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Assessment of penalties in pharmacies of the city of Goiânia-GO

Avaliação das penalidades em farmácias de Goiânia-GO

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ABSTRACT

Health surveillance has the objective of preventing and reducing risks to individual and collective health. Due to the health hazard inherent to the manipulation activity, the manipulation pharmacies are subject to health surveillance.This study purpose was to characterize the number of sanitary penalties applied to manipulation pharmacies in Goiânia-GO from 2010 to 2015. The number of penalties issued by the Municipal Health Surveillance of Goiânia-GO, as well as the existence of interrelationship between the characterized aspects, were analyzed using a quantitative, retrospective and analytical perspective. Through the collected data independent (number of pharmacists, number of annual self-inspections, class membership, property) and dependents variables (fines, seizures, prohibitions and warnings) were defined. The results indicated that pharmacies: which had a large number of pharmacists suffered fewer penalties; that carried out self-inspection suffered fewer fines; and that are affiliated to class institutions suffered a minor number of interdictions. It was also noted thatthe fact that the owner was a pharmacist raised the technical quality of the establishment. The study pointed out that the smaller the number of assessments, seizures and interdictions separately, the lower the total number of penalties.

KEYWORDS: Health Surveillance; Pharmacy; Penalty

RESUMO

A vigilância sanitária atua com a finalidade de prevenir e reduzir os riscos à saúde individual e coletiva. Devido ao risco sanitário inerente à atividade de manipulação, a farmácia magistral está a ela subordinada. Assim, o objetivo desse trabalho foi caracterizar o número de penalidades sanitárias aplicadas em farmácias magistrais de Goiânia-GO no período de 2010 a 2015. O método utilizado foi do tipo quantitativo, retrospectivo e analítico, tendo como objeto direto a caracterização do número de penalidades emitidas pela Vigilância Sanitária Municipal de Goiânia-GO, bem como a existência de inter-relação entre os aspectos caracterizados. Foram definidas as variáveis independentes (número de farmacêuticos; número de autoinspeções anuais; filiação classista; propriedade) e as dependentes (multas, apreensões, interdições e advertências). Os resultados obtidos indicaram que as farmácias que possuíam maior número de farmacêuticos sofreram menos penalidades; que as farmácias que realizaram autoinspeção sofreram menos multas; as farmácias que são afiliadas a instituições de classe sofreram um menor número de interdições e que o fato de o proprietário ser farmacêutico eleva a qualidade técnica do estabelecimento. O estudo apontou que quanto menor o número de autuações, apreensões e interdições em separado, menor o número total de penalidades.

PALAVRAS-CHAVE: Vigilância Sanitária; Farmácia magistral; Penalidade

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INTRODUCTION

Sanitary Surveillance has regulatory competence over the control of sanitary risk, as well as over the enforcement of the regulations established by it. It is regulated by Law n. 8080, of September 19, 1990[1]. Its area of activity covers: the regulatory action on therapeutic products and supplies of interest to health; normative and inspection power over the services rendered; permanent assessment and prevention of health risks; the supervision of ports, airports and borders; product registration; company licensing; import and export approvals; certificate issuance; specific studies; and the control of psychotropic and narcotic drugs, among others[2].

In Brazil, the current National Health Surveillance System (SNVS) is composed of the three spheres of government[2]. The components of the SNVS are the operators of Sanitary Surveillance actions in the three levels of public administration: at the federal level, there is the National Sanitary Surveillance Agency (Anvisa), which acts in the regulation, federal legislation and coordination of national actions, and the National Institute of Quality Control in Health (INCQS). At the state level, there are the state bodies of Sanitary Surveillance and the Central Public Health Laboratories (Lacens); and at the municipal level, there are the municipal Sanitary Surveillance bodies and the municipal laboratories, if any[1].

Today in Brazil there are approximately 7,200 compounding pharmacies[3]. They play an important role in the context of the National Medicines Policy[4] and their activities are subject to regulation in all spheres of government.

The resumed growth of the compounding pharmacy sector after the 1980s and other events, such as reported cases of clonidine and colchicine poisoning, have put the quality of compounded products under question and led to more effective sanitary surveillance actions[5].

Thus, on October 8, 2007, Anvisa published the Resolution of the Collegiate Board of Directors (RDC) n. 67[6], which deals with good handling practices for compounded and officinal preparations for use in pharmacies. RDC n. 67/2007 focused on quality and considered the characteristics inherent to this type of pharmacy[5].

