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Angelúcia Muniz
ORCID: 0000-0002-1962-4396
Universidade Federal do Rio de Janeiro – UFRJ
Email: munizangel@gmail.com

Rondineli Mendes da Silva
ORCID: 0000-0002-6243-5179
Escola Nacional de Saúde Pública
Sérgio Arouca da Fundação Oswaldo Cruz
Email: rondineli.mendes@gmail.com

FLEXIBILIDADES REGULATÓRIAS NAS COMPRAS PÚBLICAS DE TECNOLOGIAS SANITÁRIAS NO ENFRENTAMENTO DA COVID-19 NO BRASIL

REGULATORY FLEXIBILITIES IN PUBLIC PURCHASES OF HEALTH TECHNOLOGIES IN THE PANDEMIC IN BRAZIL

FLEXIBILIDADES REGULATORIAS EN LAS COMPRAS DE TECNOLOGÍAS SANITARIAS EN LA PANDEMIA EN BRASIL

CRediT

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RESUMO
Este artigo tem como objetivo caracterizar e examinar os marcos normativos alterados ou implementados pelo governo federal referentes às compras públicas pelo advento da COVID-19 no Brasil. Foi realizada uma pesquisa documental da legislação federal publicada até outubro de 2021, em portais eletrônicos de acesso público. Após, procedeu-se com o exame dos documentos para caracterizar os principais focos de mudanças instituídas, considerando cinco eixos temáticos: regras financeiras; simplificação processual; transparência e *accountability*; inovação administrativa; e regulação sanitária. Ao todo, foram identificados 10 atos legislativos. As alterações envolveram diversos mecanismos jurídicos processuais visando a maior agilidade e flexibilidade na execução das compras, através de licitação dispensável, diminuição de prazos, atualizações nos valores, eliminação de documentos, postergação de exigências de fiscalização, pagamento antecipado – todas simplificações antes não previstas na lei de licitações brasileira. Outra importante alteração foi a incorporação do sistema de registro de preços na dispensa de licitação. Houve também reforço para a publicização e a transparência na execução das compras. Assim, evidenciou-se a capacidade inovadora do setor público com medidas legais para a agilização das compras públicas. Todavia, flexibilidades aquisitivas podem acentuar práticas ilícitas, o que reforça a relevância da prestação de contas e a fiscalização da sociedade, dada a importância do papel do setor público na resposta em situações de crise.

PALAVRAS-CHAVE: Legislação; Tecnologias em Saúde; Sistema Único de Saúde; COVID-19.

ABSTRACT
The article aims to characterize and investigate legislation related to public procurement of health technologies introduced in Brazil to strengthen the fight against the COVID-19 pandemic. We conducted a documentary search of federal legislation on publicly accessible electronic portals. We then examined the documents to characterize the main focuses of the changes instituted, considering five thematic axes: financial rules, procedural simplification, transparency and accountability, administrative innovation, and health regulation. We identified ten pieces of legislation. The changes involved various procedural legal mechanisms aimed at creating greater agility and flexibility in the execution of purchases, such as dispensable bidding, shorter deadlines, updates on values, elimination of documents, postponement of inspection requirements, and payment in advance – all simplifications not previously provided for in Brazilian bidding law. Another significant change was the incorporation of the price registration system into the dispensable bidding system. There was also a reinforcement of publicity and transparency in purchase execution. The main highlight of the study was the innovative capacity of the public sector with legal measures to streamline public purchases; however, procurement flexibilities can accentuate illicit practices, which reinforces the relevance of accountability and oversight by society, given the importance of the public sector's role in responding to critical situations.

KEYWORDS: Legislation; Biomedical Technology; Unified Health System; COVID-19.

