of pharmacotherapy:** process by which the best results from the patient's pharmacotherapy are achieved, considering his/her individual needs, expectations, health conditions, cultural context and determinants of health.

**Patient:** person who asks, receives or hire orientation, counseling or other services from a healthcare professional.

**Pharmaceutical Opinion:** document issued and signed by the pharmacist containing technical demonstration and summarized on specific issues within his/her expertise. The opinion can be prepared in response to a query, or through the pharmacist's initiative to identify problems related to his/her scope of action.

**Care plan:** documented plan for clinical management of diseases and other health problems of the patient's therapy, designed to achieve the goals of treatment. It includes responsibilities and activities agreed between the patient and pharmacist, the definition of therapeutic targets, pharmaceutical interventions, actions to be taken by the patient, and scheduling for feedback and monitoring.

**Prescription:** a set of documented actions related to health care, aiming the promotion, protection and recovery of health, and prevention of diseases.

**Pharmaceutical prescription:** action by which the pharmacist selects and documents selects and documents pharmacological and nonpharmacological therapies, and other interventions for the health care of the patient, aimed at the promotion, protection and recovery of health, and prevention of diseases and other health problems.

**Self-limiting health problem:** acute disease of low gravity, and short latency period, which triggers an organic reaction which tends to occur with no harm to the patient and can be treated effectively and safely with medication and other products for therapeutic purposes whose dispensation does not require a prescription, including manufactured drugs and magistral preparations - allopathic or dynamized medicines -, medicinal plants, herbal drugs or with non-pharmacological measures.

**Technical complain:** notification made by the healthcare professional when observed a deviation from the parameters of quality required for marketing or approval in the registration process of a pharmaceutical product.

**Health tracking:** identification of probable disease or unidentified health condition through the application of tests, examinations or other procedures that can be performed rapidly with further guidance and referral of the patient to another professional or health service for diagnosis and treatment.

**Health based on evidence:** is an approach that uses the tools of clinical epidemiology, statistics, scientific methodology, and computing to work for the research, knowledge, and performance in health, with the goal of providing the best available information for decision making in this field.

**Health services:** services that deal with diagnosis and treatment of diseases, or deal with promotion, maintenance and recovery of health. They include health offices, clinics, hospitals and other, either public or private.

**Health technologies:** medicines, equipment, technical procedures, organizational, information, education and support systems, programs and assistance protocols, whereby attention and care are provided to population.

**Rational use of medicines:** process by which patients receive appropriate medicines to their clinical needs, at suitable dosage to their individual characteristics over appropriate length and at the lowest possible cost to themselves and to society.

**Safe use of medicines:** absence of preventable and accidental injury during the use of medicines. Safe use encompasses the activities of prevention and minimization of damage caused by adverse events that result from the process of the use of medicines.

### REFERENCES

AMERICAN COLLEGE OF CLINICAL PHARMACY. The definition of clinical pharmacy. *Pharmacotherapy*, v. 28, n. 6, p. 816-7, 2008.

AMERICAN PHARMACIST ASSOCIATION; NATIONAL ASSOCIATION OF CHAIN DRUG STORES FOUNDATION. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0). *Journal of the American Pharmacists Association*, v. 48, n. 3, p. 341-53, 2008.

AMERICAN PHARMACIST ASSOCIATION. Medication Therapy Management Services. Developing a practice as an independent MTM Pharmacist. Fort Myers: APhA, 2008. 8 p.

AMERICAN SOCIETY OF HEALTHY-SYSTEM PHARMACISTS. ASHP guidelines on documenting pharmaceutical care in patient medical records. *American journal of health-system pharmacy*, v. 60, n. 7, p. 705-7, 2003.

BENTZEN N. (Ed). Wonca Dictionary of General/Family Practice. Wonca International Classification Committee: Copenhagen, 2003.

BISSON, MP. Farmácia Clínica & Atenção Farmacêutica. 2ed. Barueri - SP: Editora Manole, 2007. 371 p.

BRASIL. MINISTÉRIO DA SAÚDE. Portaria MS/GM nº. 2.488, de 21 de outubro de 2011, que aprova a Política Nacional de Atenção Básica, estabelecendo a revisão de diretrizes e normas para a organização da atenção básica, para a Estratégia Saúde da Família (ESF) e o Programa de Agentes Comunitários de Saúde (PACS). Brasília: Ministério da Saúde, 2011.

BRASIL. MINISTÉRIO DA SAÚDE. DIRETRIZES DO NASF: Núcleo de Apoio a Saúde da Família. Brasília: Ministério da Saúde, 2010. 152 p.

BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE ASSISTÊNCIA À SAÚDE. DEPARTAMENTO DE SISTEMAS E REDES ASSISTENCIAIS. Protocolos Clínicos e Diretrizes Terapêuticas: medicamentos excepcionais. Brasília: Ministério da Saúde, 2002. 604 p.

BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE VIGILÂNCIA EM SAÚDE. DEPARTAMENTO DE ANÁLISE DE SITUAÇÃO DE SAÚDE. Guia metodológico de avaliação e definição de indicadores doenças crônicas não transmissíveis e rede Carmen. Brasília: Ministério da Saúde, 2007. 233 p.

BURKE, J. M. et al. Clinical pharmacist competencies. *Pharmacotherapy*, v. 28, n. 6, p. 806-15, 2008.

CORRER, C. J.; OTUKI, M. A prática farmacêutica na farmácia comunitária. Porto Alegre: Artmed; 2013. 434 p.

DIPIRO, J.; TALBERT, R. L.; YEE, G. et al. Pharmacotherapy: A Pathophysiologic Approach, 8ed. New York: McGraw-Hill Medical, 2011. 2700 p.

EUROPEAN SOCIETY OF CLINICAL PHARMACY. What is clinical pharmacy? Disponível em: <a href="http://www.escpweb.org/cms/Clinical\_pharmacy">http://www.escpweb.org/cms/Clinical\_pharmacy</a> acessado em 14/05/2013.

GOMES, C. A. P.; FONSECA, A. L.; SANTOS, J. P. et al. A assistência farmacêutica na atenção à saúde. 2ed. Belo Horizonte: FUNED, 2010. p. 144.

GRUNDY, P. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2ed. Washington DC: Patient-Centered Primary Care Collaborative, 2012. 28 p.

HEPLER, C. D. Clinical pharmacy, pharmaceutical care, and the quality of drug therapy. Pharmacotherapy, v. 24, n. 11, p. 1491-98, 2004.

LYRA JUNIOR, D. P.; MARQUES, T. C. As bases da dispensação racional de medicamentos para farmacêuticos. 1ed. São Paulo: Pharmabooks Editora, 2012. 300 p.

MENDES, E. V. As redes de atenção à saúde. 2ed. Brasília: Organização Pan-Americana da Saúde, 2011. p. 554.

MENDES, E. V. O cuidado das condições crônicas na atenção primária à saúde: o imperativo da consolidação da estratégia da saúde da família. Brasília: Organização Pan-Americana da Saúde, 2012. p. 512.

NOVAES MRCG, Lolas F, Quezada A. Ética y Farmacia. Una Perspectiva Latinoamericana. Monografías de Acta Bioethica n° 02. Programa de Bioética da OPS/OMS, 2009.

ORGANIZAÇÃO PAN-AMERICANA DA SAÚDE. Guía Servicios Farmacéuticos en la Atención Primaria de Salud. Washington, 2010 (in press).

ORGANIZAÇÃO PAN-AMERICANA DA SAÚDE. Inovando o papel da atenção primária nas redes de atenção à saúde: resultados do laboratório de inovação em quatro capitais brasileiras. Brasília: Organização Pan-Americana da Saúde, 2011. p. 137.

PARMLEY, W.W. OTC or not OTC - that is the question. Journal of the American College of Cardiology, v. 36, n. 4, p. 1426-7, 2000.

PHARMACEUTICAL SOCIETY OF AUSTRALIA. Professional practice standards - version 4 - 2010. Sidney: PSA, 2011. 104 p.

PHARMACEUTICAL SOCIETY OF AUSTRALIA. Standard and guidelines for pharmacists performing clinical interventions. Sidney: PSA, 2011. 32 p.

SCHLAIFER, M.; ROUSE, M. J. Scope of contemporary pharmacy practice: roles, responsibilities, and functions of pharmacists and pharmacy technicians. *Journal of managed care pharmacy*, v. 16, n. 7, p. 507-8, 2010.

