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Research paper

SYSTEMATIZATION AND QUALITY ASSESSMENT OF THE REGULATORY FRAMEWORK FOR THE PLANNING, DESIGN, AND CONSTRUCTION OF HEALTHCARE FACILITIES IN SERBIA

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Abstract

Previous studies in the field of architectural and interior design of patient rooms in secondary and tertiary healthcare institutions in the Republic of Serbia have highlighted the need for access to regulatory documents that legally define the requirements for the planning, design, and construction of such facilities. A key issue identified is the absence of a unified and comprehensive list of easily accessible legal and regulatory acts. The aim of this paper is to compile a complete inventory of the relevant legal frameworks and to evaluate both the scope and quality of their content. The research methodology combines literature review, analytical and synthetic approaches, and comparative analysis. The findings point to an urgent need for reform of the existing regulatory system governing the planning and development of healthcare institutions in the Republic of Serbia.

Key words: *Healthcare facilities, architectural design, regulatory framework, Serbia, legal acts*

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1. INTRODUCTION

The development of technology, new treatment methods, emerging knowledge, and their application in architectural practice have created the need to revise existing or adopt new norms, guidelines, regulations, and standards—in other words, a comprehensive regulatory framework. Such updates aim to reduce design errors in hospital architecture, improve user satisfaction with services and accommodation, and enhance working conditions and occupational safety for healthcare staff. The overriding challenge for commissioners, regulators and providers of both health and social care and associated physical environments in which care is delivered, is reconciling the need for patient safety, effectiveness and efficiency and the need for creating a truly therapeutic environment [1].

By adopting a research-informed design methodology - Evidence-Based Design, the international regulatory framework for healthcare facility design is continuously evolving and improving. The advancement of regulatory frameworks governing the planning, design, and construction of healthcare facilities is often driven by national standards bodies, governmental ministries, or professional associations. Regardless of the institutional origin, the overarching goal is to enhance the quality, safety, and efficiency of healthcare delivery through systemic regulatory improvement. Guidelines are published either as comprehensive standard manuals, e.g. *Planning, Design, and Construction of Health Care Facilities* [2] or as individual standards and regulations included in official regulatory lists for healthcare facility design e.g. *Complete List of Publications Related to NHS Estates* [3].

To determine the institutional actors responsible for the development of legal regulations in the field of healthcare facility planning and construction in the Republic of Serbia—and to assess whether this regulatory framework is being continuously updated and harmonized with international standards—a comprehensive list of current regulations will first be established in this study.

2. METHODOLOGY

The research methodology is structured into three phases.

The objective of the first phase is to identify the current regulatory framework for the planning and design of healthcare facilities in the Republic of Serbia through an extensive literature review. To achieve this, relevant sources will be examined, including official government and ministry websites, the website of the Republic Fund of Health Insurance, the Serbian Chamber of Engineers, the Institute for Standardization of Serbia, The Official Gazette, as well as other available literature related to the design of health centers and hospitals. This phase will also involve the systematization of collected data according to the type of regulation, the initiating institution, and the date of the most recent revision.

In the second phase, each document will be analyzed to determine the quantity of information related to the planning, design, and construction of healthcare facilities. This phase will identify whether the legal act refers entirely or partially to healthcare buildings and, if partially, which specific sections are applicable.

The third phase is focused on assessing the quality of the information content in each document. A qualitative and comparative analysis will be conducted to determine the extent to which the current Serbian regulatory framework for healthcare architecture is aligned with international standards.

3. RESULTS

Through database searches and literature review, a total of 15 regulatory acts relevant to the planning, design, and construction of healthcare facilities in Serbia were identified. These include five laws, six rulebooks, two government decrees, one technical specification, and one European standard. The results of the first and second phases of the research are presented in Table 1. The table includes the type of regulation, title, date of the most recent amendment, initiating institution, and an indication of whether the regulation applies entirely or partially to healthcare facilities.

The Law on Healthcare Protection and the Law on Fire Protection are fully applicable to healthcare buildings. The Law on Planning and Construction applies partially—specifically in Articles 2/24 and 2/44. The Law on Sanitary Surveillance is relevant in Article 8, and the Law on the Prevention of Discrimination Against Persons with Disabilities applies through Article 13.

Among the six rulebooks, only the Rulebook on Quality in the Field of Transfusion Medicine applies partially to healthcare facilities (Article 7). The remaining five rulebooks apply fully: Rulebook on the Conditions and Manner of Internal Organization of Healthcare Institutions, Rulebook on Detailed Conditions for Performing Healthcare Activities in Healthcare Institutions and Other Forms of Healthcare Services, Rulebook on General Sanitary Conditions Required for Facilities Subject to Sanitary Surveillance, Rulebook on Technical Accessibility Standards, Rulebook on Technical Norms for Fire Protection in Residential, Commercial, and Public Use Buildings, The Decree on the National Program for the Prevention, Treatment, Improvement, and Control of Renal Insufficiency and Development of Dialysis in the Republic of Serbia until 2020 applies in part, specifically Articles 11.2 and 11.3.3, which are relevant for design and construction processes.