RESUMEN
El artículo presenta la legislación vinculada a la contratación pública de tecnologías sanitarias introducida en Brasil para reforzar la lucha contra la pandemia del COVID-19. Para esto, se realizó una búsqueda documental de la legislación federal en portales electrónicos de acceso público. En seguida, se examinaron los documentos para caracterizar los principales focos de los cambios instituidos, considerando cinco áreas temáticas: reglas financieras; simplificación de procedimientos; transparencia y rendición de cuentas; innovación administrativa; y regulación sanitaria. Se identificaron diez actos legislativos. Los cambios comprendieron diversos mecanismos legales procedimentales, con el objetivo de crear mayor agilidad y flexibilidad en la ejecución de las compras, a través de licitaciones prescindibles, plazos más cortos, actualizaciones de valores, eliminación de documentos, aplazamiento de requisitos de inspección, pago por adelantado – todas simplificaciones no previstas anteriormente en la legislación brasileña de licitaciones. Otro cambio importante fue la incorporación del sistema de registro de precios al sistema de licitaciones dispensables. También hubo mayor publicidad y transparencia en la ejecución de las compras. El principal destaque del estudio fue la capacidad innovadora del sector público con medidas legales para agilizar las compras públicas, aunque las flexibilidades de contratación pueden acentuar las prácticas ilícitas, lo que refuerza la relevancia de la rendición de cuentas y la supervisión por parte de la sociedad, y la importancia del papel del sector público en la respuesta a situaciones de crisis.

DESCRIPTORES: Legislación; Tecnología Biomédica; Sistema Único de Salud; COVID-19.

1 INTRODUCTION

In 2019, after the first case of infection caused by the new coronavirus (SARS-CoV-2) and its rapid spread in the following months, the World Health Organization (WHO) declared a public health emergency of international concern regarding the new disease – COVID-19 - when numerous concerns arose regarding the implementation of strategies to address the health crisis that had already taken hold.

In a context reported by the WHO years earlier about countries' unpreparedness to address pandemics, the organization reported that catastrophic mortality levels would occur, with panic and economic and commercial destabilization [(1)]. Even so, the COVID-19 pandemic situation required governments and public managers to develop swift actions to confront the disease.

Therefore, these elements demanded urgent actions from health managers to address several fundamental strategic needs in the social, economic, and health fields. In this setting, the public sector became strategic in the Brazilian context, especially regarding the Unified Health System (SUS) actions and health services.

In the private health field, among the several measures to combat the disease, adopting treatment, diagnosis, and prevention technologies was essential in an initial chaotic setting with an explosive demand for consumption of health resources, disrupting the supply systems for several health technologies in Brazil and the world at large [(2)].

From this perspective, we underscore the relevance of supply management – a pillar of any organization, with strategic importance due to its financial and budgetary impact – potentially linked to the procurement of several materials, goods, and services. In this regard, Brazil has a very peculiar and complex administrative procedure, marked by the requirement to comply with successive administrative steps related to government purchases [(3)].

In Brazil, the responsibility for procurement is widely distributed across all government levels; to do so, the public organization needs to hold a bidding process. This activity is characterized by the emergence of user demand (such as from an organization), which must be sent to a sector that will receive it and seek suppliers in the market that have the skills to supply or perform a good or service within a given period. This process is submitted to a unique procedure through several discretionary and binding stages to be completed quickly and efficiently for the public sector's functioning [(3)].

According to Hassan et al.[(4)], several countries have pointed out the need to review the legal framework in the public sector to promote agility and speed in health responses amid the pandemic. Similarly, there was room for changes in bidding regulations in Brazil, which, in Oliveira's words, were "extraordinarily legal for addressing the public health crisis" [(3)].

Thus, this study aims to characterize and examine the regulatory frameworks modified or implemented by the federal government regarding the Brazilian public procurement due to the advent of COVID-19.

This study was developed based on the need to answer questions about managing health services and systems affected by the pandemic. This study is innovative because it addresses technical-administrative and legal issues directly impacting patient and health worker quality of care and safety. Furthermore, this article characterizes the changes in the rules linked to Brazilian government purchases in the pandemic outlook, which can improve measures to address other future health emergencies.

2 THEORETICAL FRAMEWORK

The New Public Procurement and Contracts Law (NLLC), enacted as Law N° 14.133/2021, marks a significant update to the legal framework for Brazilian public procurement, replacing Law N° 8.666, published in 1993. The new regulation arises as a response to the need for modernization, transparency, and efficiency in the country's bidding processes. The new law's text aims to meet demands for greater speed and flexibility, promoting innovations in bidding procedures and adapting to new practices and technologies involved in the processes. By including new modalities, reviewing judgment criteria, and incorporating provisions encouraging innovative companies' participation, the legislation aims to streamline public management and the use of resources.