This study aimed to characterize and quantify the penalties applied to pharmacies in the city of Goiânia, Brazil, correlating them with some structural variables of these establishments.

Today, very few publications establish the relation between the work of the regulatory sector and the occurrence of nonconformities in the compounding field. None of these publications refers to the city of Goiânia. However, the study of the categories of penalties in pharmacies is relevant, since it enables us to learn their characteristics and, based on this data, both the regulated sector and the regulator can draw strategies to minimize the occurrences of these nonconformities.

METHOD

Study design

The methodology used in this study is quantitative, retrospective and analytical.

Location and period

Department of Sanitary Surveillance of the Municipal Department of Health of Goiânia, from 2010 to 2015.

Population or casuistry

All the 65 compounding pharmacies located in Goiânia that performed their activities over the period between January of 2010 and December of 2015.

Inclusion and exclusion criteria

We included all the pharmacies (parent units and branches) that had their data registered in the sanitary surveillance system of the city of Goiânia. We excluded from this study the compounding pharmacies that opened after January 2010 and/or closed before December 2015.

The penalties studied here are based on the definition of Federal Law n. 6.437, of August 20, 1977[7], which establishes violations of federal sanitary legislation, except those expressly set forth in special rules. Those investigated in this study were: warning, fine, product seizure and partial or total closure of the establishment.

The method presents quantitative characteristics, based on the survey of the number of active pharmacies registered in the database of the sanitary surveillance body of the Municipal Department of Health of Goiânia, from 2010 to 2015.

The study was conducted in three stages: the first presented the dependent variables; the second, the independent variables; and the third included data characterization and synthesis.

The initial stage consisted of the survey in the computerized sanitary surveillance system of the active pharmacies in Goiânia between 1/2010 and 12/2015 and of the penalties imposed in the same period. The penalties studied herein represent the dependent variable.

The second phase comprised the survey of information collected by the inspectors during health inspections in the year 2015. That information was recorded in the inspection guides used in the pharmacies during the fiscal visits. The manual consultation of the guides provided the following data: the number of pharmacists working in the establishment; if the owner of the pharmacy was a pharmacist; if the pharmacy was a member of any trade association; and, finally, the number of self-inspections performed by the pharmacy in the year 2015. This data represented the independent variables.

The pharmacies surveyed were grouped according to the activity they performed. Therefore, group A included the compounding pharmacies that perform only one of the tasks we described; group B was composed of pharmacies that perform from two to three of those activities; finally, group C included those that perform all the proposed tasks.

The activities considered in this study were divided into four categories, namely: handling of solids, handling of semisolids and liquids, homeopathic handling and handling of hormones, antibiotics and cytostatics. They were arranged in this fashion because of the physical structure (laboratory) requirements of each one.

The third step was the characterization and synthesis of the results we obtained. In this stage, the pharmacies were divided into the three groups mentioned above.

After data collection, the dependent and independent variables were related. These were collected by the inspection team of the Compounding Pharmacy Nucleus of the Department of Inspection of Health Supplies, Drugs and Products of the Sanitary Surveillance of the Municipal Department of Health. The sample we used was determined according to the number of pharmacies registered in the database of the sanitary surveillance body. The first consultation to the database revealed a total of 131 registered pharmacies. After the inclusion and exclusion criteria were applied, we were left with the 65 pharmacies that composed the sample studied in this investigation.

The dependent variables are penalties of fine, seizure, closure and warning. The independent variables are the number of pharmacists working in the pharmacy, ownership of the pharmacy by pharmacists, number of annual self-inspections and membership in some trade association.

We analyzed the amount and type of penalties that each establishment incurred during the period of study. However, it should be noted that some of them may have occurred concurrently or not, according to Federal Law n. 6.437/1977[7].

Afterwards, we characterized and divided the penalties into warning, closure, fine and seizure. The fines were grouped into categories, in accordance with the provisions of Federal Law n. 6.437/1977[7], which characterize the sanitary infractions that give rise to each of the penalties. For the grouping in question, the similarity between categories was taken into account. The seizures were also grouped according to the same criterion.

Fines and seizures were distributed in five and four different categories, respectively, according to the characteristics shown in the Table.

Structuring the database

In the sanitary inspections, two types of inspection guides were used: the full inspection guide and the simplified version. The second applied to pharmacies that did not have a quality control

Chart. Main categories of infraction and seizure.

