JAFF

Jornal de Assistência Farmacêutica e Farmacoeconomia
v.9, n.4, p.57-60, out. 2024.
Opinion Article

Modernizing the registration of psychotropic drugs: Ordinance 344/98 needs to be updated.

Modernização da escrituração de psicotrópicos: a Portaria 344/98 precisa de atualização

Cássio Alexandre Oliveira Rodrigues[1], Higor José Pinheiro Lopes[2]

[1] Child and Adolescent Psychosocial Care Center (Centro de Atenção Psicossocial Infantojuvenil), Natal, Rio Grande do Norte, Brazil.
[2] Divine Love Hospital and Maternity (Hospital e Maternidade Divino Amor), Parnamirim, Rio Grande do Norte, Brazil.

Corresponding author:
Cássio Alexandre Oliveira Rodrigues. Centro de Atenção Psicossocial Infanto-Juvenil (Child and Adolescent Psychosocial Care Center), Av. Capitão-Mor Gouveia 896, Cidade da Esperança, Natal, RN, Brazil.
E-mail: cassioalexandr3@live.com

Received: February 18, 2024
Accepted for publication: June 27, 2024

Over the past three decades, the world has undergone significant changes and technological advances that have enabled automation and, consequently, improvements in work processes. These developments have optimized information management, reduced workloads and bureaucratic barriers—particularly in contexts with limited human resources—and thereby decreased operational time in daily routines.[1–2] In health services, especially within hospital care, it has been possible to observe the refinement and adaptation of these processes in response to the exponential increase in healthcare demands during and after the COVID-19 pandemic.[3] Furthermore, over the years, the perspectives of healthcare services have shifted, and the quality of service delivery and patient safety have become the guiding principles of healthcare practices.[4] These factors have been decisive in driving the computerization of certain tasks, which today represents an indispensable condition for the proper functioning of processes within health services. The same has occurred in hospital pharmacy; however, not all aspects related to it have progressed equally.

Ordinance 344/1998[5] regulates the entire process involving the management of medicines and substances subject to special control in Brazil, commonly known as controlled drugs. Since its publication in 1998, very few updates have been made to the text, except for changes to Annex I — the list of medicines and substances subject to special control — which is updated continuously. Therefore, this piece of legislation has not kept pace with the technological advances of recent decades and is no longer aligned with the current context of health services, rendering it, to some extent, obsolete.

In this context, we highlight Chapter VI of the aforementioned Ordinance, which covers Articles 62 to 66 and addresses the recordkeeping of medicines and substances subject to special control. It requires that facilities handling these medicines maintain manual records of controlled product movements in physical logbooks. Consequently, the computerized alternative is treated as secondary, and the text of the ordinance neither specifies nor describes the requirements for such an alternative, making its assessment a subjective process. This section of the legislation has led to disagreements between hospital pharmacy services and the Sanitary Surveillance Coordination (COVISA), since, during routine inspections, these authorities demand that hospital ser-

vices comply with the regulation and maintain updated handwritten logbooks. Many facilities, however, argue that they possess computerized records that serve as a substitute for manual documentation. Such a requirement, within the current landscape of hospital care, hinders compliance with the ordinance, considering the heavy workloads in these services, the complexity of hospital pharmaceutical care, and the quality programs that increasingly prioritize digitalization in the healthcare sector. Electronic recording of dispensing activities and drug movements is a safer and more efficient alternative, providing greater speed in the process and ensuring proper data storage. Moreover, given the sharp increase in the demand for psychotropic drugs in Brazil, eliminating manual tasks reduces work overload and optimizes the time dedicated to healthcare processes.[6] Therefore, the requirement for handwritten records runs counter to ongoing discussions emphasizing the benefits of information technology in healthcare,[7] as well as its contributions to patient safety.[8–9] Additionally, manual recordkeeping is more prone to errors.