The NLLC also aims to improve control and punishment mechanisms to prevent irregularities and ensure effective compliance with contracts between the public administration and the private sector. The introduction of instruments such as competitive dialogue and prequalification bidding reflects the search for solutions more appropriate to the specificities of different contracts, contributing to increased effectiveness in government procurement. Also noteworthy is the focus on information technology, establishing the possibility of conducting bidding processes electronically, which speeds up the process and aligns Brazil with international public procurement practices.

Thus, the NLLC emerges as a legal framework that aims to modernize, simplify, and improve public contracting processes, promoting greater efficiency, transparency, and legal security in relations between the public and private sectors.

3 METHODS

This retrospective, qualitative, and descriptive study was based on the analysis of documents on the regulatory frameworks for public procurement introduced in Brazil resulting from the fight against COVID-19.

The data sources employed were federal government legislation published up to October 2021, obtained through a direct search on public access portals on the internet. First, qualitative documentary research was conducted using different search strategies on the websites of the federal government, the Federal Court of Accounts (TCU), the National Health Surveillance Agency (ANVISA), and the Health Legislation System of the Ministry of Health (Saúde Legis/MS). The following terms were used as keywords: legislation; purchases; health technologies; Unified Health System, without specifying the object of the public purchase.

The identified standards were then subjected to preliminary analysis through free-floating reading to select only pieces exclusively related to purchases or procurement in their content. Thus, given this study's scope, regulations regarding the transfer of resources, financing rules by the Ministry of Health, and specific rules of the National Plan for the Operationalization of Vaccination against COVID-19 were not included in the sample.

Based on the analysis, a database of normative documents was structured and organized in Microsoft Excel, systematizing information such as document or rule type (law, decree, ordinance, or other classification); rule number; rule year; link to the legislation; and legislation summary. The documents were then analyzed to identify each rule's main features and the measures introduced in the legislation.

Subsequently, the measures previously established for each standard were examined and categorized into five thematic axes (cf. Table 1) based on an adaptation of a World Bank document [(5)], which presents a legal and administrative framework for national emergency public procurement following the global outbreak of COVID-19.

Table 1. Thematic axes of the federal bidding framework in public procurement implemented to combat COVID-19

Thematic axis	Description
Financial rules	Addresses payment rules, budget limits, and research/estimation methods for prices and payment values.
Procedural simplification	Includes changes and adjustments to procedural actions inherent to public bidding, involving elements linked to deadlines, modality types, flexibility in presenting documents, contract supervision, and rules for contracting companies.
Transparency and *accountability*	Covers issues that reinforce adopting measures aimed at the availability of information on government portals to publicize, to report bidding processes.
Administrative innovation	Involves flexibility measures not previously foreseen in the regulatory structure of public procurement and linked to improvements in bidding mechanisms.
Health regulation	Makes the health requirements established by ANVISA more flexible or exempt from implementing public procurement.

Source: Prepared by the authors based on a World Bank document [(5)].

4 RESULTS AND DISCUSSION

Ten federal laws established significant changes for the government acquisition of health technologies to promote flexibility and agility in their implementation during the COVID-19 pandemic in Brazil (cf. Table 2).

Table 2. Summary of federal public procurement regulations implemented to combat COVID-19

Portal	Publication	Legislation	Summary of main characteristics
Federal Government Legislation	02/06/2020	Law N° 13.979/2020	Establishes measures to address the health emergency.
			Regulates the bidding exemption in the face of the pandemic.
			Maintains publication on procurement transparency portals.