Main categories of emission of infraction.				
Category I *	**Category II**	**Category III**	**Category IV**	**Category V**
Type: Other* motivations that do not fit into any of the types described here.	Type: All infractions that refer to filling prescriptions in disagreement with established legal norms and/or with articles of Ministerial Act n. 344/1998, RDC n. 58/2007, RDC n. 52/2011.	Type: All infractions regarding expired raw materials or products and irregular or absent labeling.	Type: All notices of infraction motivated by lack of Sanitary Permit, AFE, AE for the activity performed by the pharmacy.	Type: Lack of reports of contents and uniformity of capsules smaller than 25 mg, lack of reports of purified and drinking water, lack of reports compounded formulas with hormones, antibiotics and cytostatics.
Legal basis: Article 10, section XXIX, of Federal Law n. 6.437/1977.	Legal basis: Article 10, section XI and XII, of Federal Law n. 6.437/1977; Ministerial Act n. 344/1998; RDC n. 58/2007 and RDC n. 0739 52/2011.	Legal basis: Article 10, section XV and XVIII, of Federal Law n. 6.437/1977.	Legal basis: Article 10, section XXIX, of Federal Law n. 6.437/1977.	Legal basis: Article 10, section XXIX, of Federal Law n. 6.437/1977 c/c RDC n. 67/2007.
Main categories of infraction and seizure.				
Category I	**Category II**	**Category III**	**Category IV**	
Type: all seizures that refer to expired raw materials or products.	Type: Raw materials and/or products with incorrect labeling.	Type: Seizure of prescriptions/documents or medicines and/or supplies according to Ministerial Act n. 344/1998.	Type: Seizure of irregularly stored products, or unlicensed, fraudulent, tampered products and/or products without proper notification/registration.	
Legal basis: Article 10, section XVIII, of Federal Law n. 6.437/1977.	Legal basis: Article 10, section XV, of Federal Law n. 6.437/1977.	Legal basis: Article 10, sections XI, XII and XXIX, of Federal Law n. 6.437/1977.	Legal basis: Article 10, sections IV, XXVIII and XXXV, of Federal Law n. 6.437/1977.	

*Others: failure to comply with acts from the sanitary surveillance authority; breach of the Good Handling Practices (GHP), breach of quality assurance requirements (do not approve third party reports and do not register customer complaints, do not to carry out further analysis in the event of an unsatisfactory report).

laboratory – usually branches of a parent unit. The first one applied to the pharmacies that had a quality control laboratory (usually the parent unit), since it includes the quality control items to be checked during the inspection. These guides were developed by the compounding pharmacy inspection team based on RDC n. 67/2007[6].

Dependent and independent variables

For the definition of the independent variables, the following criteria were established: the variable "number of pharmacists" considers the registered professionals as technicians or pharmacists who had a labor relationship with the establishment. The self-inspections were considered all those carried out or set forth in standard operating procedures for the year 2015. RDC n. 67/2007 establishes the obligation to carry out self-inspections at least once a year[6]. Pharmacist-owned establishments were all those where the pharmacist was defined as owner or partner-owner in the company's charter. As for trade association, all pharmacies that were properly associated with the National Association of Compounding Pharmacies (Anfarmag) were considered as members.

Ethical aspects

This study was approved by the Human Research Committee of the Federal University of Goiás (UFG), which issued the Free and Informed Consent Form (ICF), in accordance with the approval opinion issued by the Research Ethics Committee of the Federal University of Goiás, number 1.579.175.

Statistical analysis

After the characterization, we applied the Kruskall Wallis statistical test for the numerical independent variables and the Chi-squared test for the nominal independent variables. The tests enabled us to verify whether the occurrence of variation was casual and random in a sample or if the variations meant differences within the same population. The statistical calculations were applied through the Epi Info program.

The statistical tests evaluated whether the number of penalties imposed at each group of establishments (fines, seizures, closures) was related to the independent variables studied in this project. Also, we checked if there was any relationship between penalties.

RESULTS AND DISCUSSION

The characterization of penalties provides important information for the revision of the norm that regulates this sector, since it indicates the main categories of infraction of sanitary legislation and the respective penalties.

