

## Editorial

### Enhancement of the Regulatory Framework: The Consolidation of SUS Standards and updates to Decree N°. 12,002, of 2024.

Aprimoramento da Estrutura Normativa: a consolidação de normas do SUS e as atualizações do Decreto nº 12.002, de 2024.

Mejora de la Estructura Normativa: La Consolidación de Normas del SUS y actualizaciones al Decreto N° 12.002, de 2024.

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## Abstract

The process of consolidation depends on good drafting and preparation of normative acts and is an inherent consequence of the improvement of regulations. In this regard, the innovations of Decree N°. 12,002 of 2024 concerning Consolidation are presented, which mainly pertain to the mandatory maintenance of normative consolidation through amendments to the consolidated norms and periodic reviews of these norms. This constant maintenance of consolidated acts preserves the need for regulatory improvement, which is essential to ensure legal certainty, transparency in the democratic environment, and compliance with OECD regulatory policy directives. The health sector, as a pioneer in the consolidation of its infralegal normative acts, leads in the improvement of regulations and should serve as an example for other bodies.

**Keywords:** Enacted Statutes; Right to Health; Government Regulation.

## Resumo

O processo de consolidação depende de uma boa redação e elaboração dos atos normativos e é consequência inerente do aprimoramento de normas. Nesse sentido, apresenta-se as inovações do Decreto n.º 12.002, de 2024, relativas à consolidação, que dizem respeito, sobretudo, à obrigatoriedade de manutenção da consolidação normativa por meio da realização de alteração da norma consolidada e de medidas periódicas de revisão dessas normas. Essa manutenção constante dos atos consolidados preserva a necessidade de melhoria normativa, essencial para garantir segurança jurídica, transparência no ambiente democrático e cumprir as determinações da Organização para a Cooperação e o Desenvolvimento Econômico voltadas para política regulatória. A saúde, como pioneira no processo de consolidação dos seus atos normativos infralegais, tem a vanguarda no aprimoramento de normas e deve ser exemplo para outros órgãos.

**Palavras-chave:** Normas Jurídicas; Direito à saúde; Regulação governamental.

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## Resumen

El proceso de consolidación depende de una buena redacción y elaboración de los actos normativos y es una consecuencia inherente de la mejora de las normas. En este sentido, se presentan las innovaciones del Decreto n° 12.002 de 2024 relativas a la Consolidación, que se refieren principalmente a la obligatoriedad de mantener la consolidación normativa mediante la realización de modificaciones a la norma consolidada y de medidas periódicas de revisión de estas normas. Este mantenimiento constante de los actos consolidados preserva la necesidad de mejora normativa, esencial para garantizar seguridad jurídica, transparencia en el ambiente democrático y cumplir con las determinaciones de la OCDE dirigidas a la política regulatoria. La salud, como pionera en el proceso de consolidación de sus actos normativos infralegales, está a la vanguardia en la mejora de las normas y debe ser un ejemplo para otros órganos.

**Palabras-Claves:** Normas jurídicas; Derecho a la Salud; Regulación Gubernamental

The 1988 Federal Constitution<sup>(1)</sup> provides for the legislative process and the drafting of norms as a pressing function of the Legislative Branch. Article 59 deals with the types of norms to be drafted and the sole paragraph states that a complementary law (CL) will provide for the drafting, editing, amendment and consolidation of laws. Thus, the notion of consolidating rules is dealt with constitutionally, delegating its specifics to the CL. Complementary Law N°. 95 of 1998<sup>(2)</sup>, therefore came to fulfill the constitutional determination and provide for the drafting, editing, amendment and consolidation of laws and other normative acts. It is the main guideline for normative drafting.

Article 13, paragraph 1 of CL 95, of 1998, establishes the legal concept of consolidation, understood as the process of “[...] integrating all the laws pertaining to a given matter into a single piece of legislation, formally repealing the laws incorporated into the consolidation, without modifying the scope or interrupting the normative force of the consolidated provisions”<sup>(2)</sup>.

