

Ethical and legal aspects of medication prescription by nurses in the National Primary Care Policy of Brazil

Aspectos éticos e legais da prescrição de medicamentos por enfermeiro na Política Nacional de Atenção Básica do Brasil

Aspectos éticos y legales de la prescripción de medicamentos por parte de enfermeras en la Política Nacional de Atención Primaria en Brasil

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REVISA

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RESUMO

Objetivo: Identificar e discutir os aspectos éticos e legais da prescrição de medicamentos por profissional enfermeiro na Estratégia de Saúde da Família, Brasil. **Método:** Estudo exploratório, de análise documental, que tomou como base a legislação brasileira, mas especificamente às legislações do exercício profissional de Enfermagem. **Resultados:** A prescrição medicamentosa realizada por enfermeiro está suportada por legislação que regulamenta a prescrição, através de dispositivos legais e infralegais, que asseguram ao enfermeiro como integrante da equipe de saúde, a prescrição de medicamentos em programas de saúde pública e em rotina aprovada pela instituição. Esta prática está assegurada aos enfermeiros que atuam na Política Nacional da Atenção Básica, mais precisamente na Estratégia de Saúde da Família. **Conclusão:** A prescrição de medicamentos está assegurada por legislação específica apesar da não dispensação de medicamentos em Programa de Farmácia Popular do Governo Federal o que contraria a Lei do exercício profissional da Enfermagem, e dificulta o acesso da população usuária do Sistema único de Saúde a medicação prescrita por enfermeiro em programa de saúde pública.

Descritores: Enfermagem; Prática Profissional; Legislação como Assunto; Ética; Atenção Primária à saúde.

ABSTRACT

Objective: To identify and discuss the ethical and legal aspects of medication prescription by a nurse professional in the Family Health Strategy, Brazil. **Method:** Exploratory study, of documentary analysis, which was based on Brazilian legislation, but specifically on the legislation of professional nursing practice. **Results:** The medication prescription performed by a nurse is supported by legislation that regulates the prescription, through legal and non-legal provisions, which assure the nurse as a member of the health team, the prescription of drugs in public health programs and in a routine approved by the institution. This practice is assured to nurses who work in the National Primary Care Policy, more precisely in the Family Health Strategy. **Conclusion:** The prescription of medications is ensured by specific legislation despite the non-dispensation of medications in the Federal Government's Popular Pharmacy Program, which contradicts the Law of Professional Nursing Practice, and hinders the access of the population using the Single Health System to medication prescribed by a nurse in a public health program.

Descriptors: Nursing; Professional Practice; Legislation as Topic; Ethic; Primary health care.

RESUMEN

Objetivo: Identificar y discutir los aspectos éticos y legales de la prescripción de medicamentos por un profesional de enfermería en la Estrategia de Salud Familiar, Brasil. **Método:** estudio exploratorio, de análisis documental, que se basó en la legislación brasileña, pero específicamente en la legislación de la práctica profesional de enfermería. **Resultados:** la prescripción de medicamentos realizada por una enfermera está respaldada por la legislación que regula la prescripción, a través de disposiciones legales y no legales, que aseguran a la enfermera como miembro del equipo de salud, la prescripción de medicamentos en programas de salud pública y en una rutina aprobada por la institución. Esta práctica está garantizada para las enfermeras que trabajan en la Política Nacional de Atención Primaria, más precisamente en la Estrategia de Salud Familiar. **Conclusión:** La prescripción de medicamentos está garantizada por una legislación específica a pesar de la no dispensación de medicamentos en el Programa de Farmacia Popular del Gobierno Federal, que contradice la Ley de Práctica Profesional de Enfermería y dificulta el acceso de la población que usa el Sistema Único de Salud a medicamentos. recetado por una enfermera en un programa de salud pública.

Descriptores: Enfermería; Práctica profesional; Legislación como tema; Ética; Atención primaria de salud.

Introduction

In Brazil, the prescription of medications by nurses is part of the Family Health Strategy (ESF) policy, which represents a significant and structuring alternative for Brazilian health policy, with a view to meeting the provisions of the 1988 Brazilian Constitution on health, and the principles of the Unified Health System (SUS).¹⁻² The prescription of medications by a professional nurse is ensured by Law no. 7,498 / 1986 and by Decree no. 94.406 / 1987 that regulate the profession, being established as an activity of the nurse who is part of the health team in public health programs and in a routine approved by the health institution.^{3,4} Even provided by law, this practice has sparked intense debates with criticism, especially from the medical category.⁵

Despite legal support, and despite legal disputes, the discussion among professionals is still incipient, creating doubts among them. As a result of this situation, different practices related to this assignment are observed in health services. In addition, at all times, due to the constant technological advancement, new laws are being implemented in the health sector, some even referring to the issue of prescription of medicines and the request for exams by nurses, constantly highlighting it, since their limits do not seem clear to many health professionals, including nurses.⁶