The result obtained during the categorization of pharmacies is shown in the Figure. We can observe that the results have shown the predominance of group B, that is, the establishments that perform from 2 to 3 activities, followed by group A, those that only perform one activity. Group C, which includes the pharmacies that perform all activities, presented the smallest numbers.

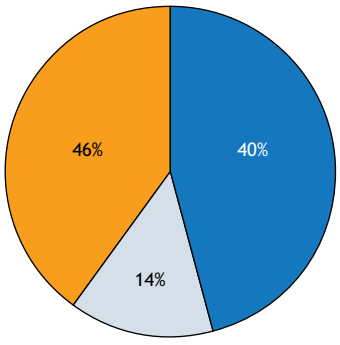
In this context, it should be clarified that the current market model is characterized by a parent establishment, capable of centralizing some of the activities allowed by RDC n. 67/2007[6], and its so-called branches. In most cases, the branches perform less complex activities, with lower operational cost and fewer health risks. Thus, more complex activities, like handling hormones, antibiotics and cytostatics, involve higher sanitary risks due to the pharmacological characteristics of this type of substance, requiring greater technical and operational apparatus. These are usually done only in the parent unit, since the demand for these products tends to be smaller and incur higher operating costs. Therefore, the result found and presented in the Figure reiterates this market behavior, which centralizes the activities of greater complexity in the parent unit and directs all others to the branches.

In relation to the number of penalties applied in the period, we verified that, in total, 202 were applied, distributed as follows: 98 fines (48%), 79 seizures (39%), 14 closures (6.9%) and 11 warnings (5.4%).

Regarding the independent variables, there are differences in relation to the number of pharmacists, trade association and number of self-inspections in the three groups of pharmacies.

In this study, we verified that 58.4% of the pharmacies received at least one penalty. Among the categories of infractions, we noticed that 29.2% of the pharmacies were fined for filling prescriptions in disagreement with Ministerial Act n. 344, of May 12, 1998[8] and/or RDC n. 58, of September 5, 2007[9] and/or RDC n. 52, of October 6, 2011[10]. This infraction seemed to be the main category for fines. We also noticed that 47.7% of the compounding pharmacies received no fine. Another important fact is that only a minority of these pharmacies were fined more than five times: a percentage of 7.7%.

Aguiar et al.[11], in a study carried out in compounding pharmacies in the city of São Luís, state of Maranhão, Brazil, showed the percentages of establishments that committed sanitary



Source: own author (2016).

Figure. Categorization of pharmacies into groups according to the number of activities.

infractions and, consequently, were penalized: 21.4% in 2006; 25% in 2007; and 22% in 2008. These percentages differ from those found in our study. It should also be noted that in the study of Aguiar et al.[11], the most applied penalty was the warning, whereas in our study it was the least common. This is probably due to the particular characteristics of each city in the conduction of administrative proceedings.

In a study by Silva and Vieira[12] , sanitary infractions related to irregular trade of drugs subject to special control (39%) were detected, as well as 10% of infractions related to exposure/storage of expired drugs.

Even though the study of Silva and Vieira[12] was about drugstores, they found similar results to those found in this investigation. The main category of fine detected here (35%) is also the first category found in their study (39%) and the values in both are similar.

In this study, we could observe that 27% of the fines were due to the exposure/storage of expired products, representing the highest percentage of occurrence in the pharmacies of Goiânia.

Furthermore, in relation to the study by Aguiar et al.[11], we note that, in 2007, one of the most frequent health infractions was related to the violation of Ministerial Act n. 344/1998[8]. Compared to this study, this penalty is the main sanitary infraction that led to fines in compounding pharmacies, accounting for 35% of the total fines.

Freitas and Santos[13] have shown that in the city of Franca, state of São Paulo, Brazil, 35.77% of the irregularities detected in high-complexity health facilities concern failures or shortcomings in documentation, 23.36% refer to physical structure, followed by 12.4% related to the quality of the products. These also include expiration date, licensing, quality control of packaging and, finally, inadequate storage and transportation. The items listed above were also frequent irregularities found in the compounding pharmacies of Goiânia.

In the period from 1/2010 to 12/2015, 34 of all the pharmacies we studied had some type of product or document seized, which means a percentage of 52.3%. The results also showed that 47.7% of the pharmacies did not suffer any type of seizure. Most of the seizures were due to problems related to expiration date. This category is probably the most frequent because it can be detected in any of the groups of pharmacies, both in the production area (raw materials and supplies) and in the dispensing area (finished product). We observed that in 26.2% of the pharmacies there was at least one penalty of seizure of expired products. The verification of the expiration date is also a nonconformity that is easy for inspectors to detect (it does not depend on external resources for detection and it is sufficient to verify the date on the product label), contributing to its predominance over the other items.