Portal	Publication	Legislation	Summary of main characteristics
			Allows the hiring of companies with unsuitable registration or suspension.
Federal Government Legislation	03/20/2020	MP N° 926/2020	Adds articles to Law N° 13.979/2020. Introduces procedures for contracting engineering services. Sets a deadline for publicizing acts on transparency portals. Enables the acquisition of usable medical equipment. Waives bidding. Converted into Law N° 14.035/2020.
ANVISA and the Health Legislation System	03/23/2020	RDC ANVISA N° 356/2020	Allows the acquisition of personal protective equipment (PPE) and medical devices not registered with ANVISA. Provides general health standards.
Federal Government Legislation	04/15/2020	MP N° 951/2020	Innovates with the possibility of waiving bidding through price registration, with publication of minutes. Closed in 08/2020.
ANVISA and the Health Legislation System	04/30/2020	RDC ANVISA N° 379/2020	Amends RDC No. 356/2020, adding the possibility of international procurement to acquire medical devices. Adds the possibility of importing PPE and medical devices not regulated by ANVISA.
Federal Government Legislation	05/06/2020	MP N° 961/2020	Authorizes advance payment in bids and contracts. Expands the limits of bidding waivers. Converted into Law N° 14.065/2020.
Federal Government Legislation	08/11/2020	Law N° 14.035/2020	Amends points of Law N° 13.979/2020. Removes the requirement to prepare preliminary technical studies. Manages contracting risks during contract management. Simplifies terms of reference or basic design. Dispenses with the need for price estimates provided that they are justified. Allows for contracts with prices higher than the estimate. Did not maintain the possibility of waiving bidding and using the price registration system. Introduces the auction modality (electronic or in-person), reducing the procedure deadlines by half.
Federal Government Legislation	09/30/2020	Law N° 14.065/2020	Amends Article 4 of Law N° 13.979/2020, increasing the guidelines for waiving bidding processes for acquisitions and services to combat COVID-19. Reincorporates the waiving of bidding processes using the price registration system. Readjusts the limit values for waiving bidding processes.
Federal Government Legislation	05/03/2021	MP N° 1.047/2021	Converted into Law N° 14.217/2021.
Federal Government Legislation	10/13/2021	Law N° 14.217/2021	Addresses the bidding exemption modality. Maintains the reduction of deadlines in the electronic or in-person auction modality. Maintains the possibility of advance payments.

Source: Prepared by the authors (2022).
Captions: MP: Provisional Measure; RDC: Collegiate Board Resolution.

The most significant volume of regulations was identified from the Federal Government Legislation Portal (eight out of ten). Subsequently, specific legislation was obtained from the ANVISA portal and the Health Legislation System of the Ministry of Health. The federal entity's laws and provisional measures were more comprehensive in regulating public procurement and were frequent in this study's sample.

4.1 Federal regulations on public procurement during the COVID-19 public health emergency: General characteristics

Law N° 13.979 of February 6, 2020, was enacted before the first case occurred on Brazilian soil. It was the first law to be enacted with measures to combat COVID-19, subsidizing actions targeting the Brazilian general population (distancing measures, among others) and the public administration [6]. This law had specific content regarding procedures related to emergency acquisitions and introduced several measures, especially regarding the bidding waiver (BW). This modality became applicable for acquiring health goods, services, and supplies intended to address the public health emergency of international concern resulting from the coronavirus while it persisted. However, given the barriers of the Brazilian context, such as the lack of suppliers and shortages, it was necessary to increase the legal provision with new adjustments to increase the flexibility level and step up acquisitions.

Thus, in order to reduce existing procedural steps and even reiterate the publicity of public administration actions, considering the advancing pandemic, new laws were added throughout the pandemic to fill the existing gaps, namely, Law N° 14.035 of August 11, 2020; Law N° 14.065 of September 30, 2020; and Law N° 14.217 of October 13, 2021. On this point, we should stress the use of Provisional Measures (MPs), as they allowed to implement some of the legislation and its updates quicker; that is, the MPs played a catalytic role in the structural process of promoting speed in acquisitions. Three of the four MPs established were converted into law (MP N° 926 of March 20, 2020, became Law N° 13.979 of February 6, 2020; MP N° 961 of May 6, 2020, became Law N° 14.065, of September 30, 2020; and MP N° 1.047 of May 3, 2021, became Law N° 14.217 of October 13, 2021). Only MP N° 951 of April 15, 2020, was extinguished.

Furthermore, the MPs incrementally induced new procurement flexibilities, such as the innovative introduction of the price registration system (SRP) for the bidding waiver, when applied exclusively to combating COVID-19.

4.2Thematic axes of the new federal bidding framework on public procurement to combat COVID-19

The “financial rules” axis was found in the four laws dedicated to promoting the restructuring of public procurement to combat the pandemic. They were introduced gradually and addressed mainly issues related to simplifying price estimates, final contracts with values above the initial estimate, increased contract value limits, advance payment in contracts, and the expanded use of the differentiated contracting regime.