The technical specification SRPS CEN/TS 16244:2018, Ventilation for Hospitals – Coherent Hierarchical Structure and Common Terms and Definitions for Standards Related to Hospital Ventilation, as well as the European standard SRPS EN 60598-2-25:2010 – Luminaires – Part 2-25: Particular Requirements – Luminaires for Use in Clinical Areas of Hospitals and Healthcare Facilities, are both fully applicable in the design and construction of healthcare facilities.

Table 1. Overview of Serbian Regulatory Framework for Healthcare Facility Planning and Construction

Type of Regulation	Title	Date of Last Amendment	Initiating Institution	Relevant Article(s)
Law	Law on Planning and Construction [4]	Official Gazette of RS, No. 62/2023, July 27	Ministry of Construction, Transport and Infrastructure, Government of RS	Articles 2/24 and 2/44
Law	Law on Healthcare Protection [5]	Official Gazette of RS, No. 29/2025, April 04	Ministry of Health, Government of RS	Entire document

Law	Law on Sanitary Surveillance [6]	Official Gazette of RS, No. 125/2004, November 22	Ministry of Health, Government of RS	Article 8
Law	Law on Prevention of Discrimination against Persons with Disabilities [7]	Official Gazette of RS, No. 13/2016, February 19	Ministry of Labour, Employment, Veteran and Social Affairs, Government of RS	Article 13
Law	Law on Fire Protection [8]	Official Gazette of RS, No. 87/2018, November 13	Ministry of Interior, Government of RS	Entire document
Rulebook	Rulebook on the Conditions and Manner of Internal Organization of Healthcare Institutions [9]	Official Gazette of RS, No. 126/2014, November 19	Ministry of Health, Government of RS	Entire document
Rulebook	Rulebook on Detailed Conditions for Performing Healthcare Activities in Healthcare Institutions and Other Forms of Healthcare Services [10]	Official Gazette of RS, No. 16/2018, March 5	Ministry of Health, Government of RS	Entire document
Rulebook	Rulebook on General Sanitary Conditions Required for Facilities Subject to Sanitary Surveillance [11]	Official Gazette of RS, No. 47/2006, June 10	Ministry of Health, Government of RS	Entire document
Rulebook	Rulebook on Technical Accessibility Standards [12]	Official Gazette of RS, No. 22/2015, February 27	Ministry of Labour, Employment, Veteran and Social Affairs, Government of RS	Entire document
Rulebook	Rulebook on Technical Fire Protection Norms for Residential, Commercial and	Official Gazette of RS, No. 22/2019, March 28	Ministry of Interior, Government of RS	Entire document

	Public Use Buildings [13]			
Rulebook	Rulebook on Quality in the Field of Transfusion Medicine [14]	Official Gazette of RS, No. 6/2019, February 1	Ministry of Health, Government of RS	Article 7
Government Decree	Decree on the Plan of the Network of Healthcare Institutions [15]	Official Gazette of RS, No. 101/2024, December 20	Ministry of Health, Government of RS	Entire document
Government Decree	Decree on the National Program for the Prevention, Treatment, Improvement and Control of Renal Insufficiency and the Development of Dialysis in the Republic of Serbia until 2020 [16]	Official Gazette of RS, No. 11/2011, February 22	Government of RS	Articles 11.2 and 11.3.3
Technical Specification	SRPS CEN/TS 16244:2018 Ventilation for Hospitals – Coherent Hierarchical Structure and Common Terms and Definitions for Hospital Ventilation Standards [17]	August 31, 2018	Institute for Standardization of Serbia	Entire document
European Standard	SRPS EN 60598-2-25:2010 Luminaires – Part 2-25: Particular Requirements – Luminaires for Use in Clinical Areas of Hospitals and Healthcare Facilities [18]	June 30, 2010	Institute for Standardization of Serbia	Entire document

In order to assess the quality of information contained in the regulatory acts of the Republic of Serbia related to the planning, design and construction of hospitals, a comparative analysis was conducted in the third phase of the research, starting with a review of relevant international and national regulations. The design regulations analyzed were: International Guidelines for Healthcare Facilities – iHFG [19], FGI Guidelines for Hospital Design and Construction 2018 [20], as well as the Complete List of Guidelines of the National Health Service (NHS) for the United Kingdom [3] and the Russian regulation SP 158.13330.2014 - Buildings and Premises for Healthcare Facilities [21]. The analysis found that these regulations are systematically organized and, within the framework of design guidelines, address a wide range of areas including structural flexibility, modularity, building construction, interior finishes and equipment, accessibility and mobility, environmental design and ergonomics, occupational health and safety, infection control, engineering services, feasibility planning and cost estimation, functional planning units with technical annexes, and standard room components.