We noted that the less frequent reason for seizure concerns nonconformities of absence of license/fraud and/or incorrect storage of raw materials or finished products. This low frequency in the records may be due to the fact that inspectors have to be more familiar with the legislation governing health products and pharmaceutical supplies. This legislation establishes the types of products that must be notified or registered and there is a huge range of products and classifications, making it difficult for inspectors to identify some product irregularities.

Another influencing factor is the need to consult Anvisa's website to confirm that the label data is true, according to the numbers reported. Nevertheless, during the inspection it is not always possible to check that. This hampers the work of identifying nonconforming products and probably makes it more difficult to seize them.

Table 1 presents the results found for the independent variables of each group of pharmacies separately.

No significant difference was found in the number of closures, warnings and fines in the three groups of pharmacies classified here. However, we observed that there is variation in relation to the category of seizures and their number in each group studied presented in Table 2.

Thus, in group A (only one activity), none of its members had products or documents seized throughout the study, representing a total of 65.4%. On the other hand, groups B and C presented rates of 43.3% and 11.1%, respectively, for the absence of seizures in the investigated period.

When the owner is not a pharmacist, he or she is subject to pressures at the time of making a decision, sometimes feeling pressured to adopt inappropriate postures. However, when the owner is a pharmacist, he or she might yield to the temptation to choose higher profits. At any rate, the commercial factor inherent to the pharmacy will always be taken into account in the decision making process of the owner, whether he or she is a pharmacist or not.

In this study, we observed that the pharmacies of group C have a greater range of functions to perform and a large inventory of raw materials and finished products, making management, inventory control and production monitoring of these various activities more complicated for them.

In group A, the opposite occurs because the establishments have a smaller inventory, in addition to a smaller diversity of activities and processes to be monitored and controlled. This makes work easier, contributing to fewer seizures of pharmacy products or nonconforming documents.

We verified that there is significance only in relation to categories 2 and 4 and that both have $p < \alpha$. Category 2 refers to nonconformities on labeling, whether irregular or absent. Category 4 concerns the seizure of nonconforming products in relation to licensing and storage and storage conditions. In category 2, group B presented a rate of only 3.3% for pharmacies that were imposed seizures, while group A showed a percentage of 26.9% of facilities that had seizures in this category (Table 2).

In this case, 66.7% of group C establishments were seized with nonconforming products in relation to licensing and/or storage

and conservation, whereas in group A only 7.7% of the establishments had seized products by the same category (Table 2). Group C is composed of pharmacies that carry out all activities, thus having a wider range of supplies, and probably a more numerous and diversified inventory compared to the pharmacies in groups A and B. Thus, theoretically, group C is more likely to have nonconforming products in its inventories.

In Table 3, we can see that there is significance between the groups of activities performed and the amount of penalties received. In group C, only 11.1% of the establishments did not receive any kind of penalty (fine, seizure, warning or closure). In groups A and B, the percentage of pharmacies that did not receive any penalties at the time of the survey rose to 53.8% and 40%, respectively. This result is in agreement with the previous ones, with respect to the greater occurrence of penalties in group C (several activities) in contrast to a smaller number in the other groups.

The results of the analysis of the relationship between dependent and independent variables in group A show that the criteria of "number of pharmacists" and "self-inspections" do not influence the amount of fines (Table 4). However, of the

Table 1. Relationship of independent variables with each group of pharmacies.

Aspect	Group (activities performed)						P
	A (only 1)		B (more than 1)		C (all)		
	n (n = 26)	%	n (n = 30)	%	n (n = 9)	%	
Number of pharmacists							0.012[1]
1	5	19.2	4	13.3	-	0	
2	19	73.1	18	60.0	4	44.4	
3	2	7.7	1	3.3	3	33.3	
≥ 4	-	0	7	23.3	2	22.2	
Number of self-inspections							0.032[1]
0	2	7.7	3	10.0	-	0	
1	5	19.2	14	46.7	6	66.7	
2	8	30.8	9	30.0	2	22.2	
≥ 4	11	42.3	4	13.3	1	11.1	
Associated							0.022[2]
No	3	11.5	9	30.0	-	0	
Yes	23	88.5	21	70.0	9	100.0	
Pharmacist owner							0.150[2]
No	1	3.8	5	16.7	-	0	
Yes	25	96.2	25	83.3	9	100.0	

[1]Test: Kruskall Wallis; [2]Test: Chi-squared

Table 2. Main reasons for seizure orders issued in compounding pharmacies in Goiânia, Brazil, from January 2010 to December 2015, by group of activities performed by the pharmacy.

