

The Regulatory Complex for Health Care in the Federal District, Brazil and the challenge for integrating levels of health care

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Abstract *The integration among levels of care is a continuous challenge even in consolidated and high performance health systems. The reform of public health system of Distrito Federal, based on the strengthening of primary health care associated to the reconfiguration of specialized attention (ambulatory and hospital) and of its of urgency and emergence network brought, as a challenge, the need for integration between these levels. Thus, became necessary to create an instrument to perform the role of gatekeeper, leading to equanimous, transparent and safe access to specialized and hospital care. Thus, the Regulatory Complex in Health of Distrito Federal (CRDF) and its Regulatory Centers (CR) were created to carry out the regulatory process of access to care services, such as hospitalization, ambulatory care (procedures and specialized consultations), elective surgeries, complex procedures, sanitary transport, urgencies and transplants of patients of the Federal District and outside it. This article describes the process of the CRDF implementation and its CRs, aiming to reflect on the potential and challenges of its role as an instrument of integration among the levels of care.*

Key words *Health regulation, Health services accessibility, Health care networks, Coordination of care, Integrated care*

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Introduction

The fragmentation in health care is currently one of the greatest obstacles to effective and quality care, especially when considering the impact of the population's aging and the burden of morbidity on people's health and quality of life^{1,2}. The lack of coordination of care tends to result in health access difficulties and its continuity³, precisely for those patients with complex health needs and who require the actions of several health professionals and at different levels of the health system^{4,5}.

The loss of coordination throughout the levels of care is one of the most frequent causes of poor quality of care, with duplication of diagnostic tests, polypharmacy, inadequate referrals, disagreement about care plans and increased risk of unnecessary interventions⁶, in addition to increased costs to the entire system².

Health services with greater equity, efficiency and quality can originate from the implementation of care integration strategies. Increases in access, continuity and coordination of care can also promote the process⁷.

Within this context, several countries have developed strategies for this purpose, including Brazil⁸. Some studies have revealed important barriers to care coordination, related both to the health model adopted in the country and the organization of the health networks⁹.

In Brazil, questions such as the transfer of clinical information between levels of health care, access difficulties, clinical management deficits and inadequate working conditions were considered barriers to the integration process in health care networks. Another study¹⁰, carried out in four Brazilian capital cities, reported that the use of computerized regulation systems and regulation models focused on Primary Health Care (PHC) were important for the health care network integration, in addition to improving access. Albeit with different results among these 4 municipalities, the monitoring of the waiting period for specialized care and the implementation of clinical protocols and electronic medical records were important mechanisms for this integration.

Following the same idea, the organization of Integrated Health Care Networks (RICS) or arrangements of organizations that promote or organize themselves to promote continuous and coordinated health care services to a certain population, for which it assumes clinical and sanitary responsibility, as well as health outcomes,

has been developed aiming at promoting greater integration between the levels of care¹¹⁻¹³.

Under this aegis, the National Council of Health Secretariats (CONASS) recommends regulation in health as a component of crucial importance and that should, at first, become the structure responsible for the communication between the primary level of care and the other levels (specialized outpatient and hospital care)¹³.

Originating from the field of economic sciences and with the meaning of control over marketing failures, the term "regulation" is based on the supply and demand components in the labor market. In health, it brings up important issues related to supplementary health, especially in relation to health plans and health insurance¹⁴. Moreover, in Brazil, it brings the pressing need to regulate health systems in an attempt to mediate the dispute between supply and demand, with several impacts on access to specialized and hospital services¹⁵.

Regulation brings in its concept fundamental ideas of control (adjustment and regulation), balance (correction and conservation), adaptation (interaction and transformation) and direction (negotiation and control)¹⁶. The first two are related to the operational and logistic processes of access regulation, regulatory processes with an important degree of inflexibility. Adaptation and direction translate its political role, especially the one related to decision-making¹⁷.

The division of regulation into two processes is also suggested: micro-regulation (related to the consumption of health services, that is, how people have their needs solved in daily life) and macro-regulation (strategic management mechanisms)¹⁶. Finally, the concept of the World Health Organization (WHO) (2000) has been frequently used, which reduces the regulation to the adequate care alternative in a timely manner¹⁸.

In the Brazilian Unified Health System (SUS - *Sistema Único de Saúde*), the regulation initially had an approach that was more focused at the control and evaluation mechanisms and, subsequently, it was directed towards the assistance mechanisms¹⁵. Since 2008, the National Policy on Health Regulation (PNRS)¹⁹ has the definition of Health Care Regulation as the production of direct and final health care actions, being therefore directed at public and private providers, and their respective public managers as subjects, defining strategies and macro-guidelines for the regulation of access to care, in addition to controlling the provision of services and actions for the monitoring, evaluation, auditing and surveillance of health care and assistance within SUS.