SHPA COMMITTEE. SHPA Standards of practice for clinical pharmacy. *Journal of Pharmacy Practice and Research*, v. 35, n. 2, p. 122-46, 2005.

SOARES, M. A. Medicamentos Não Prescritos. Aconselhamento Farmacêutico (2ª ed.). Volume I e II. Lisboa: Associação Nacional de Farmácias, 2002.

STORPIRTIS, S.; MORI, A. L. P. M.; YOCHIY, A.; RIBEIRO, E.; PORTA, V. Farmácia Clínica e Atenção Farmacêutica. Rio de Janeiro: Guanabara Koogan, 2008, 492p.

STEWART, M.; BRONW, J. B.; WESTON, W. W. et al. Patient-centered Medicine: transforming the Clinical Method, 2ed., Radcliff Medical Press, UK, 2003.

THE SOCIETY OF HOSPITAL PHARMACISTS OF AUSTRALIA. Standards of practice for clinical pharmacy. 2004. Disponível em<a href="http://www.shpa.org.au">http://www.shpa.org.au</a> Acessado em 14/05/2013.

UNITED KINGDOM CLINICAL PHARMACY ASSOCIATION. The UKCPA statement on pharmaceutical care. 1996. Disponível em: <a href="http://www.ukcpa.net">http://www.ukcpa.net</a> Acessado em 14/05/2013.

WORLD HEALTH ORGANIZATION (WHO). Annex 8: Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services. The Hague: World Health Organization, 2011. 20 p.

WORLD HEALTH ORGANIZATION. Developing pharmacy practice - A focus on patient care. Geneva: Who, 2006. 97 p.

WORLD HEALTH ORGANIZATION. The role of the pharmacist in self-care and self-medication. Report of the 4th WHO Consultive Group on the role of the pharmacist. Hague: WHO, 1998.

WORLD HEALTH ORGANIZATION. Promoting rational use of medicines: core components. Disponível em: <a href="http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf">http://apps.who.int/medicinedocs/pdf/h3011e/h3011e.pdf</a> Acessado em 14/05/2013.

# Resolution N° 586

OF AUGUST 29, 2013

**Summary:** This resolution regulates pharmaceutical prescription and gives other measures

### **PREAMBLE**

In contemporary world, models of health care go through profound and sensitive transformation resulting from the demand for services, incorporation of technologies and sustainability challenges of their funding. These factors cause changes in the way of producing health care of people at a time they contribute to the redefinition of the social division of labor between health professions.

The idea of expanding to other healthcare professionals, including pharmacists, greater responsibility in the clinical management of patients, enhancing the care process, has allowed changes in regulatory frameworks in several countries. Based on these changes, the authorization for different professionals to select, start, add, replace, adjust, repeat or discontinue drug therapy was established. This tendency has emerged from the need to expand the coverage of healthcare services and increase the ability to provide these services.

It is a fact that in many healthcare systems, non-medical professionals are not allowed to prescribe medicines. Thus it appears a new model of prescription as multi-professional practice. This practice has specific modes for each profession and is effective according to the needs of patient care, and the responsibilities and limits of performance for each healthcare professional. This improves access and increases control over spending, thereby reducing costs with the provision of rational pharmacotherapy, besides providing better therapeutic results.

International literature demonstrates benefits of prescription by pharmacists according to different models, performed either independently or in collaboration with other professional health team. The pharmacist, in the latter case, prescribes medicines defined in health programs within public systems, routines of institutions or according to pre-established clinical protocols and therapeutic guidelines.

This resolution concludes the conception of prescription as an action to recommend something to the patient. This recommendation may include the selection of therapeutic options, the provision of pharmaceutical services, or referral to other health professionals and services.

It is noteworthy that conceptions of pharmaceutical prescription are fragmented in both health and professional legislation. This resolution innovates because considers pharmaceutical prescription as a pharmacist's clinical assignment, and define its nature, specify and extend its scope beyond the product and describe its process from the perspective of good practices, setting its limits and the need to document and evaluate the activities of prescription.

The Brazilian Federal Pharmacy Council (Conselho Federal de Farmácia - CFF), once regulates pharmaceutical prescription, is in line with the trends of greater integration of the pharmaceutical

profession with other healthcare professions, and reinforce its mission to ensure the wellbeing of the population and provide the technical-scientific and ethical valuation of the pharmacist.

The Brazilian Federal Pharmacy Council (CFF), in the exercise of its powers granted by the Federal Law number 3.820 of November 11, 1960, and

considering the provisions of Article 5, item XIII of the Federal Constitution, which grants freedom of exercise, work or profession, observing the qualifications established by the law;

considering that the CFF, in its particular area of expertise and as an entity of profession regulation, performs typical activity of the State, under Article 5, item XIII, Article 21; item XXIV and Article 22, item XVI, all from Federal Constitution;

considering the legal grant to CFF ensure public health, promoting actions of pharmaceutical assistance at all levels of health care, according to the letter "p", Article 6 of the Federal Law No. 3.820, November 11, 1960, amended by Federal Law No. 9.120, October 26, 1995;

considering CFF's attribution to issue resolutions for effectiveness of the Federal Law No. 3820, of November 11, 1960, and, also, it is responsible for setting or modify the competence of Pharmacy professionals in its scope, according to Article 6, letters "q" and "m";

considering the Federal Law No. 8078 of September 11, 1990, that disposes about consumer protection and gives other measures;

considering the Federal Decree No. 85878 of April 7, 1981 that establishes rules for the implementation of the Federal Law No. 3,820, of November 11, 1960, that disposes about the exercise of the pharmacist, and gives other provisions;

considering the resolutions of the International Conference on Primary Health Care held in Alma-Ata, promoted by the World Health Organization (WHO) and United Nations Fund for Children (UNICEF), on September 6-12, 1978;

considering the Ordinance MS / GM No. 687, of March 30, 2006, which adopted the Policy on Health Promotion;

considering the Ordinance MS / GM No. 4279, dated December 30, 2010 establishing guidelines for the organization of the health care network within the public health system (SUS);

considering the Ordinance MS / GM No. 3124, of December 28, 2012, which redefines the parameters of binding Centers of Support for Family Health (NASF) Types 1 and 2 to the Family Health Teams and / or Primary Care Teams to specific populations, creates the NASF mode 3, and gives other provisions;

considering the Ordinance MS / GM No. 529 of April 1, 2013, establishing the National Patient Safety Program (PNSP);

considering the resolution of the National Health Council (CNS) No. 338, of May 6, 2004, approving the National Pharmaceutical Assistance Policy, in particular the item IV of Article 1, in relation to pharmaceutical care;

considering the Resolution / CFF No. 386 of November 12, 2002, that disposes about the pharmacist's duties within the home care in multidisciplinary teams;

considering the Resolution / CFF No. 357, April 27, 2001 approving the technical regulation for good pharmacy practices;

considering the Resolution / CFF No. 417 of September 29, 2004, approving the Code of Ethics for Pharmaceutical Profession;

considering the Resolution / CFF No. 467 of November 28, 2007, which regulates and sets the duties and responsibilities of the pharmacist in handling medicines and other pharmaceutical products;

considering the Resolution / CFF No. 499, December 17, 2008, that disposes about the provision of pharmaceutical services in pharmacies and drugstores, and gives other provisions, amended by Resolution / CFF No. 505 of 23 June 2009;

considering the Resolution / CFF No. 546 of July 21, 2011, that disposes about the pharmaceutical indication of medicinal plants and herbal exempt from prescription and their registration;

considering the Resolution / CFF No. 555, of November 30, 2011, which regulates the registration, custody and handling of information resulting from the practice of pharmaceutical care in health services;

considering the Resolution / CFF No. 585, of August 29, 2013, which regulates the pharmacist's clinical assignments and gives other measures;

considering the Normative Instruction (IN) of the Brazilian Health Surveillance Agency (Anvisa) No. 5, of April 11, 2007, that disposes about limits on power for the recording and notification of dynamized drugs;

considering the Board Resolution (RDC) Anvisa No. 138 of May 29, 2003, that disposes about the framework in the category of selling drugs;

considering the Anvisa RDC No. 222 of July 29, 2005 approving the 1st edition of the Brazilian Formulary, prepared by the Subcommittee on National Formulary, the Standing Committee on Revision of the Brazilian Pharmacopoeia (CPRVD);

considering the Anvisa RDC No. 26 of March 30, 2007, that disposes about the registration of industrial dynamized homeopathic medicines, and anthroposophic and antihomotoxic;

considering the Anvisa RDC No. 67 of October 8, 2007, that disposes about the Good Practices for Handling Magistral Preparations and Workshops for Human Use in Pharmacies, amended by Anvisa RDC No. 87 of November 21, 2008, and,

considering the Anvisa RDC No. 44 of August 17, 2009, that disposes about good pharmaceutical practice for the sanitary control of operation, dispensing and sale of products and the provision of pharmaceutical services in pharmacies and drugstores and gives other measures, **DECIDES**:

- **Article 1 -** Regulating pharmaceutical prescription under this resolution.
- **Article 2 -** Pharmaceutical prescription is a prerogative of the legally qualified and registered pharmacist at the Pharmacy Regional Council of his/her jurisdiction.
- **Article 3** For the purposes of this resolution, it is defined pharmaceutical prescription as the action by which the pharmacist selects and documents pharmacological and non-pharmacological therapies, and other interventions related to health care for the patient, aiming at promotion, protection and recovery of health, and prevention of diseases and other health problems.
- **Sole Paragraph** Pharmaceutical prescription is a pharmacist's clinical assignment and shall be performed based on the needs of the patient, the best scientific evidence, ethical principles and in accordance with current health policies.
- **Article 4** Pharmaceutical prescription may occur in different pharmaceutical establishments, clinics, services and levels of health care, since it is observed the principle of confidentiality and patient privacy in attendance.