Aspect	Group						p
	A (only 1)		B (more than 1)		C (all)		
	n (n = 26)	%	n (n = 30)	%	n (n = 9)	%	
Total reasons for seizure							0.01[1]
0	17	65.4	13	43.3	1	11.1	
1	6	23.1	7	23.3	4	44.4	
2	1	3.8	5	16.7	1	11.1	
3	2	7.7	2	6.7	1	11.1	
≥ 4	-	0	3	10.0	2	22.2	
Category 1: Expired							0.073[2]
No	23	88.5	20	66.7	5	55.6	
Yes	3	11.5	10	33.3	4	44.4	
Category 2: Labeling							0.042[2]
No	19	73.1	29	96.7	7	77.8	
Yes	7	26.9	1	3.3	2	22.2	
Category 3: Ministerial Act n. 344/1998							0.056[2]
No	25	96.2	23	76.7	6	66.7	
Yes	1	3.8	7	23.3	3	33.3	
Category 4: Irregular product/storage							0.001[2]
No	24	92.3	23	76.7	3	33.3	
Yes	2	7.7	7	23.3	6	66.7	

[1]Test: Kruskall Wallis;[2] Test: Chi-squared

establishments that did not commit any infraction, 94.7% were members of some trade association. From another perspective, of the pharmacies that had four fines in the period, 50% were not members of any trade association.

In this sense, the data reveals that the fact that the establishment is a member of a trade association indicates a decrease in the likelihood of receiving notices, and the degree of significance is 0.023% < p = 0.05%. The same factor is observed in relation to the criterion of "ownership of the establishment by a pharmacist", because the result found points to the fact that 100% of establishments that did not receive any fine were owned by a pharmacist. We also verified that of the group A establishments that received more than four fines in the course of the research, 50% were not owned by a pharmacist (Table 4).

The fact that the compounding pharmacy is a member of a trade association that has quality improvement and monitoring programs may have influenced the establishment and its employees to adopt a more severe and effective quality policy and may contribute to reducing the number of infractions.

The same remark can be used to explain the fact that pharmacies where pharmacists were the owners committed fewer violations compared to pharmacies owned by non-pharmacists. This is perhaps because the pharmacist has the necessary technical knowledge to invest and prioritize activities that improve the quality of the service and the process, either in the form of allocation of specific investments in quality assurance or through courses or certifications that contribute to reducing nonconformities. Additionally, pharmacists-owners are more independent to make decisions, whereas non-pharmacists need the approval of other parties.

We observed that the only factor that influenced the total seizures of group A was whether the establishment was owned by a pharmacist or not (p = 0.007). Thus, if the pharmacy was owned by a pharmacist, it was less likely to incur seizures than those that were owned by non-pharmacists (Table 4).

When we related the number of partial or total closures suffered by group A pharmacies, we noticed that the fact that the pharmacy is part of a trade association and the owner is a pharmacist reduces the chance of the establishment being closed (p = 0.021 and < 0.001, respectively). Of the pharmacies that suffered two closures in the period, 100% of them were not members of any trade association and were owned by non-pharmacists (Table 4).

Regarding the independent variables and the dependent variables in group B, analyzing the number of fines received, we could verify that, of the establishments that were not fined, 77.8% performed more than two self-inspections annually. Likewise, of the establishments that received five notices in the period, 66.7% did not carry out any self-inspection. Thus, if group B conducts more self-inspections per year, there will be a decrease in the occurrence of fines (p = 0.011 < α) (Table 5).

According to item 15.6 of RDC n. 67/2007[6], "self-inspection is an appropriate resource for the verification and evaluation of the compliance of the GMP adopted by the pharmacy". Therefore, the contribution of a well-executed self-inspection is relevant to decrease the occurrence of nonconformities in general, since it is basically an early check of the items that will be verified in the sanitary inspection. It is a valuable tool for reducing and preventing the occurrence of nonconformities. Moreover, according to Silva and Vieira[12], the role of health education, in the light of sanitary law, is fundamental for the implementation of sanitary surveillance actions regarding the improvement of public health.