It is carried out by the entire health network and aims to guarantee the adequate provision of services to the population and its object. The Assistance Access Regulation, derived from the first, can be called access regulation or assistance regulation, which is a modality of regulation that has the organization, control, management and prioritization of access and assistance flows as objects, and their respective public managers as subjects. Finally, the PNRS regulated the organization, implementation and mode of operation of the Regulatory Complex in its three levels (municipal, state and federal).

Based on this premise, the restructuring of the public health system of the Federal District, based on the strengthening of PHC, mainly through the Family Health Strategy²⁰⁻²² and associated with the reconfiguration of specialized care (ambulatory²³ and hospital care²⁴) and its urgency and emergency network²⁵⁻²⁷ brought the need to promote integration between these levels as an important challenge for this system management.

Thus, it was necessary to organize as instrument responsible for receiving the requests that originated, mostly, from the PHC teams and that played the role of gatekeeper, leading to the equal, transparent and safe access to specialized and hospital care. Hence, the Federal District Health Regulatory Complex (CRDF)²⁸ and its Regulatory Centers (CR) were created to carry out a regulatory access process based on the development of scenarios for the provision of health services in the regionalization model of the Federal District.

Thus, the aim of this article is to present the implementation of the health regulation process developed in the State Health Secretariat of the Federal District (SHS-DF), as well as to characterize it after the implementation of the CRDF, and to consider future challenges and perspectives, based on the assumption of health access regulation as a fundamental instrument for care.

We will specifically address the organization, association and communication between the users' demand and the established capacity of the services under regulation, that is, specifically the access to assistance component, as it is the one most closely related to access.

History of access to assistance regulation in the Federal District

The implementation of access to assistance regulation in the Federal District is a unique experience in Brazil, since it presents a different

administrative structure from the other states of the federation, requiring the adoption of a specific implementation strategy to encompass its peculiarities. The first initiatives date back to 2004, even before the PNRS, with the creation of the Assistance Regulatory Technical Group (GTRA), of which mission was to disseminate the ministerial concepts and guidelines of regulation among the managers of the SHS-DF network, in order to implement the first regulatory actions in the Federal District. Subsequently, the GTRA was implemented as the General Coordination of the Assistance Network Regulation Management (CGGRRRA). Among its competences were the definition, structuring, implementation and direction of the future Regulatory Complex, according to the current guidelines of the Ministry of Health (MoH)²⁹. In this context, the Regional Assistance Regulatory Coordination Units (CORA) were also created, implemented in each health area of the Federal District, to provide regional support to CGGRRRA. In 2006, the CGGRRRA became a managerial unit and was officially included into the SHS-DF organizational chart.

Understanding the relevance of care access regulation as an important component for public management, in order to guarantee more equity and integral care, in addition to promoting greater transparency for citizens, the Regulatory Board of Directors (DIREG) was created in July 2007, subordinated to the Programming, Regulation, Evaluation and Control Sub-secretariat (SUPRAC). This board was responsible for the definition of strategies to control the provision of services and the access of users to health care.

Since its creation, DIREG has been structured with the support of three management units (Management of Ambulatory Care Regulation, Management of Hospital Admission Regulation, and Management of High Interstate Complexity Regulation, in addition to their respective nuclei). In 2009, the Regulatory Complex was institutionalized in the Federal District through the publication of SHS-DF Ordinance N. 189, dated of 10/7/2009³⁰.

The creation and implementation of the first SHS-DF Regulation Center took place on September 1, 2006 with the implementation of the Hospital Admission Central Regulation Center (CRIH). This administrative act was officialized through Ordinances GAB/ SES n. 41 of 8/30/06 and n. 42 of 08/31/06, which defined the operational flows related to the operation of the Center, as well as the competences of its employees. The need to organize the referrals of severely-ill

patients to Intensive Care in the SHS-DF was the result of a managerial decision, in agreement with the DF General Accounting Office (TCDF) and the Ministry for Territorial Administrations and the DF (MPTDF), as part of a remedial process against the scandals reported in the media at the time. The partnership / monitoring of this implementation by the TCDF and MPTDF allowed all ICU beds to enter the regulation^{31,32}.

Prior to the creation of CRIH, ICU bed occupancy occurred in a disordered manner and the rules for the transfer of severely-ill patients were not standardized. For the most part, these beds were occupied according to personal influence with the intensive care units, giving this process characteristics of clientelism. There was no managerial control over bed occupancy in the entire SHS-DF network, which made it difficult to obtain information about their availability^{29,30}.