- **Article 5 -** The pharmacist may perform prescription of medicines and other products for therapeutic purposes, which dispensing does not require medical prescription, including manufactured drugs and magistral preparations allopathic or dynamized -, medicinal plants, herbal drugs and other categories or relation of drugs that must be approved by the federal health agency for prescription by the pharmacist.
- § 1° The performance of this action must be based on knowledge and clinical skills that cover good prescribing practices, pathophysiology, semiology, interpersonal communication, clinical pharmacology and therapeutics.
- § 2° Prescribing dynamized medicines and therapies related to complementary and integrative therapies practices should be based on knowledge and skills related to these practices.
- **Article 6** The pharmacist might prescribe medicines which dispensation requires a medical prescription, given an evidence of previous diagnosis and only when provided in programs, protocols, guidelines and technical norms approved for use within healthcare institutions or when formalizing collaboration agreements with other prescribers or healthcare institutions.
- **Paragraph 1** To perform this action the Pharmacy Regional Council shall require the pharmacist from its jurisdiction, recognition of qualification as specialist or professional pharmacist specialist in the clinical area, with evidence of training that includes knowledge and skills in safe prescription practices, pathophysiology, symptomatology, interpersonal communications, clinical pharmacology and therapeutics.
- **Paragraph 2** For prescription of dynamized medicines the Pharmacy Regional Council will require to the pharmacist from its jurisdiction, recognition of the title of specialist in Homeopathy or Anthroposophy.
- § 3° The pharmacist is forbidden to modify the patient medicine prescription issued by other prescriber, except when provided in a collaboration agreement, and in this case the modification must be informed to the other prescriber, accompanied by the equivalent justification.
  - **Article 7** The process of pharmaceutical prescription is constituted by the following steps:
  - I. identification of the patient needs related to health;
  - II. definition of the therapeutic objective;
  - III. selection of therapy or intervention for health care, based on its safety, efficacy, cost and convenience, within the care plan;
  - IV. writing prescription;
  - V. patient orientation;
  - VI. assessment of outcomes:
  - VII. documentation of the prescribing process.
- **Article 8** When prescribing, the pharmacist should adopt measures to contribute to the promotion of patient safety, among there are highlighted:
  - I. basing his/her actions in better scientific evidences;
  - II. making decisions in a shared and patient-centered manner;
  - III. considering the existence of other clinical conditions, use of other medicines, habits and the context of care regarding the patient;

- IV. being aware of legal and ethical aspects related to documents that will be delivered to the patient;
- V. adequately inform the patient, his/her legal guardian or caregiver, the decisions and recommendations, so that they understand them completely;
- VI. adopting measures to ensure that the results in the patient, resulting from pharmaceutical prescription, are monitored and assessed.
- **Article 9** The pharmaceutical prescription must be written out legibly in the vernacular, and it must be observed the nomenclature and the official system of weights and measures, without amendments or erasures, containing at least the following components:
  - I. identification of the pharmacist, clinic or health service establishment to which the pharmacist is associated;
  - II. full name and contacts of the patient;
  - III. description of the pharmacological therapy, when applied, including following information:
    - a) name of medicine or formulation, concentration/ dynamization, pharmaceutical form and way of administration;
    - b) dosage, frequency of the medicine administration, and the length of treatment;
    - c) additional instructions, when necessary.
  - IV. description of the non-pharmacological therapy or another intervention related to the healthcare of patient, when applied;
  - V. full name of pharmacist, signature and register number at the Pharmacy Regional Council;
  - VI. place and date of prescription.
- **Article 10 -** The pharmaceutical prescription, under the Unified Health System (SUS), will necessarily be in accordance with the Brazilian Common Denomination (BCD) or, in its absence, with the International Common Denomination (ICD).
- **Article 11 -** Pharmaceutical prescription, in private scope, will preferably occur in accordance with the BCD or, in its absence, with ICD.
- **Article 12-** It is forbidden to the pharmacist prescribing without his/her identification and without patient's identification, and it is also forbidden prescribing in a secretly, codified, abbreviated, and illegibly way; or sign blank sheets of prescriptions.
- **Article 13** Confidentiality of patient data and information obtained as a result of pharmaceutical prescription will be guaranteed, and it is forbidden their use for any purpose other than sanitary interest or supervision of professional activity.
- **Article 14 -** When prescribing, the pharmacist should guide his/her actions in an ethical manner, always observing the benefit and interest of the patient, maintaining professional and scientific autonomy in relation to companies, institutions and individuals who have a commercial interest or who might get advantages from pharmaceutical prescription.
  - **Article 15** It is forbidden any use of pharmaceutical prescription as advertising and publicity. **Article 16**-Thepharmacistwillmaintainregistered the whole process of prescription as provided by law.

**Article 17** - For the purposes of this resolution there are considered the preamble, definition of terms (glossary) and references in Annex.

**Article18** - This Resolution shall come into force on this date, and any provisions in contrary are revoked.

### WALTER DA SILVA JORGE JOÃO President - CFF

### ANNEX

### **GLOSSARY**

**Collaboration agreement:** is a formal partnership between the pharmacist and prescriber or institution with an explicit agreement between who is delegating (prescriber or institution) and who is receiving the authorization (pharmacist) to prescribe.

**Concentration:** amount of active or inactive substance contained in a given unit of mass or volume of a pharmaceutical product.

**Pharmaceutical office:** pharmaceutical workplace to assist patients, families and caregivers, where it is held privately pharmaceutical consultation. It can operate autonomously or as reliance on hospitals, clinics, community pharmacies, multidisciplinary units of health care, long term care institutions and other health services in the public and private spheres.

**Dosage:** amount of medicine to be administered at one time, or total amount administered fractionated over a period of time.

**Dynamization:** dilution process followed by rhythmic shaking or succussion, and / or successive trituration of the active ingredient in a suitable inert ingredient whose purpose is the development of therapeutic capacity of the drug.

**Brazilian Common Denomination:** denomination of drug or pharmacologically active ingredient approved by the Federal Agency responsible for Sanitary Surveillance.

**International Common Denomination:** denomination of drug or pharmacologically active ingredient, recommended by the World Health Organization.

**Plant drug:** medicinal plant, or its parts, which contain substance or classes of substance responsible for the therapeutic action after collection processes, stabilization, when applied, and drying. And it may be in full form, erased, ground or pulverized.

**Pharmaceutical establishment:** sustainable establishment focused on meeting the health needs of the individual, family and community, through the provision of pharmaceutical services and the provision of medicines, and other health products for the promotion and restoration of health, prevention of diseases, and other health problems.

**Clinical Pharmacy:** field of pharmacy focused on science and practice of the rational use of medicines, where pharmacists take care of the patient to optimize the pharmacotherapy, promote health and wellness and prevent diseases.

**Medicine:** pharmaceutical product obtained or elaborated technically, with prophylactic purpose, curative, and palliative, or for diagnostic purposes.

**Dynamized medicine:** medicine prepared from substance that is subjected to trituration or successive dilutions followed by succussion, or other form of rhythmic shaking with preventive or curative purpose to be administered in accordance with homeopathic, anthroposophic or homotoxicological therapeutic.

**Herbal medicine:** allopathic medicines, obtained by technologically appropriate processes, using exclusively vegetable raw material, with prophylactic, curative, palliative or diagnostic purposes.