The flexibilities resulting from the regulations related to the reduced deadlines for completing the bidding process stages, the simplified presentation of the terms of reference, the excluded requirement for a preliminary technical study, the postponed risk management after contracting, and the extension of contracts every six months (during the duration of the health emergency) were the increases observed in the “procedural simplification” axis, identified in all the laws analyzed.

Regarding the “transparency and accountability” axis, already established as a challenge to the legal Brazilian bidding setting, the need to guarantee accessible information via government portals on the Internet

was ratified. In this context, we highlight Law N° 14.035/2020, which introduced changes to the wording of Law N° 13.979/2020, such as the requirement that acquisitions include (within a maximum period of five business days after the event) several pieces of information on an official website, such as (a) contractor data; (b) contractual terms; (c) amounts; (d) data on the acquisition/contracting process and the act authorizing direct contracting or the statement resulting from the contract (conferred by Law N° 14.065/2020).

Another important aspect concerns "administrative innovation", which involves introducing new public procurement mechanisms previously unforeseen in the Brazilian structure. Measures such as using the SRP in purchases that do not require bidding, with extended bidding minutes, and introducing the intention to register prices (IRP) stand out.

Regarding the "health regulation" axis, two ANVISA Collegiate Board resolutions (RDC) were identified on the acquisition of several types of health technologies – essential for combating COVID-19 –, both published in 2020: RDC N° 356 and RDC N° 379. The RDCs waived the requirement for operating authorization and notification of companies for manufacturing, importing, and acquisition. Despite the lack of regularization with ANVISA, the products should have been regularized and marketed in a jurisdiction that is a member of the International Medical Device Regulators Forum – a global collaboration group to accelerate the standardization and convergence of international regulations for medical devices. The RDCs also did not exempt manufacturers from their responsibility regarding their products' quality, safety, and efficacy, along with market controls.

4.3 Combating COVID-19 and regulatory flexibilities in public procurement of health technologies in Brazil

The need to implement several actions to combat COVID-19 by Brazilian and world government entities was identified during the pandemic caused by the novel coronavirus. To this end, it was necessary to introduce new legislation for public procurement in Brazil and even review some technical and health aspects, such as ANVISA's RDCs. In short, the pandemic promoted reviews and changes in direct and regulatory procurement procedures to pursue several flexibilities.

It would not be prudent for government entities to rely exclusively on a 1993 law, even with its updates and exception mechanisms for purchases in emergencies and public calamities (according to Article 24 of Law N° 8.666/1993) since the rule set a deadline of up to 180 days for the conclusion of the emergency [7]. There was no evidence of how to predict its duration in the COVID-19 pandemic.

The OECD highlighted that the COVID-19 pandemic has revealed the widespread use of emergency purchases of essential goods and services, affecting how governments planned and conducted (to varying degrees) their purchases. Furthermore, the organization endorsed that most countries were forced to rethink their current procurement frameworks, adding new exceptions to the standard for urgent and emergency purchases.

Thus, several member countries – such as France, the United Kingdom, and Spain – have introduced temporary public procurement regulations or developed legislation with specific public procurement provisions to support buyers in making purchases during the crisis, from detailing emergency procedures to implementing changes to ongoing contracts or using specific payment terms [8].

Several exceptions were observed related to financial issues, which allowed for simplification in the price research stage, which is an important public procurement step. The authorization to conduct market surveys, expanding the adoption of several, resulted in greater flexibility in the search for prices.

Additionally, the exceptionality of not conducting a price estimate was incorporated, which could be justified by the many difficulties at the time of the research, the fluctuation and constant change in prices charged by health technology suppliers, and the internal competition between public and private buyers. Viana [9] highlights numerous adversities during the bidding process regarding research in several public bodies, which have also been the subject of repeated guidelines and decisions by control bodies and courts.

Another highlight was the release of acquisitions with advance payments, which are strictly prohibited under normal conditions since, as a rule, payment of the expense can only be made after receiving the object. This exception was not a prerogative that could be used broadly and unrestrictedly since its application must represent an exception justified in the contracting records.