Table 3. Penalties incurred by compounding pharmacies according to the group of activities performed by the pharmacy.

Aspect	Group						p
	A (only 1)		B (more than 1)		C (all)		
	n (n = 26)	%	n (n = 30)	%	n (n = 9)	%	
Total penalties							0.012
0	14	53.8	12	40.0	1	11.1	
1	9	34.6	8	26.7	2	22.2	
2	1	3.8	3	10.0	3	33.3	
3	2	7.7	3	10.0	1	11.1	
≥ 4	-	0	4	13.3	2	22.2	

Test: Kruskall Wallis.

Table 4. Value of p for the significance of the relationship between dependent and independent variables in group A.

Group A	Fines (p value)	Seizures (p value)	Closures (p value)
Number of pharmacists	0.308	0.971	0.194
Number of self-inspections/year	0.083	0.711	0.121
Trade association	0.023	0.3	0.021
Ownership	0.017	0.007	< 0.001

The results presented in Table 5 also indicate that the number of seizures and closures is not influenced by any of the independent variables analyzed here.

The results obtained for the interrelationship between the independent and dependent variables in group C did not present a significant result between the penalties committed by this group and any of the related independent variables. The result found in this study may not represent a real significance due to the small number of establishments included in group C (n = 9), requiring a larger number for statistical analysis to represent with confidence the result of the analysis. However, the number used represents 100% of the sample available for inclusion.

The results shown in Tables 6, 7 and 8 corroborate the finding that a compounding pharmacy that receives some of the penalties mentioned above is more likely to receive other penalties. Additionally, it may happen that most establishments - those that have high incidence of a type of penalty - also have a more frequent occurrence of the other types of penalties discussed in this paper. A plausible explanation for this is the possibility that the inspector imposes one or more penalties individually or cumulatively for one and the same nonconformity. The inspector's decision follows the principle of discretion, which is provided for by the law[12].

According to Tancredi et al.[14], discretionary power is what the Law grants to the administration, explicitly or implicitly, for the practice of administrative acts with freedom in choosing its convenience, timeliness and content. In these cases, the power of administration is discretionary, because the adoption of one or another solution is made according to criteria of opportunity, convenience, justice and equity of the authority, since they are not defined by the legislator.

The result shown in Table 6 reveals that 74.2% of the establishments that did not receive a fine did not incur any seizure either. In contrast, 60% of them were noticed more than five times, incurring more than three seizures in the period. Likewise, we noticed that the establishments that did not receive a fine (96.8%) did not have any closure either. Similarly, 60% of the pharmacies that received five or more fines also received four or more other penalties.

The data presented in Tables 6, 7 and 8 shows that establishments that incurred more than one of these types of penalties incurred the same types of penalties, concurrently or not.

Table 5. Value of p for the significance of the relationship between dependent and independent variables in group B.

Group B	Fines (p value)	Seizures (p value)	Closures (p value)
Number of pharmacists	0.534	0.84	0.353
Number of self-inspections/year	0.011	0.272	0.116
Trade association	0.295	0.434	0.437
Ownership	0.774	0.635	0.344

Table 6. Number of fines versus seizures and closures.

Analytical aspect	Number of fines												p
	0 (n = 31)		1 (n = 13)		2 (n = 7)		3 (n = 3)		4 (n = 6)		≥ 5 (n = 5)		
	n	%	n	%	n	%	n	%	n	%	n	%	
Number of seizure orders													< 0.01
0	23	74.2	4	30.8	4	57.1	-	0	-	0	-	0	
1	7	22.6	5	38.5	2	28.6	-	0	2	33.3	1	20	
2	1	3.2	3	23.1	-	0	1	33.3	1	16.7	1	20	
≥ 3	-	0	1	7.7	1	14.3	2	66.7	3	50.0	3	60	
Number of closures													0.001
0	30	96.8	13	100.0	4	57.1	3	100.0	3	50.0	3	60	
1	1	3.2	0	0	3	42.9	-	0	1	16.7	1	20	
≥ 2	-	0	-	0	-	0	-	0	2	33.3	1	20	
Total penalties													< 0.001
0	21	67.7	3	23.1	3	42.9	-	0	-	0	-	0	
1	9	29.0	5	38.5	3	42.9	-	0	1	16.7	1	20	
2	1	3.2	3	23.1	-	0	1	33.3	2	33.3	-	0	
3	-	0	2	15.4	-	0	1	33.3	2	33.3	1	20	
≥ 4	-	0	-	0	1	14.3	1	33.3	1	16.7	3	60	

Test: Kruskall Wallis.