**Patient:** person who asks, receives or hire orientation, counseling or other services from a healthcare professional.

**Medicinal plant:** vegetable species cultivated or not, used for therapeutic purposes.

**Care plan:** documented plan for clinical management of diseases and other health problems of the patient's therapy, designed to achieve the goals of treatment. It includes responsibilities and activities agreed between the patient and pharmacist, the definition of therapeutic targets, pharmaceutical interventions, actions to be taken by the patient, and scheduling for feedback and monitoring.

**Prescription:** a set of documented actions related to health care, aiming at promotion, protection and recovery of health, and prevention of diseases and other related problems.

**Prescription of medicines:** action by which the prescriber selects, initiates, adds, replaces, adjusts, repeats or terminates the pharmacotherapy of patients and record these actions towards the promotion, protection and recovery of health, and prevention of diseases and other health problems.

**Health based on evidence:** is an approach that uses the tools of clinical epidemiology, statistics, scientific methodology, and computing to work for the research, knowledge, and performance in health, with the goal of providing the best available information for decision making in this field.

**Health services:** services that deal with diagnosis and treatment of diseases, or deal with promotion, maintenance and recovery of health. They include health offices, clinics, hospitals and other, either public or private.

**Rational use of medicines:** process by which patients receive appropriate medicines to their clinical needs, at suitable dosage to their individual characteristics over appropriate length and at the lowest possible cost to themselves and to society.

**Safe use of medicines:** absence of preventable and accidental injury during the use of medicines. Safe use encompasses the activities of prevention and minimization of damage caused by adverse events that result from the process of the use of medicines.

### **REFERENCES**

AMERICAN COLLEGE OF CLINICAL PHARMACY. The definition of clinical pharmacy. Pharmacotherapy, v. 28, n. 6, p. 816–7, jun. 2008.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA). Resolução nº 157, de 31 de maio de 2002.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA). Resolução nº 26, de 30 de março de 2007. Dispõe sobre o registro de medicamentos dinamizados industrializados homeopáticos, antroposóficos e anti-homotóxicos. http://portal.saude.gov.br/portal/arquivos/pdf/rdc\_26\_30\_03\_07\_registro\_medic\_dinamizados.pdf

ARONSON, J. K. Balanced prescribing. British Journal of Clinical Pharmacology, v. 62, n. 6, p. 629–32, dez. 2006.

BARBANEL, D.; ELDRIDGE, S.; GRIFFITHS, C. Can a self-management programme delivered by a community pharmacist improve asthma control? A randomised trial. Thorax, v. 58, n. 10, p. 851-4, Oct. 2003.

BENRIMOJ, S. L.; FROMMER, M.; RYCHETNIK, L. et al. The value of pharmacist professional services in the community setting: a systematic review of the literature October 2002 - March 2005. 2005. 158p. Disponível em: <a href="http://www.5cpa.com.au/iwov-resources/documents/The\_Guild/PDFs/CPA%20and%20Programs/3CPA%20General/2002-508/2002-508\_fr1.pdf">http://www.5cpa.com.au/iwov-resources/documents/The\_Guild/PDFs/CPA%20and%20Programs/3CPA%20General/2002-508/2002-508\_fr1.pdf</a>.

BLEKINSOPP, A.; PAXTON, P. Symptoms in the pharmacy: a guide to the management of common illness, 4ed. BlackwellPublishing, 2002.

BRASIL. MINISTÉRIO DA EDUCAÇÃO. Resolução CNE/CESU nº. 2/02 de 19 de fevereiro de 2002. Institui Diretrizes Curriculares Nacionais do Curso de graduação em Farmácia. Diário Oficial [da] República Federativa do Brasil, Poder Executivo, Brasília, DF, 04 de março de 2002. Seção 1 p.9.

BRASIL. CONSELHO NACIONAL DE SAÚDE. Resolução n.º 466, de 12 de dezembro de 2012, que aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União, Poder Executivo, Brasília, DF, 2012.

BRASIL, Lei n.º 9787, de 10 de fevereiro de 1999. Estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências. Diário Oficial da República Federativa do Brasil, Brasília, 11 fev. 1999.

BRASIL. CASA CIVIL. SUBCHEFIA PARA ASSUNTOS JURÍDICOS. Lei nº 11.903, de 14 de janeiro de 2009. Dispõe sobre o rastreamento da produção e do consumo de medicamentos por meio de tecnologia de captura, armazenamento e transmissão eletrônica de dados. Diário Oficial da União, Poder Executivo, Brasília, DF, 15 jan. 2009.

BRASIL. CASA CIVIL. SUBCHEFIA PARA ASSUNTOS JURÍDICOS. Lei nº 7.498, de 25 de junho de 1986. Dispõe sobre a regulamentação do exercício da enfermagem e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 26 jun. 1986.

BRASIL. CASA CIVIL. SUBCHEFIA PARA ASSUNTOS JURÍDICOS. Lei nº 8.234, de 17 de setembro de 1991. Regulamenta a profissão de Nutricionista e determina outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 18 set. 1991.

BRASIL. COMISSÃO DE LEIS DO BRASIL. Decreto nº 20.931, de 11 de janeiro de 1932. Regula e fiscaliza o exercício da medicina, da odontologia, da medicina veterinária e das profissões de farmacêutico, parteira e enfermeira, no Brasil, e estabelece penas. Poder Executivo, Brasília, DF, 31 dez. 1932.

BRASIL. Congresso Nacional. Lei nº 5.991, de 17 de dezembro de 1973. Dispõe sobre o controle sanitário do comércio de drogas, medicamentos, insumos farmacêuticos e correlatos, e dá outras providências. D.O.U. Diário Oficial da União; Poder Legislativo, Brasília, 19 dez. 1973.

BRASIL. Congresso Nacional. Lei nº 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. D.O.U. Diário Oficial da União; Poder Legislativo, Brasília, 20 set. 1990.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Resolução nº 477, de 28 de maio de 2008. Dispõe sobre as atribuições do farmacêutico no âmbito das plantas medicinais e fitoterápicos e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, O2 jun. 2008.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Estabelecimentos farmacêuticos no brasil. Base de Dados, abril, 2012. Brasília, 2012.BRASIL. CONSELHO FEDERAL DE FISIOTERAPIA E TERAPIA OCUPACIONAL. Resolução nº. 380, de 03 de novembro de 2010. Regulamenta o uso pelo fisioterapeuta das práticas integrativas e complementares de saúde e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 11 nov. 2010.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Resolução n° 499, de 17 de dezembro de 2008. Dispõe sobre a prestação de serviços farmacêuticos, em farmácias e drogarias, e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 23 dez. 2008.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Resolução nº 546, de 21 de julho de 2011. Dispõe sobre a indicação farmacêutica de plantas medicinais e fitoterápicos isentos de prescrição e o seu registro. Diário Oficial da União, Poder Executivo, Brasília, DF, 26 jul. 2011.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Resolução nº. 357, de 20 de abril de 2001. Aprova o regulamento técnico das boas práticas de farmácia. Diário Oficial da União, Poder Executivo, Brasília, DF, 27 abr. 2001. Seção 1, p. 24-31.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Resolução nº. 465, de 24 de julho de 2007, que dispõe sobre as atribuições do farmacêutico no âmbito da Farmácia Antroposófica e dá outras providências.

BRASIL. CONSELHO FEDERAL DE FARMÁCIA. Resolução nº. 492, de 26 de novembro de 2008, que regulamenta o exercício profissional nos serviços de atendimento pré-hospitalar, na farmácia hospitalar e em outros serviços de saúde, de natureza pública ou privada;

BRASIL. CONSELHO FEDERAL DE NUTRIÇÃO. Resolução n° 304, de 26 de fevereiro de 2003. Dispõe sobre critérios para prescrição dietética na área de nutrição clínica e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 28 fev. 2003.

BRASIL. CONSELHO FEDERAL DE NUTRIÇÃO. Resolução n° 402, de 30 de julho de 2007. Regulamenta a prescrição fitoterápica pelo nutricionista de plantas in natura frescas, ou como droga vegetal nas suas diferentes formas farmacêuticas, e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 06 ago. 2007.

BRASIL. CONSELHO NACIONAL DE SECRETÁRIOS DE SAÚDE. Assistência Farmacêutica no SUS. Brasília, 2007. 186 p.