The former republics of the Socialist Federal Republic of Yugoslavia, now independent states in the Balkan region, once shared a common system of JUS standardization as well as unified laws and regulations governing the planning, design, and construction of healthcare facilities. For the purposes of this research and documentation, the regulatory frameworks of Montenegro, North Macedonia, Bosnia and Herzegovina, as well as Croatia and Slovenia were examined. A higher level of regulatory development was anticipated in the cases of Croatia and Slovenia, given their membership in the European Union. The most significant progress in regulatory development was achieved solely by Slovenia, whose Ministry of Health adopted a comprehensive regulatory document for healthcare facilities in December 2021, titled *Tehnična smernica za graditev TSG-12640-002:2021 (Technical guideline for construction TSG-12640-002:2021)* [22]. These guidelines are fully harmonized with European Union regulations and may serve as a valid and practical model of successfully implemented regulation for other countries in the region.

A comparison between Serbian regulations and both international standards and those of regional countries such as Slovenia reveals that domestic regulations are not unified. Depending on the specific area, regulatory initiatives originate from various entities, including different ministries, the Government of the Republic of Serbia, and private companies engaged in standardization. As a result, the regulatory framework does not comprehensively cover the full spatial configurations of healthcare facilities, including all structural and functional requirements necessary to ensure a pleasant and humane environment for all users of the space—both patients and healthcare professionals. Furthermore, the regulations are not aligned with contemporary minimum technical standards.

4. DISCUSSION

A comparative analysis aimed at assessing the quality of regulatory content was conducted using the standards related to patient rooms. In the Republic of Serbia, these are defined through the minimum spatial dimensions stipulated in the Rulebook on Detailed Conditions for the Provision of Healthcare Services in Healthcare Institutions and Other Forms of Healthcare Service, specifically in Article 45, item 5, which states: Patient room: 5.5 m² per adult bed; 3.5 m² per bed for children under two years of age; 4 m² per bed for children up to six years of age; and in intensive care and emergency rooms, 6.5

m² per bed. The spacing between beds should be 60 cm, in intensive care 100 cm, and the distance from beds to the wall should be 20 cm in regular patient rooms and 60 cm in intensive care and emergency rooms [10]. These specified areas and spatial clearances are in fact lower than the standards applied during the former Yugoslavia and should instead be expanded and harmonized with contemporary European or international regulations. According to the *Manual of Hygiene* from 1966, the planning and design guidelines for general hospitals stipulated that multi-bed patient rooms should provide 6.5 m² per bed, while single-bed rooms should offer 9 m². The room height was fixed at 3.2 meters. The required spacing between beds was 75 cm, and the distance from the wall to the bed ranged from 75 to 125 cm [23].

It is noteworthy that this Rulebook does not define even the minimum floor-to-ceiling heights of patient rooms. In fact, this parameter was removed in the most recent amendment to the Rulebook, effectively enabling the establishment of private hospitals and clinics in residential buildings with insufficient floor heights. Additionally, the regulation fails to define the necessary furniture and equipment, as well as the positioning of required utility installations. The comparative overview of the selected parameters for various countries is shown in Table 2.

Table 2. National Regulatory Standards for Multi-Bed Patient Room Design

Country	Source	Min. area per bed in multi-bed adult room (m²)	Min. bed-to-bed distance (cm)	Min. bed-to-wall distance (cm)	Min. clear ceiling height (m)
SFRY (former)	Manual of Hygiene [23]	6.5	75	75–125	3.20
Serbia	Rulebook [10]	5.5	60	20	not specified
Montenegro	Rulebook [24]	5.5	60	20	not specified
Croatia	Rulebook [25]	6.0	75	75	2.60
Bosnia and Herzegovina	Rulebook [26]	5.0	100	60	2.60
North Macedonia	Rulebook [27]	6.0	80	75	2.50
Slovenia	Rulebook [22]	16.0	not specified	not specified	4.50 (floor-to-floor height)
Russia	SP 158.13330.2014 [21]	10.0	80	120	2.60

In contrast, the 2018 International FGI Rulebook recommends designing only single-bed rooms. The maximum number of beds per room in medical/surgical patient care units will be one. Two beds per room are permitted when approved by the competent authority. This rulebook also requires the design of all four functional zones - for the patient, employees, family and hygiene. The minimum area and dimensions of the rooms are also defined. The minimum area of a unit with a family zone must be at least 23.22m2, and if possible, an

additional 2.79m2 should be provided per family member. Newly built single-bed rooms should be at least 3.66 m wide and 3.96 m deep, or 14.86m2, excluding the toilet, closet, cabinets, anteroom and niche [28]. The Slovenian Rulebook also defines the design of only single-bed and double-bed rooms.