We could verify that the pharmacies that did not have any episode of seizure and/or closure accounted for 96.8% and those that did not incur any other penalty amount to 87.1%. This data demonstrates that if an establishment experiences seizure of any kind, it is also more likely to be totally or partially closed (Table 7).

In Table 8, we can observe that the establishments that did not have any closure episode account for 46.4%. These are the same that did not incur any other penalty. This allows us to state that places with no or fewer closures are less likely to incur other types of penalties.

Overall, based on the results described in this paper, we can affirm that the occurrence of a type of penalty in an establishment means it is also more likely to incur other penalties. We assume that the measures adopted by the Municipal Sanitary Surveillance body are still incipient, as well as those adopted by the other spheres of government, which act to prevent nonconformities, sanitary education of the regulated sector and of the population. They seek to act as agents of change and thus reduce these nonconformities, as well as raise awareness of the importance of sanitary surveillance among the population, educating the people to act as informal inspectors of the services they use in their daily lives.

CONCLUSIONS

Regarding the characterization of pharmacies, the most numerous group was B, with establishments that perform from two to three activities. This is consistent with the quantification of the independent variables in most pharmacies that have two active pharmacists, make one to two self-inspections per year, declare themselves members of some trade association and in which most establishments are owned by pharmacists.

The main category of fine relates to the supply of medicines in disagreement with the regulatory standard of Ministerial Act n. 344/1998 (category 2, 35%). The largest category of seizure was category 1 (expired raw material or finished product). There is a significant difference in the number of pharmacists per establishment, in the number of self-inspections, in trade association status, in the number of fines and seizures and the total number of penalties incurred between groups of pharmacies classified according to the activities they performed.

For group A, strong correlations were found between the decrease in the occurrence of fines and closures and the fact

Table 7. Number of seizures versus closures and total penalties.

Evaluated aspect	Number of seizures								p
	0 (n = 32)		1 (n = 17)		2 (n = 7)		≥ 3 (n = 10)		
	n	%	n	%	n	%	n	%	
Number of closures									0.002
0	30	96.8	14	82.4	7	100.0	5	50.0	
1	1	3.2	2	11.8	-	0	3	30.0	
≥ 2	-	0	1	5.9	-	0	2	20.0	
Number of penalties									< 0.001
0	27	87.1	-	0	-	0	-	0	
1	4	12.9	14	82.4	1	14.3	-	0	
2	-	0	3	17.6	4	57.1	-	0	
3	-	0	-	0	2	28.6	4	40.0	
≥ 4	-	0	-	0	-	0	6	60.0	

Test: Kruskall Wallis.

Table 8. Number of closures versus total penalties issued.

Number of penalties	Number of closures						p
	0 (n = 56)		1 (n = 6)		≥ 2 (n = 3)		
	n	%	n	%	n	%	
0	26	46.4	1	16.7	-	0	
1	17	30.4	2	33.3	-	0	
2	6	10.7	-	0	1	33.3	0.012
3	4	7.1	1	16.7	1	33.3	
≥ 4	3	5.4	2	33.3	1	33.3	

Test: Kruskall Wallis.

that the pharmacy is a member of some trade association and the owner is a pharmacist. Pharmacies owned by pharmacists were more likely to have a smaller number of seizures.

In group B, we obtained an expressive correlation between the independent variables of "number of self-inspections per year" and the dependent variable of "number of fines". The results indicated that the fact that the establishment has incurred some of the penalties studied here has to do with the possibility of incurring others. The survey revealed that the places that incurred seizure were the same ones that incurred closure.

The penalties of the pharmacies of group C were not influenced by any of the independent variables studied here.

It is understood, therefore, that the pharmacies that incurred a penalty were the same ones that had more seizure and closure episodes. We also found that the occurrence of a type of penalty in an establishment means it is more likely to incur other penalties also discussed in this research.

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Conflict of Interest

Authors have no potential conflict of interest to declare, related to this study's political or financial peers and institutions.

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