The nursing professional acts autonomously and in line with ethical and legal, technical-scientific and theoretical-philosophical precepts; carries out its activities with competence to promote the human being in its entirety, in accordance with the Principles of Ethics and Bioethics, and participates as a member of the Nursing and health team in the defense of Public Policies, with emphasis on health policies that guarantee universality of access, integral care, resolution, preservation of people's autonomy, community participation, hierarchization and political-administrative decentralization of health services.⁷

Method

Type of exploratory study, where a documentary research of Brazilian legislation was carried out which regulates the prescription of medicines by nurses. This methodological resource is applied to the proposed objectives, since the documents are sources of records that report events, values and discourses of a certain social group in a historical period, explaining intrinsic forms of social relations.⁸

The document is a title or diploma that serves as proof: historical document. Any object or fact that serves as proof, confirmation or testimony: photographic documents".⁹ Document can also be seen as "everything that is a vestige of the past, everything that serves as a testimony, is considered as a document or 'source'.¹⁰ In the nursing area, we cite laws, decrees, ordinances, resolutions, protocols, etc.

Documentary research is widely used in the area of history, through the analysis of historical documents, records and everything that has been mentioned about the fact to be researched. The documents were selected from their preliminary assessment¹¹ in the dimensions proposed by Cellard (2008)¹⁰: analysis of the context, the author / authors, the authenticity and reliability of the text, the nature of the text, the key concepts and the internal logic text. Documentary analysis favors the observation of the maturation or evolution

process of individuals, groups, concepts, knowledge, behaviors, mentalities, practices, among others.¹¹

The laws that regulate the prescription of medications by a professional nurse in the Family Health Strategy were analyzed, inserted in the service network as a priority strategy for organizing Primary Care in Brazil, through the National Primary Care Policy (PNAB), with a view to revision of the current implementation and operationalization regulations, within the scope of the Unified Health System (SUS), which ensure that nurses act as part of the health team when prescribing medications in public health programs and in a routine approved by the institution, in accordance with with the Nursing Professional Exercise Law n. 7,498/1986³, and Decree no. 94,406/1984⁴.

The Ministry of Health currently regulates the prescription through Ordinance No. 2436 / GM / MS12, of September 21, 2017, which approves the National Primary Care Policy (PNAB), with a view to reviewing the current implementation and operationalization regulations, within the scope of the Unified Health System (SUS), establishing guidelines for the organization of the Primary Care component in the Health Care Network (RAS).

Other legal and non-legal provisions related to the subject in the health sector were analyzed, among them: the Medical Act Law n. 12,842 / 2013¹³; the Resolutions of the Collegiate Board (RDC) n. 44/2010¹⁴ and n. 20/2011¹⁵ related to the use of antimicrobials and Ordinance no. 184/2011, which provides for the Popular Pharmacy Program in Brazil.¹¹

After the prescription rules were taken over by nurses, the legislation was analyzed through the following phases: pre-analysis, exploration of the material or coding, treatment of results, inference and interpretation.¹⁶ There was no need to submit the research project to the ethics committee, as it is documentary research with public domain legislation available on the internet and on institutional websites.

Results and Discussion

Legal devices that regulate the act of prescribing by a professional nurse in Brazil

The first document that mentions the prescription of medication by a nursing professional in Brazil was initially described in 1932, through Decree no. 20931, for regulation and inspection of the practice of medicine, dentistry, veterinary medicine and the professions of pharmacist, midwife and nurse. The decree says nothing about the prescription of medicines by nurses, only doctors and dentists were considered prescribers, excluding nurses and pharmacists.¹¹

Historically, the act of prescribing medicines by nursing was provided to midwives in urgent cases, through Decree no. 20931, which allowed them to prescribe medications, when urgently claimed by the need to avoid or combat serious accidents that compromise the life of the parturient, fetus or newborn.¹⁷ The regulation of medication prescription by nurses was guaranteed in 1986, through the approval of Law no. 7.498³, which regulates the Professional Nursing Practice, which describes in its article 11, item II, item "c", to the nurse as a member of the health team the prescription of medications in public health programs and in a routine approved by the institution of health (Law n.7498, 1986) and in Decree n.94.4064 of June 1987, which legally ensure such

assignment, related to the prescribing nurse in public health programs, listed by the Ministry of Health.

Infralegal devices related to the act of prescribing by a professional nurse in Brazil

In the 1990s and 2000s the normative and regulatory resolutions of the nursing process in Brazil were instituted, being established by the Cofen / Federal Nursing Council, the disciplining of the Nursing Care Systematization (SAE) and implementation of the nursing process in public environments and private in which professional nursing care occurs through Resolution no. 272/2002¹⁸ and n. 358/2009.¹⁹ In this situation, without the SAE approach and if it is not inserted within the context of the nursing consultation, the prescription of medications tends to be a reproduction of the complaint-conduct model²⁰, whose professional-user relationship is based on the restricted verbalization of symptoms by the user who receives an immediate curative procedure in return.¹¹

Despite the fact that the Ministry of Health's programs do not contemplate the Systematization of Nursing Assistance in health programs, the nursing prescription must be guided by the SAE, a tool through which the theoretical structure is applied to Nursing practice.²⁻⁵ As part of this integrative work process is the nursing consultation, an independent activity, whose objective is to provide conditions for improving the quality of life of users, family and community¹¹, through a contextualized and participatory approach.²¹

In 1993, COFEN approved Resolution no. 159 that regulates nursing consultation, and in the 2000s Resolution no. 271/2002²² that regulates nurses' actions in the consultation, prescription of medicines and ordering of exams, attributions contemplated in Law n° 7.498³, and in Decree n° 94.406⁴, which were later revoked, as there is no need to establish an infralegal device to regulate the procedure, due to the legal fragility and the existence of a federal law legitimizing the nurse the act of prescribing medicines and conducting a nursing consultation, except for the request for exams by nurses, a standardized procedure through Resolution Cofen n. 195/97²³ which provides for the request for routine and complementary examinations by nurses.