Justen Filho [10], when discussing the legal issues surrounding advance payment, highlights the existence of jurists and doctrinal trends in favor of this measure, converging with situations already found in the private sector. However, in calamities and health emergencies, such as that caused by the COVID-19 pandemic, the issue of payment before item delivery should be addressed with parsimony. Adopting this unusual condition in the public sector was also reinforced by the renowned jurist [10].

The regulations also greatly simplified procurement process management since there were several obstacles to meeting the growing demand for health supplies, including supplier restrictions and customs barriers between countries. Along the same lines, Gao [11] highlights the importance of reducing procedural conduct in public procurement to speed up acquisitions and address the pandemic more efficiently, mitigating the risks of stockouts, for example.

However, as Rose-Ackerman (12) pointed out when enabling the delivery of documents or the realization of studies, it was also necessary to combine policies to mitigate the risk of corruption, even more so in emergencies, given its adverse effects on process repute and government integrity.

Regarding this issue, the regulations reaffirmed the importance of transparency and accountability since these attributes are related to one of the guiding principles of public procurement: publicity. Furthermore, they align with Law N° 12.527/2011, which regulates access to information in Brazil. Therefore, transparency actions are significant for greater regulation and control by society of public administration activities. To this

end, international studies [13] highlight several problems involving the lack of transparency and weak supervision and oversight, exacerbating corruption and fraud problems.

Steingrüber et al. [14] highlight corruption types under normal circumstances in many low- and middle-income countries. These countries had frequent emergency acquisitions during the epidemic, which elevated the risks of corruption, price manipulation, market competition, and increased entry of inferior-quality and counterfeit products into stocks.

We should highlight that decision-making needs to be kept under public interest scrutiny. This requires the involvement of civil society organizations in monitoring health outcomes and procurement systems to track budget expenditures and provide feedback to users, enabling the process to occur with transparency and accountability [14].

Piratelli and Nascimento Neto [15] emphasized that the flexibility and new policies created by the federal government, although important, can also enhance procurement illegalities. The authors argue that the several scandals in the press have triggered regulatory agencies and the police. Thus, they emphasize that the increase in new technologies, such as artificial intelligence, combined with transparency measures, can curb the negative aspects of regulatory flexibility measures in public procurement.

Some can be considered innovative in the evolutionary and incremental process of changes. One of them was adopting the price registration system for emergency acquisitions. This strategy allows dozens of purchasing agencies to supply their stocks in a standardized, centralized, and swift fashion in a single acquisition. This system is indicated mainly for acquiring goods with regular demand (with systematic purchase frequency) and installment deliveries, which allows for streamlining financial resources. Thus, purchases shared by SRP are faster and have more significant economies of scale, reducing the workforce of the other public bodies involved[16].

Notably, this measure was never registered before and maintained in the NLLC (Law N°14.133/2021), which shows that the flexibilities adopted innovated the procurement procedure and may have served as a “laboratory” to test measures of interest to public buyers. This mechanism – acquisition by waiving bidding with the use of SRP – increases suppliers’ interest in participating in bidding processes since it has advantages such as predictability of future supply; streamlined production and sales planning; reduced participation in several bidding processes in the same institution or for several of them for the same object; and predictability of the delivery period without the need to form large stocks in advance.

Changes introduced by ANVISA directly interfere with the SUS procurement processes, with direct consequences for public purchases. As highlighted, the deliberations exempted the request for commonly required health regularization documents. These measures may contribute to maintaining the continuous supply of materials, avoiding the risk of shortages of strategic products in the Brazilian market.

Similarly, the United States regulatory agency for health technologies – the Food and Drug Administration (FDA) – has also issued emergency use authorizations to help address issues regarding the availability of specific personal protective equipment types – face shields and respiratory protective devices, such as N95 respirators, among other equipment – during the COVID-19 pandemic [17].

On the other hand, there are also concerns about the safety and quality of the technologies due to the emergency opening granted by the FDA. Plana et al. [18] analyzed several PPEs (N95 masks manufactured to international standards, such as KN95 from China and PFF2 from the European Union) used in medical centers in Boston. The study pointed out several problems in the respirator masks, whose quality and filtration efficiency were unacceptable for use in health environments such as hospitals.