The International Health Facility Code (iHFG) in the chapter Standard Components provides detailed information on the most common rooms and spaces in health facilities. Each component consists of a Room Data List (RDS) and a Room Drawing List (RLS). Single rooms have an area of 15, 16.5 and 18 m2 and are rooms with two clearly defined zones (patient and hygiene). Single units of 28m2, 30 or 50m2 contain a family zone for the permanent stay of a family member. This code contains codes for double rooms of 28 and 30m2, which, like single rooms, do not have a zone for employees and family, but only for visitors. Four-bed units have an area of 42, 49 and 60m2, in addition to the patient area and two hygiene areas and a space for visitors. Six-bed units are units with the maximum number of beds according to this nomenclature, and can have an area of 44 and 75m2.

The aforementioned Rulebook on Detailed Conditions for Performing Healthcare Activities in Healthcare Institutions and Other Forms of Healthcare Services [10], in Article 44, paragraphs 5 and 6, addresses sanitary facilities as follows: 5) Cold and hot running water shall be available in work areas, patient rooms, and sanitary units; 6) A sanitary facility with an anteroom must be provided adjacent to the waiting area, and in hospitals, one sanitary facility and a shower with a bathtub shall be provided per every 10 beds. The critical importance of having dedicated sanitary facilities within each patient room for effective infection control has long been acknowledged.

Comparable national regulations from Slovenia, Croatia, Russia, England, as well as relevant international standards, explicitly prescribe the inclusion of sanitary facilities and bathrooms within patient accommodation units. In contrast, the regulations of other countries from the former SFRY region, as well as Serbia, require the presence of a shared sanitary facility and bathroom at the hospital ward level. Consequently, the existing regulatory framework warrants thorough revision and enhancement to align with best practices in healthcare facility design.

5. CONCLUSION

Based on the presented research findings regarding regulations in the field of planning, design, and construction of healthcare facilities in Serbia, the following conclusions can be drawn:

The regulatory framework in this domain is neither systematized nor available through a centralized, publicly accessible governmental portal. It has been structured only through this research, and it is recommended that such a systematization be formally published.

The existing regulations do not comprehensively address the entire hospital complex. There are no guidelines regarding structural systems with optimal spans that would enable modularity and flexible spatial organization. There is also a lack of recommendations for the selection and use of construction materials, or for interior finishes across different functional zones in a manner consistent with infection control principles. Where they do exist, such guidelines are often overly general, such as those found in the Regulation on General Sanitary Conditions.

The regulations do not encompass all engineering disciplines involved in the design and construction of healthcare facilities. Norms for the minimum dimensions of rooms are not aligned with international standards. Additionally, the provisions regarding the organization, surface area, and minimum equipment of patient rooms are outdated. Sanitary regulations and infection prevention measures are not in line with current global recommendations. Moreover, the regulations do not incorporate knowledge and principles stemming from the Evidence-Based Design (EBD) approach.

The current standard for lighting in healthcare facilities is obsolete, as it only accounts for incandescent, fluorescent, and discharge lamps, without considering modern LED lighting technologies.

Building upon the present study's systematization and evaluation of the regulatory framework for healthcare facility planning, design, and construction in Serbia, future investigations could focus on empirical assessments of how identified regulatory gaps affect the quality, safety, and operational efficiency of healthcare environments. Such work may include post-occupancy evaluations of newly built or renovated healthcare facilities, examining the relationship between design compliance and measurable outcomes such as patient recovery rates, staff satisfaction, and operational performance.

Further research could explore comparative policy analyses between Serbia and countries with advanced regulatory systems that have successfully integrated Evidence-Based Design principles. This would provide deeper insights into effective pathways for regulatory reform, with particular attention to adapting international guidelines to the Serbian socio-economic and healthcare context, ensuring proposed standards are both aspirational and feasible.

Another important avenue involves interdisciplinary studies on the integration of emerging technologies—such as smart building systems, advanced infection control measures, and sustainable design strategies—into regulatory frameworks. These approaches can contribute to creating resilient healthcare environments that adapt to evolving medical practices, demographic shifts, and public health challenges.

In addition, examining governance structures, institutional capacities, and stakeholder engagement mechanisms needed for the continuous update and harmonization of regulations could support the establishment of a dynamic, participatory regulatory model. Such a model would help ensure that healthcare facility design standards remain current, evidence-based, and responsive to both user needs and global best practices.

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