BRASIL. Decreto nº 5.775, de 10 de maio de 2006. Dispõe sobre o fracionamento de medicamentos, dá nova redação aos arts. 2º e 9º do Decreto nº 74.170, de v10 de junho de 1974, e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 11 maio 2006ª. Disponível em: http://www.planalto.gov.br/ccivil\_03/\_Ato2004-2006/2006/Decreto/D5775.htm. Acesso em: 10 set.2013

BRASIL. Decreto nº 57.477, de 20 de dezembro de 1965. Dispõe sobre manipulação, receituário, industrialização e venda de produtos. Utilizados em Homeopatia e dá outras providências. Diário Oficial da República Federativa do Brasil, Brasília, 28 dez. 1965.

BRASIL. Ministério da Educação. CONSELHO NACIONAL DE EDUCAÇÃO. CÂMARA DE EDUCAÇÃO SUPERIOR Resolução CNE/CES nº 2, de 19 de fevereiro de 2002. Institui diretrizes curriculares nacionais do curso de graduação em Farmácia. Diário Oficial da União, Poder Executivo, Brasília, DF, 04 mar. 2002.

BRASIL. Ministério da Educação. Lei nº. 9.394 - de 20 de dezembro de 1996. Estabelece as diretrizes e bases da educação nacional. Diário Oficial [da] República Federativa do Brasil, Poder Executivo, Brasília, DF, 23 de dezembro de 1996.

BRASIL. MINISTÉRIO DA SAÚDE. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Resolução RDC nº 44, de 17 de agosto de 2009. Dispõe sobre boas práticas farmacêuticas para o controle sanitário do funcionamento, da dispensação e da comercialização de produtos e da prestação de serviços farmacêuticos em farmácias e drogarias e dá outras providências. Diário Oficial da União, Poder Executivo, Brasília, DF, 18 ago. 2009.

BRASIL. MINISTÉRIO DA SAÚDE. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Resolução RDC nº 138, de 29 de maio de 2003. Dispõe sobre o enquadramento na categoria de venda de medicamentos. Diário Oficial da União, Poder Executivo, Brasília, DF, 06 jan. 2004.

BRASIL. MINISTÉRIO DA SAÚDE. Portaria Interministerial nº 2.960, de 9 de dezembro de 2008. Aprova o Programa Nacional de Plantas Medicinais e Fitoterápicos e cria o Comitê Nacional de Plantas Medicinais e Fitoterápicos. Disponível em: <a href="http://bvsms.saude.gov.br/bvs/saudelegis/gm/2008/pri2960\_09\_12\_2008.html">http://bvsms.saude.gov.br/bvs/saudelegis/gm/2008/pri2960\_09\_12\_2008.html</a>>. Acesso em: 10 set. 2013.

BRASIL. MINISTÉRIO DA SAÚDE. Portaria nº 1.625, de 10 de julho de 2007. Altera as atribuições dos profissionais das Equipes de Saúde da Família (ESF) dispostos na Política Nacional de Atenção Básica. Diário Oficial da União, Poder Executivo, Brasília, DF, 11 jul. 2007.

BRASIL. MINISTÉRIO DA SAÚDE. Portaria nº 2.488, de 21 de outubro de 2011. Aprova a Política Nacional de Atenção Básica, estabelecendo a revisão de diretrizes e normas para a organização da atenção básica, para a Estratégia Saúde da Família (ESF) e o Programa de Agentes Comunitários de Saúde (PACS). Diário Oficial [da] República Federativa do Brasil, Poder Executivo, Brasília, DF, 24 out. 2011. Seção 1, p. 48.

BRASIL. MINISTÉRIO DA SAÚDE. Portaria nº 3.916, de 30 de outubro de 1998. Aprova a política nacional de medicamentos. Diário Oficial [da] República Federativa do Brasil, Brasília, DF, 10 nov. 1998. Seção 1, p. 18.

BRASIL. MINISTÉRIO DA SAÚDE. Portaria nº 971, de 03 de maio de 2006. Aprova a Política Nacional de Práticas Integrativas e Complementares (PNPIC) no Sistema Único de Saúde. D.O.U. Diário Oficial da União, Poder Executivo, Brasília, 04 mai. 2006a.

BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE ATENÇÃO À SAÚDE. DEPARTAMENTO DE ATENÇÃO BÁSICA. Doenças respiratórias crônicas. Brasília, 2010. 160 p.

BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE CIÊNCIA, TECNOLOGIA E INSUMOS ESTRATÉGICOS. DEPARTAMENTO DE ASSISTÊNCIA FARMACÊUTICA E INSUMOS ESTRATÉGICOS. Diretrizes para estruturação de farmácias no âmbito do Sistema Único de Saúde. Brasília, 2009. 44 p.

BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE CIÊNCIA, TECNOLOGIA E INSUMOS ESTRATÉGICOS. DEPARTAMENTO DE ASSISTÊNCIA FARMACÊUTICA E INSUMOS ESTRATÉGICOS. I Fórum Nacional de Educação Farmacêutica: o farmacêutico de que o Brasil necessita: relatório. Brasília: Editora do Ministério da Saúde, 2008. 68 p.

BRASIL. MINISTÉRIO DA SAÚDE. SECRETARIA DE GESTÃO ESTRATÉGICA E PARTICIPATIVA. Decreto no 7.508, de 28 de junho de 2011: Regulamentação da Lei no 8.080/90. 1ed. 1 reimpr. Brasília: Ministério da Saúde, 2011. 16 p. - (Série E. Legislação de Saúde).

BRASIL. PRESIDÊNCIA DA REPÚBLICA. Decreto nº 5.813 de 22 de junho de 2006.Aprova a Política Nacional de Plantas Medicinais e Fitoterápicos e dá outras providências.D.O.U. Diário Oficial da União, Poder Executivo, Brasília, 23 jun. 2006b.

- BRASIL. PRESIDÊNCIA DA REPÚBLICA. Decreto-Lei nº 94.406, de 08 de junho de 1987. Regulamenta a Lei nº 7.498, de 25 de junho de 1986, que dispõe sobre o exercício da enfermagem. Diário Oficial da União, Poder Executivo, Brasília, DF, 09 jun. 1987.
- BRASIL. SUBCHEFIA PARA ASSUNTOS JURÍDICOS. Decreto nº 85.878, de 07 de abril de 1981. Estabelece normas para execução da Lei nº 3.820, de 11 de novembro de 1960, sobre o exercício da profissão de farmacêutico, e dá outras providências. Diário Oficial da União, Poder executivo, Brasília, DF, 09 abr. 1981.
- BRODIE, D. C. Drug-use control: keystonetopharmaceuticalservice. Drug IntellClin Pharm, v. 1, p. 63-5, 1967.
  - BRODIE, D. C. Pharmacy's societal purpose. Am J Hosp Pharm, v. 38, n.12, p.1893-1896, 1981.
- BRODIE, D. C.; PARISH, P. A.; POSTON, J. W. Societal needs for drugs and drug related services. Am J PharmEduc, v. 44, p. 276-8, 1980.
- CECILIO, L. C. O. As necessidades de saúde como conceito estruturante na luta pela integralidade e equidade na atenção em saúde. In: PINHEIRO, Roseni; MATTOS, Ruben Araújo de. Os sentidos da integralidade na atenção e no cuidado à saúde. Rio de Janeiro: IMS ABRASCO, p. 113-26, 2001.
- CHAN, S. et al. Chronic disease self-management program for Chinese patients: a preliminary multi-baseline study. Int J Rehabil Res, v. 28, n. 4, p. 351-4, 2005.
- CIPOLLE, R. J.; STRAND, L. M.; MORLEY, P. C. Pharmaceutical care practice: the clinicans guide. 2ed. New York: McGraw-Hill, 2004. 394 p.
- CLYNE, W.; BLEKINSOPP, A.; SEAL, R.A guide to medication review 2008.2th editio. NPC PLus. London: NationalPrescribing Centre; 2008. p. 39.
- CORRER, C. J.; OTUKI, M. F.; SOLER, O. Assistência farmacêutica integrada ao processo de cuidado em saúde: gestão clínica do medicamento. Revista Pan-Amazônica de Saúde, v. 2, n. 3, p. 41-49, 2011.
- CURTISS, F. R.; FRY, R. N.; AVEY, S. G. Framework for pharmacy services quality improvement a bridge to cross the quality chasm. Part I. The opportunity and the tool. J Manag Care Pharm. v. 10, n. 1, p.60-78, 2004.
- DEPARTMENT OF HEALTH. Improving patients' access to medicines: a guide to implementing nurse and pharmacist independent prescribing within the NHS in England. Department of Health, 2006. 76p.
- EMERTON, L.; SHAW, J.; KHEIR, N. Asthma management by New Zealand pharmacists: a pharmaceutical care demonstration project. J Clin Pharm Ther, v. 28, n. 5, p. 395-402, 2003.
- EMMERTON, L.; MARRIOTT, J.; BESSELL, T.; NISSEN, L.; DEAN, L. Pharmacists and Prescribing Rights: Review of International Developments. JournalofPharmacyandPharmaceuticalSciences. v. 8, n. 2, p. 217–25, 2005;
- FRADE, J. C. Q. P. Desenvolvimento e avaliação de um programa educativo relativo à asma dedicado a farmacêuticos de uma rede de farmácias de Minas Gerais. 2006. 190 f. Dissertação (Pós-Graduação em Ciências da Saúde)-Centro de Pesquisas René Rachou, Fundação Oswaldo Cruz, Belo Horizonte, 2006.
- FREEMAN, C. R. COTTRELL, W. N.; KYLE, G. et al. An evaluation of medication review reports across differente settings. Int J ClinPharm, v. 35, n. 1, p. 5-13, 2013.
- FREIDSON, E. Para uma análise comparada das profissões: a institucionalização do discurso e do conhecimento formais. REVISTA BRASILEIRA DE CIÊNCIAS SOCIAIS. São Paulo, v. 11, n. 31, p.141-145, 1996.