In a context of complete absence of computerized technologies, maintaining handwritten records would be appropriate. However, that is not the case today. There are currently hospital management software systems available that can be evaluated, analyzed, and have their technical aspects discussed by sanitary surveillance authorities. Tools such as Smart®, MV Soul®, Salux®, Tasy®, and Hórus®, among others, are commonly used alternatives across various healthcare services. Although the digitalization of this process is not explicitly provided for in Ordinance 344/98, a normative instruction issued in 1999 opened the possibility for records to be computerized.[10] Article 94 of Ordinance No. 06/99 states that recordkeeping may be carried out electronically, provided it contains at least the data established in Annex XVIII of Ordinance 344/98. These data basically include information related to inventory position and details of entries, outputs, and losses, along with the respective dates of these movements—information that is naturally incorporated into such software systems. In cases where an institution opts for electronic recordkeeping, a request can be submitted to the local sanitary authority. However, despite the legal provision and the fact that sanitary authorities acknowledge that healthcare services possess computerized systems, COVISA inspections continue to insist on handwritten recordkeeping and resist the adoption of hospital management software.

Despite the issues described, not everything appears static. In 2007, the National System for the Management of Controlled Products (SNGPC) was created through RDC No. 27,[11] which, among other regulations, allowed for the replacement of physical recordkeeping with computerized records in pharmacies and drugstores. This aimed to improve control and monitoring by sanitary surveillance authorities. At first glance, it may seem contradictory that an RDC regulates something that is still not fully clarified in Ordinance 344/98—the main regulation on the subject. However, such paradoxes in this area are not uncommon, and this issue has already been discussed in previously published research.[12] Since the establishment of the SNGPC, there has been a gradual transition from handwritten to computerized processes, with an update issued in 2014,[13] which remains in effect today. Nevertheless, these changes are limited to a specific niche within the pharmaceutical field. Meanwhile, hospital pharmacy services do not have access to the same system and therefore tend to standardize the management software provided by their institutions. This situation often leads to repeated inquiries and citations in Sanitary Inspection Reports, particularly regarding the validation of such systems by sanitary surveillance authorities, despite the existing legal provision established by normative instruction.[1] However, reverting to a handwritten process is neither a viable, responsible, nor coherent alternative in light of the current demands faced by hospital pharmacy services.

Health information systems, or hospital management software, are reliable tools for recording data related to the production, handling, distribution, prescription, and dispensing of psychotropic substances. Continuous updates and improvements to these systems allow for the creation of customized reports that meet the specific needs of each service. As an example, we highlight Hórus®, the National Pharmaceutical Services Management System, used

by a large number of pharmacies within the Brazilian Unified Health System (SUS). In addition to ensuring the proper storage of data concerning the management of pharmaceutical products, Hórus® also provides a specific report for medicines subject to special control, closely resembling a traditional logbook (Figure 1). This feature allows users to extract data related to a single drug or to all products within the corresponding list, thereby representing an interesting alternative for both hospital services and sanitary surveillance authorities seeking to regularize these regulatory issues.

An alternative that could be considered is the creation of a system similar to the SNGPC for hospital pharmacy services. However, a proposal of this nature must be carefully evaluated, taking into account the software systems already in use within these services, which, in this context, would likely not be replaced. Moreover, the possibility of using two separate software systems to manage psychotropic drug inventories would render the work impractical. Nonetheless, these are scenarios that should be explored, analyzed, discussed, and, if feasible, implemented.

Figure 1. Report of Medicines Subject to Special Control in Hórus®

BR0284106 - RISPERIDONE 1 MG/ML ORAL SOLUTION 30 ML							BOT.
Date	History	Batch	Movement			Stock	Note
			Entry	Exit	Loss		
01/08/2024	[redacted]	23E91R		3		5	Nº: [redacted] - PRESCRIPTION: DATE: 01/08/2024 - COUNCIL: 4903
01/15/2024	[redacted]	23E91R		1		4	Nº: [redacted] - PRESCRIPTION: DATE: 01/05/2024 - COUNCIL: 7552
01/16/2024	[redacted]	23E91R		1		3	Nº: [redacted] - PRESCRIPTION: DATE: 01/16/2024 - COUNCIL: 10372
01/17/2024	[redacted] 14231741433	23E91R		3		0	Nº: [redacted] - PRESCRIPTION: DATE: 01/17/2024 - COUNCIL: 4657