Therefore, health regulation issues are highly relevant in ensuring health technologies' safety, effectiveness, and quality. Simplifying the production, import, and purchase of health technologies has possibly created uncertainty for buyers and managers regarding the ability to assess the quality of these materials, which is a minimum requirement when products are registered as health products.

Indeed, after the acute health crisis, it is appropriate to analyze the positive and negative aspects of the aforementioned exceptional rules, including refining the legislation applicable to public procurement in typical situations [3].

In this sense, a limitation of the present study refers to the exclusive mapping of federal regulations, preventing the capture of other legislation published by states and municipalities with the same objective of bringing flexibility and agility in implementing government purchases to face COVID-19.

5 FINAL CONSIDERATIONS

Given the above, the public system's resilience in establishing responses to COVID-19 was observed, leading the legislator to consent to several exceptions, simplifications, innovations, and flexibilities previously not found in the legislative body for emergency public purchases. Notably, the legal-administrative framework established by the set of federal government laws identified in this study was gradually introduced as the pandemic progressed and constantly demarcated by uncertainties of the health crisis.

The increases made the processes faster and more factual in response to the demands from the health situation observed. Additionally, in the pandemic, the public and private sectors disputed the same supplies, which would make it infeasible for the public sector to make purchases – due to its previously established limitations – supported by a strict and excessively formal structure, which was, therefore, insufficient to promptly meet the challenges necessary for the SUS to face COVID-19.

Assessing the real impact of the changes in weakening or strengthening Brazilian public procurement processes is difficult. This fact points to the divergences and challenges of being excessively permissive to avoid discontinuous supply, potentially harming healthcare amid the pandemic. On the other hand, there would also be difficulties in continuing to impose rules that could hinder the procurement process, generating

other consequences. Furthermore, the NLLC has incorporated some of the innovative measures portrayed by the new legislation introduced when the pandemic was in full swing.

However, balancing these two aspects requires constant attention from public managers in a crisis, who must mobilize the capacity for ethical and coherent decision-making to address the challenges of public procurement and sound administration principles. In Brazil and internationally, several problems involving a lack of transparency and weak supervision and oversight exacerbate corruption and fraud. On the other hand, public measures against these crimes have not kept pace with the need for responses to the developing crisis.

Another point to be highlighted is the Brazilian State's bureaucratic nature, which, in the public health sector, has characteristics and complexities that challenge its management capacity since it has specialized work processes requiring a supply system that involves different types of health technologies. Thus, the several layers of bureaucracy and decision-making processes inherent to public administration reinforce the debate on the need for efficient and responsible administrative purchasing processes that promote a balance between bureaucracy and agility, considering the need for flexibility for dynamic, responsive management broadly based on legality and transparency, and accountability.

Thus, the study portrayed in an original way that the legal changes promoted in the COVID-19 pandemic directly interfere with the response capacity of health services since agility and speed in the purchase of health technologies – such as medicines, personal protective equipment, devices, and medical equipment – affect the availability of these critical resources for the adequate delivery of care to patients and workers in the health service network. Also, the flexibilities previously implemented can serve as institutional learning in the face of health emergencies and other upcoming events that may affect public health.

Finally, the COVID-19 pandemic has exposed the inadequacies in systems, processes, and underlying vulnerabilities in the supply chain of the global and Brazilian health systems. However, the State and public sector procurement role is important in the government's response to health crises.

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AUTHORS' BIOGRAPHY OR CURRICULUM

Angelúcia Muniz.Ph.D. student in Public Health at the Institute of Public Health Studies at the Federal University of Rio de Janeiro (UFRJ), Master in Public Health from the Sérgio Arouca National School of Public Health of the Oswaldo Cruz Foundation. She is currently the planning coordinator for the hospital and health complex at UFRJ.

Rondineli Mendes da Silva.Ph.D. and Master in Public Health from the Institute of Social Medicine of the State University of Rio de Janeiro (IMS/UERJ). Public health researcher at the Department of Drug Policy and Pharmaceutical Services (NAF) of the Sérgio Arouca National School of Public Health (ENSP) of the Oswaldo Cruz Foundation. He currently coordinates the Academic Postgraduate Program in Public Health at ENSP/Fiocruz.