- FREIDSON. E.t Renascimento do profissionalismo: teoria, profecia e política. São Paulo: Ed. USP, 1998.
- GALVIN, M. JAGO-BYRNE, M. C.; FITZSIMONS, M.; GRIMES, T. Clinical pharmacist's contribution to medication reconciliation on admission to hospital in Ireland.Int J ClinPharm, v. 35, n. 1, p.14-21. 2013.
- GOLDIM, J.R. Conflito de interesses na área da saúde. 2002. Disponível em: <a href="http://www.bioetica.ufrgs.br/conflit.htm">http://www.bioetica.ufrgs.br/conflit.htm</a> Acesso em 16 de setembro de 2013.
- GRIFFITHS, C.; MOTILIB, J.; AZARD, A. Randomised controlled Trial of a lay-led self-management proramme for bangladeshi patients with chronic disease. Br J Gen Pract, v. 55, n. 520, p. 831-7, 2005.
- HAMMOND, R. W.; SCHWARTZ, A. H.; CAMPBELL, M. J. et al. ACCP position statement american college of clinical pharmacy collaborative drug therapy management by pharmacists 2003. Pharmacotherapy, v. 23, n. 9, p. 1210-25, 2003.
- HARMAN, R. J.; MASON, P. Handbook of Pharmacy Healthcare: Diseases and Patient Advice, 2ed. London: Pharmaceutical Press, 2002, 592 p.
- HEPLER, C. D. Pharmacy as a clinical profession. Am J Hosp Pharm., [S.l.], v. 42, n. 6, p. 1298-1306, Jun. 1985.
- HEPLER, C. D.; STRAND, L. M. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm., [S.l.], v. 47, n. 3, p. 533-43, Mar. 1990.
- HERBORG, H.; SOENDERGAARD, B.; FROEKJAER, B. et al. Improving drug therapy for patients with asthma-part 1: Patient outcomes. J Am Pharm Assoc, v. 41, n. 4, p. 539-50, 2001.
- HERBORG, H.; SOENDERGAARD, B.; FROEKJAER, B. et al. Improving drug therapy for patients with asthma-part 2: Use of antiasthma medications. J AmPharmAssoc, v. 41, n. 4, p. 551-9, Jul-Aug. 2001.
- HINO, P.; Ciosak, S. I.; Serpa da Fonseca, R. M. G. et al. Necessidades em saúde e atenção básica: validação de Instrumentos de Captação. Rev. Esc. Enferm. USP, v. 43, n. 2, p. 1156-67, 2009.
- HOLLAND, R. W.; NIMMO,C. M. Transitions in Pharmacy Practice, part 3: Effecting change the three-ring circus. Am J Health-Sys Pharm, v. 56, p. 2235-41, 1999.
- HOLLAND, R. W.; NIMMO, C. M. Transitions in Pharmacy Practice, part 4: Can a leopard change its spots? Am J Health-Sys Pharm, v. 56, p. 2458-62, 1999.
- HOLLAND, R. W.; NIMMO, C. M. Transitions in Pharmacy Practice, part 5: Walking the tightrope of change. Am J Health-Sys Pharm, v. 57, p. 64-72, 2000.
- HOLLAND, R. W.; NIMMO,C. M. Transitions, part 1: Beyond pharmaceutical care. Am J Health-Sys Pharm, v. 56, p. 1758-64, 1999b.
- HOLLAND, R. W.; NIMMOC. M. Transitions in Pharmacy Practice, part 2: Who does what and Why. Am J Health-Sys Pharm, v. 56, p. 1981-7, 1999.
- HOLMAN, H.; LORIG, K. Patient self-management: a key to effetiviness and efficacy in care chronic disease. Public Health Rep, n. 119, p. 239-43, 2005.
- JANG, Y.; YOO, H. Self-management programs based on the social cognitive theory for Koreans with chronic disease: a systematic review. Contemp Nurse, v. 40, n. 2, p. 147-59, 2012.
- KALMAN, S. H.; SCHLEGEL, J. F. Standards for practice for the profession of pharmacy. Am Pharm, v. 19, n. 3, p. 21-33, 1979.

KHEIR, N.; EMMERTON, L.; SHAW, J. Can pharmacists influence the health-related quality of life of patients with asthma? The New Zealand Pharmaceutical Care experience. SQU Journal for Scientific Research: Medical Sciences, v. 3, n. 2, p. 69-75, 2001.

FEDERACIÓN INTERNACIONAL FARMACÉUTICA; ORGANIZACIÓN MUNDIAL DE LA SALUD. Directrices conjuntas FIP/OMS sobre buenas prácticas en Farmácia: éstandares para la calidad de los servicios farmacéuticos. [S.l.], 2012. 18 p.

LAW, M. R. MA, T.; FISHER, J. et al. Independent pharmacist prescribing in Canada. Canadian Pharmacists Journal, v. 145, n. 1, p. 17-23, 2012.

MANGIAPANE, S. et al. Community pharmacy-based pharmaceutical care for asthma patients. Ann Pharmacother, v. 39, n. 11, p. 1817-22, 2005.

MARIN, N. et al. Assistência Farmacêutica para gerentes municipais.Rio de Janeiro: OPAS/OMS, 2003. 334 p.

MARTINEZ CARRETERO, J. M. Los métodos de evaluación de la competencia profesional: la evaluación clínica objetivo estructurada (ECOE). Educ. méd. [online]. v.8, suppl 2, p. 18-22. 2005.

MARUSIC, S. GOJO-TOMIC, N.; ERDELJIC, V. et al. The effect of pharmacotherapeutic counseling on readmissions and emergency department visits. Int J Clin Pharm, v. 35, n. 1, 37-44, 2013.

MCLEAN, W.; GILLIS, J.; WALLER, R. The BC Community Pharmacy Asthma Study: A study of clinical, economic and holistic outcomes influenced by an asthma protocol provided by specially trained community pharmacists in British Columbia. Can Respir J, v. 10, n. 4, p. 195-202, 2003.

MILLER, G. E. The assessment of clinical skills/competence/performance. Acad Med, v. 65, suppl. 9, p. S63-7, 1990.

NISSEN, L. Pharmacists prescribing: what are the next steps? Am J Health-Syst Pharm, v. 68, p. 2357-61, 2011.

NKANSAH, N. et al. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. Cochrane DatabaseSystRev, v. 7, n. 7, CD000336, 2010.

OGUISSO, T.; FREITAS, G. F. Enfermeiros prescrevendo medicamentos: possibilidades e perspectivas. Rev. bras. enferm. [online], v. 60, n. 2, p. 141-144, 2007.

ORGANIZAÇÃO PAN-AMERICANA DE SAÚDE. FEDERAÇÃO INTERNACIONAL DE FARMACÊUTICOS. FÓRUM FARMACÊUTICO DAS AMÉRICAS. GRUPO TÉCNICO PARA EL DESARROLLO DE COMPETENCIAS PARA LOS SERVICIOS FARMACÉUTICOS. CONFERENCIA PANAMERICANA DE EDUCACIÓN FARMACÉUTICA et al. Competencias del farmacéutico para desarrollar los servicios farmacéuticos (SF) basados en atención primaria de salud (APS) y las buenas prácticas en farmacia (BPF). Washington, 2012. 72 p. (in press).