This regulatory framework was the basis for the unprecedented process of consolidating the ordinances of the Office of the Minister of Health, published from 1990-2017, which resulted in six thematic consolidation ordinances. This process was carried out under the SUSLegis project, coordinated by the Health Law Program/Fiocruz<sup>(3)</sup>.

Both the 2017 and 2019 Decrees were repealed by Decree 12.002 of 2024, which came into force on June 1 and established new parameters for the preparation, drafting, amendment and consolidation of normative acts. Decree N°. 12.002 of 2024<sup>(4)</sup> is an innovation in terms of consolidation, with a specific section on the subject applied to normative acts that are less than a decree.

The section addresses the competence to revise and consolidate these acts, establishing that, as a general rule, this competence lies with the body or entity that issued the act. It also deals with the revocation of a joint normative act and future revisions and consolidations. On the latter subject, it makes it compulsory to maintain the normative consolidation by amending the consolidated norm each time a new act with a theme that adheres to it is issued. Finally, the new Decree provides for the need for periodic measures to review and consolidate regulations, as established in the work plan of each body or entity.

The political agenda for regulatory improvement has been a recommendation of the Organization for Economic Cooperation and Development (OECD) since 2012 and Brazil's efforts to join this forum require improvements to its regulatory structure<sup>(5)</sup>. In this context, the improvement of regulatory consolidation processes is relevant, since the main function of consolidation is the “institutional

guarantee of the principle of legal certainty, revealed by its characteristics as a singular norm for the continuous and permanent updating of regulatory systems”<sup>(6)</sup>.

Improvements with the publication of new rules on normative development, such as Decree 12.002 of 2024, indicate that the Brazilian state is seeking to improve its legal framework. And the continuous process of revising norms that this new Decree indicates must be a collective effort by the various bodies and entities of the Public Power, with health as an example given its avant-garde position.

## References

1. Brasil. Constituição da República Federativa do Brasil de 1988. Presidência da República. Casa Civil. 1988 [cited on June 14, 2024]. Available from: [https://www.planalto.gov.br/ccivil\\_03/constituicao/constituicao.htm](https://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm)
2. Brasil. Lei Complementar nº 95, de 26 de fevereiro de 1998. Dispõe sobre a elaboração, a redação, a alteração e a consolidação das leis, conforme determina o parágrafo único do art. 59 da Constituição Federal, e estabelece normas para a consolidação dos atos normativos que menciona. Presidência da República. Casa Civil. 1998 [cited on June 14, 2024]. Available from: [https://www.planalto.gov.br/ccivil\\_03/leis/lcp/lcp95.htm](https://www.planalto.gov.br/ccivil_03/leis/lcp/lcp95.htm)
3. Santos AO, Aranha MI, Delduque MC, Alves SMC (org). Consolidação, Simplificação e Revisão do arco normativo infralegal da saúde: um projeto, muitas vozes. Brasília, DF: CONASS, 2024.
4. Brasil. Decreto nº 12.002, de 22 de abril de 2024. Presidência da República. Casa Civil. 2024 [cited on June 14, 2024]. Available from: [https://www.planalto.gov.br/ccivil\\_03/\\_ato2023-2026/2024/decreto/d12002.htm](https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2024/decreto/d12002.htm)
5. Salinas N, Gomes L. A Adesão do Brasil à OCDE e seus efeitos sobre a política regulatória brasileira. Regulação em Números. FGV Direito Rio [Internet]. [cited on June 14, 2024]. Available from: <https://regulacaoemnumeros-direitorio.fgv.br/post/adesao-do-brasil-ocde-e-seus-efeitos-sobre-politica-regulatoria-brasileira>
6. Aranha MI, Lima JAO. Consolidação de atos normativos: a especificidade da técnica legislativa e a consolidação do Sistema Único de Saúde. Cad. Ibero Am. Direito Sanit. [Internet] 2021 [cited on June 10, 2024]; 10(Suplemento): 32-52. Available from: <https://www.cadernos.prodisa.fiocruz.br/index.php/cadernos/article/view/840>

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