Other legal and infralegal provisions that permeate the prescription of medications by nurses

The legal actions imposed by the Federal Council of Medicine against the prescription of medicines by nurses are constant until the emergence and regulation of Law n° 12842/2013²⁴ which provides for the practice of Medicine in Brazil. We emphasize that legislation proposed to the practice of medicine contrary to the prescription of medicines and other procedures shared with other health professionals, was guided by national mobilizations that ensured the nurses' own legal provisions, through the Federal Nursing Council, Unions and other class Councils.

*“§ 5th Except for the list of private activities of the doctor:
(...)”*

§ 7th The provisions of this article will be applied in such a way that the skills of the professions of social worker, biologist, biomedical, nurse, pharmacist, physiotherapist, speech therapist, nutritionist, physical education professional, psychologist,

occupational therapist and technician and radiology technologist are safeguarded."

Recognition by ANVISA- National Health Surveillance Agency about the nurse's prescription drug

"ANVISA recognizes the nurse's assignment on the prescription of drugs established in public health programs and in routine approved by the health institution, according to Law No. 7498/86.

Recently, the Regional Nursing Council of Rio de Janeiro (Coren-RJ) sent a letter requesting the revision of RDC No. 44/2010²⁵, which provides for the control of antimicrobial drugs for use under prescription, a request accepted with the edition of RDC No. 20, dated 05/05/2011.²⁶

Thus, with art. 4 of the RDC n ° 20/2011¹⁵ it is clear that the prescription of drugs is the responsibility of each and every professional regularly qualified, therefore, it is not an exclusively medical act. Through this ANVISA Resolution, it was established that the federal legislation already provided that nurses make prescriptions for medications belonging to the public health program, also considering the list of certain medications and provided for in the institution's program or routine."

Ordinance No. 111²⁷, of January 28, 2016, which provides for the Popular Pharmacy Program of Brazil (PFPB), determines as a requirement for dispensing that the user *must present a valid medical prescription, with the presentation of a medical prescription, report or certificate being mandatory. doctor with the patient's address information, which is provided for in Law No. 5,991 / 73, which provides for the Sanitary Control of the Trade in Drugs, Medicines, Pharmaceutical Supplies and Related Products, and provides other measures (PFPB, 2016).*

In 2017, an injunction from the Federal Court, which complied with a request from the Federal Council of Medicine Federal Council of Medicine (CFM), prohibiting nurses from making requests for exams and consultations in Primary Care was suspended by the Federal Regional Court (TRF) of the 1st Region, who accepted the appeal that was contrary to the injunction, which partially suspended Ordinance No. 2,488 of 2011, in the part that allows nurses to order exams.²⁸

Currently, Ordinance No. 2,436 / MS¹² of 2017, repeals Ordinance No. 2,488/GM/MS²⁹, which approves the National Primary Care Policy, establishing the revision of guidelines for the organization of Primary Care, within the scope of the Unified Health System (SUS), which determines as specific duties of nurses working in Primary Care: perform nursing consultation, procedures, request complementary tests, prescribe medications according to protocols, clinical and therapeutic guidelines, or other technical regulations established by the federal, state, municipal manager or the Federal District, subject to the legal provisions of the profession.²⁹

The Working Group established by the Federal Nursing Council (Cofen) presented to the Pharmaceutical Assistance Department of the Ministry of Health (DAF / MS), a proposal for the inclusion of nurses as prescribers of the Popular

Pharmacy Program.³⁰

The Law establishes and ensures the prescription of medications and not transcription as many medical and nursing professionals understand, but for this act to be performed without malpractice and/or imprudence, the professional nurse must exercise Nursing with freedom, technical, scientific and health, autonomy, and to be treated without discrimination of any kind, according to legal, ethical and human rights principles and assumptions, 30 not guiding professional practice in Primary Care, only in the prescription of medicines, assisting the SUS user in a holistic way with “quality of life nursing assistance to the person and family in the process of being born, living, dying and mourning”.⁷

Conclusion

The prescription of medications by nurses as part of the health team in public health programs in Brazil is consolidated and ensured by specific legislation. The non-dispensation of medications prescribed by nurses in public health programs in the Popular Pharmacy Program of the Federal Government contradicts the law of professional nursing practice, and makes it difficult for the population using the Single Health System to access prescribed medication, diverging from what is recommended by the National Primary Care Policy.

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