ORGANIZACIÓN PANAMERICANA DE LA SALUD; ORGANIZACIÓN MUNDIAL DE LA SALUD. Desarrollo y fortalecimiento de los sistemas locales de salud en la transformacion de los sistemas nacionales de salud: los medicamentos esenciales. Washington, 1990.

ORGANIZACIÓN PANAMERICANA DE LA SALUD. Guía servicios farmacéuticos en la atención primaria de salud. Washington, 2011. 84 p.(in press).

PARMLEY, W.W. OTC or not OTC - that is the question. Journal of the American College of Cardiology, v. 36, n. 4, p. 1426-7, 2000.

PEELING, R.; YE, H. Diagnostic tools for preventing and managing maternal and congenital syphilis: an overview. Bull World Health Organ], v. 82, n. 6, p. 439-46, 2004.

PENNA, R. P. Pharmaceutical care: pharmacy's mission for the 1990s. Am J Health Syst Pharm, v. 47, n. 3, p. 543-549, 1990.

PENNA, R. P. Pharmacy: a profession in transition or a transitory profession? Am J Hosp Pharm, v. 44, n. 9, p. 2053-9, 1987.

PHARMACEUTICAL SOCIETY OF AUSTRALIA. Principles for a national framework for prescribing by non-medical health professionals. 2010. Disponível em: <a href="http://www.psa.org.au/archives/2257">http://www.psa.org.au/archives/2257</a>. Acessado em 25 maio 2012.

PIERPAOLI, P. G. An iconoclastic perspective on progress in pharmacy practice. Am J Health SystPharm, v. 52, n. 16, p. 1763-70, 1995.

PINHEIRO, R. M. Serviços farmacêuticos na atenção primária à saúde. Rev. Tempus ActasSaúde Cole, v. 4, n. 3, p. 15-22, 2010.

ROUGHEAD, L.; SEMPLE, S.; VITRY, A. The value of pharmacist professional services in the community setting: a systematic review of the literature 1990-2002. Adelaide: Quality Use of Medicines and Pharmacy Research Centre, School of Pharmaceutical, Molecular and Biomedical Sciences, University of South Australia, 2003. 202p. Disponível em: <a href="http://beta.guild.org.au/uploadedfiles/Research\_and\_Development\_Grants\_Program/Projects/2002-507\_fr.pdf">http://beta.guild.org.au/uploadedfiles/Research\_and\_Development\_Grants\_Program/Projects/2002-507\_fr.pdf</a>.

SAINI, B.; KRASSS, I.; ARMOUR, C. Development, implementation, and evaluation of community pharmacy-basead asthma care model. Ann Pharmacother., [S.l.], v. 38, p. 1954-60, Nov. 2004.

SOARES, M. A. Medicamentos Não Prescritos. Aconselhamento Farmacêutico (2ª ed.). Volume I e II. Lisboa: Associação Nacional de Farmácias, 2002.

TONNA AP. Aninternational overview of some pharmacistprescribingmodels. Journal of the Malta College of Pharmacy Practice, p. 20–6, 2008.

VAN MIL, J. W. F.; SCHULZ, M. A review of pharmaceutical care in community pharmacy in Europe. Health Highlights, v. 7, n. 1, p. 155-68, 2006.

WALKER, C. et al. Exploring the role of self-management programmes in caring for people from culturally and linguistically diverse backgrounds in Melbourne, Australia. Health Expectations, n. 8, p. 315-23, 2005.

WORLD HEALTH ORGANIZATION; ORGANISATION MONDIALE DE LA SANTE. The Role of the Pharmacist in the Health Care System: Report of a WHO Consultative Group New Delhi, India 13-16 December 1988; Report of a WHO Meeting Tóquio, Japan 31 August-3 September 1993. Geneva, 1994. (WHO/PHARM/94.569).

WORLD HEALTH ORGANIZATION (WHO). Estrutura conceitual da Classificação Internacional sobre Segurança do Doente. Relatório Técnico Final. Direção Geral da Saúde. 2011; 142 p. Disponível em: http://apps.who.int/iris/bitstream/10665/70882/4/WHO\_IER\_PSP\_2010.2\_por.df

WORLD HEALTH ORGANIZATION (WHO). World Alliance for Patient Safety: Forward programme 2006–2007. Geneva. Disponívelem: http://www.who.int/patientsafety/World Health.

# Open Letter On Pharmaceutical Prescription

Ensuring the provision of services and products for the care of people is a public health issue. The need to access and use therapeutic resources is higher than the capacity of funding and provision in health care systems. Due to lack of medical care, people often times make treatment decisions on their own, selecting therapies that in many cases are neither effective nor safe, and for this reason not indicated. This may lead to the aggravation of the clinical condition. It can also create additional health problems and even delaying early diagnosis and initiation of effective and safe therapy. The lack of access to basic health care services can cause harm to people, increasing the costs to health systems.

Pharmacies are widely available in Brazil due to their high geographical distribution. Pharmacists often represent the first option of the population to access health care services. This is even more prominent for families from low socioeconomic status. However, even though pharmacists occupy a strategic position in the health care systems, their expertise is often underutilized.

In the contemporary world, healthcare models are going through profound changes. There is an increase in the demand for services. New technologies have been emerging and being incorporated to health systems, which present challenges to sustainable funding. These factors impact the way that health care is delivered to people. As a result, the social division of labor among health professions needs to be redefined. New players are active in these new models.

The idea of expanding to other professionals greater responsibility in the clinical management of patients has promoted changes in regulatory frameworks. The patient care process is intensified. Following these changes, several health care professions have been legally authorized to define therapeutic actions to better care for patients. The right to prescribe a drug is not exclusive of physicians. More and more, other health care professionals are legally allowed to select, start, add, replace, adjust, repeat or discontinue a given drug therapy. This tendency emerged from the need to expand the coverage of health services with the goal of increasing the capacity of these services. The result is a more effective problem solving process.

Over the years, non-medical professionals have been authorized to prescribe medications. Several health care systems around the world have been implementing policies addressing this issue. This fact has positioned the act of prescribing as a multidisciplinary task. This practice has specific modes for each profession and is substantiated in accordance to the needs of the patient. It is needles to say that each profession involved in prescribing has its own responsibilities and limitations. These initiatives facilitate access to medicines and increases control over spending. The result is a reduction over expenditures with the provision of a more rational pharmacotherapy. Ultimately, the result is the development of better therapeutic outcomes.

We can easily say that the discussion of prescription rights by pharmacists is not an easy task to accomplish. Historically, Brazilian pharmacists have been afraid to use terms such as: pharmacist

counseling, pharmaceutical care, pharmacist office, and pharmacist prescription. In our country, those terms and expressions are still considered taboos. Conversely, in countries in which the pharmacy profession is more advanced, those terms are already part of pharmacists' technical language. In Brazil, we often justify the non-appropriateness of using these terms. Instead, we prefer euphemisms such as pharmacist recommendation, documented dispensing, among others. The same resistance is not observed in other health care professions as nursing, nutrition and physical therapy. We can speculate that the boldness of those other health professions may have contributed to significant progress in their role as active patient care providers.

In the year of 2013, the Brazilian Federal Pharmacy Council (Conselho Federal de Farmácia – CFF) conducted a Public Consultation (Consultation 6/2013) inquiring the public about the prescription rights by pharmacists. After reviewing more than 200 contributions submitted in response to that, we decided to prepare this document. We focus on the most frequent questions and topics. They are summarized. It is important to say that 85% of the responses were favorable to the pharmacists' rights to prescribe.

- 1. Definition and scope of the pharmacist prescription;
- 2. Jurisdiction of CFF in regulating this subject and legality of the regulation;
- 3. Education / qualification / certification of pharmacists to prescribe and,
- 4. The alleged conflict of interest between dispensing and prescribing medicines.

These issues are discussed below in the form of questions and answers.

### 1. WHAT ARE THE DEFINITION AND SCOPE OF PHARMACIST PRESCRIPTION?

Prescribing is one of the **clinical pharmacist's activities** and must be performed according to the health needs of the patient. The resolution defines prescription as **'an action of recommending something to the patient**. The recommendation may include the selection of a **therapeutic option**, **the supply of pharmacy services or referral to either other health professionals or services**. The act of prescribing is not a clinical service *per se* but one of the activities that compose the process of patient care.