Therefore, considering the topic discussed, it is essential that regulatory and sanitary surveillance agencies prioritize the needs of hospital pharmacy services regarding the issues addressed herein. It is also necessary for legislation to be updated and adapted to the ongoing technological changes and advancements, so as not to become obsolete. Lawmakers must keep pace with evolving contexts in order to propose the appropriate and necessary updates. In the context of this article, Ordinance 344/98 clearly requires revision and modernization.

Authors' Contributions

CAOR: conception and design or analysis and interpretation of data; drafting of the article or critical revision of the content for important intellectual input; final approval of the version to be published; and accountability for all aspects of the work to ensure the accuracy and integrity of any part of the manuscript; HJPL: drafting of the article or critical revision of the content for important intellectual input; final approval of the version to be published; and accountability for all aspects of the work to ensure the accuracy and integrity of any part of the manuscript.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Responsible Reviewers

Lindemberg Assunção Costa and Juliana Machado.

References

1. Santos TO, Pereira LP, Silveira DT. *Implementation of Health Information Systems: A Systematic Review.* Reciis – Electronic Journal of Communication, Information and Innovation in Health. 2017;11(3):1–11.
2. Alotaibi YK, Federico F. *The impact of health information technology on patient safety.* Saudi Med J. 2017;38(12):1173–1180.
3. Santos P, Oliveira R, Albuquerque M. *Inequalities in hospital service provision in the context of the COVID-19 pandemic in Brazil: an integrative review.* Saúde em Debate [Internet]. 2022;46(spe1):322–337.
4. Arimany-Manso J, Martin-Fumadó C. *The importance of clinical safety.* Med Clin (Barc). 2017;148(9):405–407.
5. Brazil. Ministry of Health. Health Surveillance Secretariat. *Ordinance No. 344, of May 12, 1998* [Internet]. Brasília. [Accessed 2024 Feb 08]. Available from: https://bvsms.saude.gov.br/bvs/saudelegis/svs/1998/prt0344_12_05_1998_rep.html

6. Souza VP, Santos OF, Wolosker N. *Health information system.* Einstein (São Paulo). 2013;11(4):7–8.
7. Huckvale C, Car J, Akiyama M, et al. *Information technology for patient safety.* Qual Saf Health Care. 2010;19(Suppl 2):i25–i33.
8. Poon EG, Keohane CA, Yoon CS, et al. Effect of bar-code technology on the safety of medication administration. N Engl J Med. 2010;362:1698–1707.
9. Seibert HH, Maddox RR, Flynn EA, Williams CK. Effect of barcode technology with electronic medication administration record on medication accuracy rates. Am J Health Syst Pharm. 2014;71:209–218.
10. Brazil. Ministry of Health. Health Surveillance Secretariat. Ordinance No. 06, of January 29, 1999 [Internet]. Brasília. [Accessed 2024 Feb 08]. Available from: https://antigo.anvisa.gov.br/documents/10181/2718376/PRT_6_1999_COMP2.pdf
11. Brazil. Ministry of Health. National Health Surveillance Agency (ANVISA). Resolution RDC No. 27, of March 30, 2007 [Internet]. Brasília. [Accessed 2024 Feb 09]. Available from: https://antigo.anvisa.gov.br/legislacao#/visualizar/27965
12. Rodrigues C, Lopes H, Martins R. Guaranteeing pharmaceutical care in the face of the regulatory contradictions of the Brazilian State. J Assist Farm Farmacoecon. 2018;3(2):34–37.
13. Brazil. Ministry of Health. National Health Surveillance Agency (ANVISA). Resolution RDC No. 22, of April 29, 2014 [Internet]. Brasília. [Accessed 2024 Feb 09]. Available from: https://antigo.anvisa.gov.br/legislacao#/visualizar/29176