The pharmacist's prescription proposed in Brazil is a broad concept that goes beyond the selection of medicines. Similar view is adopted by other health care professions and represents a strategy for the inclusion of this activity in the health care system. The reason is that it broadly meets the needs of patients, minimizing overlapping areas of expertise that are exclusive to other professional categories.

With regards to medicines and other health products that may be prescribed by pharmacists, the present resolution is aligned with current sanitary regulations. In addition, it creates legal basis for pharmacist prescription of new categories of drugs that may be approved by the federal sanitary agency.

In countries in which pharmacists are allowed to prescribe medicines, policies were implemented based on a clear hierarchy of pharmacists' professional autonomy. They were implemented taking into consideration the complexity of therapy, type of service, training and professional certification, as well as the types of products authorized by the regulatory sanitary agency.

Based on international experiences, two types of pharmacist prescription of medicines were established:

- a) The independent prescription in which the pharmacist can independently prescribe drugs whose **dispensing does not require a medical prescription**.
- b) Regarding to prescription drugs or those whose dispensing requires a medical prescription, the resolution allows the specialist pharmacist to perform the role of a prescriber. In this situation, the pharmacist can either start or make changes in pharmacotherapy. It is important to make clear that the prescription can only be made following rigorous protocols, clinical guidelines and technical standards approved for use within specific healthcare institutions. Also, it is necessary to implement formal collaborative agreements with other prescribers such as doctors and dentists.

### 2. IS CFF ABLE TO REGULATE PHARMACIST PRESCRIPTION?

Yes. The CFF is authorized by law (# 3820 of November, 11/1960) to "expedite resolutions, defining or modifying responsibility as well as professional competencies of pharmacist professionals according to future needs."

### 3. IS LEGAL FOR PHARMACISTS TO PRESCRIBE?

Yes. The possibility of prescription by pharmacists is implicit in various regulations for both OTC medicines and for those requiring continuous use (in situations of continuing treatment previously prescribed).

The law that describes the tracking of production and consumption of drugs (Law 11903 of January 14, 2009), defines the following categories of drugs: a) exempt from prescription; b) selling under prescription with prescription retention; and c) selling under the responsibility of the pharmacist without prescription retention. The possibility of pharmacist prescription is implied for drugs of both categories "a" and "c".

In 2001, the CFF published a Resolution (No. 357 of April 27, 2001) in which the pharmacist prescription is portended under the term 'responsible self-medication, associated with OTC drugs'. Another Resolution of CFF (No. 467 of November 28, 2007) points out that the pharmacist is responsible for handling, dispensing and selling OTC drugs independently of prescription. This resolution also indicates that in the case of chronic medications previously dispensed, pharmacists are allowed to make a decision (and be accountable for that) for handling, dispensing and selling the product regardless of the existence of a new prescription.

Another directive that addresses this issue includes the role of the pharmacist in prescribing medicinal plants or herbal products to treat minor, self-diagnosed or self-limiting disease conditions (Resolution No. 477 of May 28, 2008). Also, pharmacists can legally recommend the use of medicinal plants and non-prescription herbal products (Resolution No. 546 of July 21, 2011). The Brazilian Health Surveillance Agency (ANVISA) defines in a legal norm (No. 44 of August 17, 2009) that pharmaceutical services performed by pharmacists need to be registered in a specific formulary. This includes the recommendation of nonprescription medication.

Finally, the Decree No. 20931 of January 11, 1932 that "regulates and supervises the practice of medicine, dentistry, veterinary medicine and the profession of pharmacy, midwife and nurse in Brazil", mentions the prescription as "prescription drugs". According to the Decree, the act of prescribing

is related to both the professions of medicine as well as dentistry. There is no explicit mention to prescription made by pharmacists. Therefore, we conclude that there is no legal impediment for pharmacist prescription.

## 4. DOES THE PHARMACIST HAVE REQUIRED EDUCATION AND QUALIFICATION TO PRESCRIBE MEDICINES?

The resolution establishes pharmacist prescription with different levels of complexity. Pharmacists are trained in areas that provide them with appropriate knowledge on drugs – since its development until the indication as well as commercialization, including mechanisms of action, doses, pharmacokinetic and safe conditions of use. Moreover, given the different levels of complexity of pharmacist prescription and the constant evolution of the therapeutic resources, it is necessary to develop actions to improve pharmacists' qualification to prescribe. The resolution recommends the minimum desirable contents to qualify the pharmacist who wishes to take on this responsibility. The resolution also defines minimum standards for the recognition of specialist training in the clinical area for those professionals who wish to exercise the right to prescribe drugs for situations with higher levels of complexity.

An interesting instance on how the regulation of new professional duties can be positive to the search for continuous education was seen in the past, when pharmacists were allowed to work with clinical cytopathology. The new regulation directly influenced the inclusion of new courses in pharmacy profession curricula with the goal to attend the new professional assignment.

# 5. IS THERE ANY CONFLICT OF INTEREST BETWEEN THE PHARMACIST PRESCRIBING AND TRADING MEDICINES?

Before any consideration, it is necessary to clarify that the professional exercise does not correspond to a commercial activity. The primary function of the pharmacist is to provide clinical services to the patient with the main goal of meeting the patient's health needs in an ethical as well as responsible manner.

Professor José Roberto Goldim (a Brazilian prominent scholar and academic author in Bioethics) constant applies the definition of conflict of interest as established by Thompson. The latter defines it as "a set of conditions in which the professional judgment concerning a primary interest tends to be influenced improperly by a secondary interest." The former argues, "in general, people tend to identify conflict of interest only in situations involving economic aspects." However, "other important aspects can also be considered when dealing with conflict of interest." He continues, "one cannot forget other areas of conflict such as personal, social, scientific, and others related to healthcare, education, religion that goes beyond the economic."

What characterizes the so-called "primary interest" are moral values considered superior constituting the core principles of professional ethics. The primary interest is what guides a professional conduct directed to promoting the well being of the patient.

Goldim argues that a conflict of interest can occur in several situations. For instance: there are situations of potential conflict in the professional relationship with an institution to which the professional provides services or have any collaborative relationship. Also, conflicts may arise between professionals

or between professionals and their customers as well as recipients of services. In the healthcare area, in some circumstances there may be no coincidence between **the interests** of a professional and the interests of his/her patient. The author comments that "the better the bond between individuals who are related, greater is the awareness of their expectations and values." He adds, "(...) this interaction can reduce the possibility of the occurrence of a conflict of interest."

From this explanation, we consider that when a patient voluntarily demands for pharmacy services in order to be assisted in the treatment of a self-limiting health problem (e.g. when a prescription of an over the counter medicine can meet the patient's expectations), this act does not characterize a conflict of interest. Any attitude that leads the pharmacist to give in to demands of economic order is considered as inappropriate professional conduct, which can be hindered by disciplinary sanctions as provided by the Code of Ethics.

The possibility of conflict of interest between the activities of prescribing and dispensing performed by the same pharmacist was subject of debate in all countries that have regulated the pharmacist prescription. In this instance, the considerations of the Alberta College of Pharmacists (Canada) on the subject deserve to be highlighted: "The act of prescribing and dispensing medicines by pharmacists is similar to other professional who prescribe services and then offer them. Examples include doctors, dentists, veterinarians, chiropractors, physiotherapists, all that evaluate the patient and recommend the necessary services, so if the patient agrees, the services are provided. The same way as other health professionals, the pharmacist must exercise their practice according to a strict code of ethics (...)."

Given the above, the Brazilian Federal Pharmacy Council (Conselho Federal de Farmácia – CFF) and the Regional Pharmacy Council (Conselhos Regionais de Farmácia) have the necessary tools to restrain inappropriate professional pharmacist practice and, above all, to protect the interests of the patient.

### FINAL CONSIDERATIONS

The resolution innovates when consider prescription as a clinical assignment of the pharmacist, define its nature, specify and extend its scope beyond the product, describe the process from the perspective of good practices, setting its limits and the need to document and evaluate the activities related to a prescription.

The action of the CFF in regulating the pharmacist prescription is in accordance to the trend of greater integration of the pharmacist with other professions in the healthcare arena, and it reinforces its mission to ensure the well being of the population and provides for pharmacist's technical-scientific and ethical appreciation.

Considering the different realities and particular demands of the population, society calls for more attention to their healthcare needs. Responding to this call is a big challenge, but it is also a unique opportunity for the pharmacist to take on an important role as the protagonist of actions in favor of the Brazilian population.

Brasília/DF, 25 de setembro de 2013.

PRESIDENT Walter da Silva Jorge João