Despite having as its primary function the regulation the hospital beds, of both public and private health establishments linked to SUS in the Federal District, the CRIH had as its initial and immediate aim the regulation of intensive care unit bed occupancy (currently about 403 beds) followed by intermediate neonatal care beds. Until the CRDF reconfiguration in 2017, there was no regulation of general hospital beds in the SHS-DF (approximately 4,000 beds). Since its creation, CRIH has been working 24 hours on an on-duty schedule. It uses its own information system, developed by a company that provides information technology services to SHS-DF.

The Consultation and Examination Appointment Regulation Center (CMCE) was created in 2004 and is responsible for the regulation of patients' access to specialized consultations, examinations and diagnostic and therapeutic support services.

Although the regulatory process was designed, it was estimated at that time that only 33% of the services performed by SHS-DF were available for regulation, since there were no institutionalized mechanisms to control the supply of services performed by the institution^{29,30}.

The new regulatory component in the SHS-DF structure

The Assistance Access Regulation is carried out by the CRDF and its operational units, encompassing the medical regulation as the sanitary authority to guarantee protocol-based access, risk classification and other prioritization criteria defined and agreed upon between the managers

involved for the provision of the alternative care more adequate to the citizens' needs by attending to the urgencies, consultations, bed requests and others that may be necessary. It contemplates the following actions: a) Medical regulation of pre-hospital and hospital care to urgencies; b) Control of available beds and consultation schedules and specialized procedures; c) Standardization of requests for procedures through assistance protocols; d) Establishment of references between units of different levels of complexity, of local, interregional and interstate coverage, according to approved flows and protocols.

The regulation of interregional references is the responsibility of the district manager, expressed in the coordination of the process of construction of approved and integrated health care programming, the process of regionalization and network design.

The CRDF is part of the SHS-DF as a District Reference Unit (URD), that is, it is a public healthcare unit characterized by its specific features regarding assistance, specialization or purpose, as a reference for all Health Regions. Its purpose is to coordinate the entire process of regulating access to health services in the SHS-DF, whether their own, hired or associated services. The competences of the CRDF are shown in Chart 1.

The operational structures of the CRDF are called Regulatory Centers (CR) and develop the means-actions of the regulatory process, that is, they receive the requests, process and schedule/direct the service/referral according to the determined scope. These are attributions of these Centers. The competences of the CR are shown in Chart 1.

The CRDF includes eight (08) CRs, depending on the scope of action: Hospital Admission Regulation Center (CERIH), Ambulatory Regulation Center (CERA), Interstate and High Complexity Regulation Center (CERAC), Elective Surgery Regulation Center (CERCE), Sanitary Transport Regulation Center (CERTS), Urgency Regulation Center (CERU), of Toxicological Information and Psychosocial Assistance Center (-CEITAP) and State Transplants Center (CET).

The responsibilities and associations of each of the Regulatory Centers are described in Chart 1. The CRDF Regulation Centers are linked to three Board of Directors: Ambulatory and Hospital Care Regulation Board of Directors (DIRAAH), State Transplant Center Board of Directors (CET) and the SAMU Board of Directors. The detailed description of each Regulation Cen-

Chart 1. Attributions of the CRDF and its CR, Federal District, 2018.

Health Regulatory Complex (CRDF)
To guarantee access to public health services in an adequate manner, considering the principles of equity, universality and integrality;
To implement actions that focus on service providers, public and private, in order to guide an efficient, effective and efficacious production of health actions;
To encourage information use and qualification for the registration of users, establishments and health professionals on nationally based operational platforms;
To advise the boards of directors of the SHS/DF own hospitals, convened and hired ones, to adopt administrative and assistance measures necessary for the operation of the patient care network;
To control the availability of hospital beds, as well as the schedule of consultations, exams and procedures;
To standardize the regulatory protocols for the regulated areas after the agreement of the managers involved;
Establish standards of referral and counter-referral between units, according to standardized flows and protocols, diagnosing, adapting and guiding the flows of care;
To permanently train the regulatory teams that will work in the health units;
To subsidize the actions of planning, control, evaluation, auditing in health and the processing of production information for decision-making;
To subsidize the agreed and integrated programming;
To organize specialized interregional and interstate reference flows.
Regulatory Centers (CR)
To absorb or integrate authorization processes, according to the previously established protocols;
To manage and monitor hospital bed occupation and health unit schedules;
To carry out the control of the physical and financial boundaries of the services under regulation, according to the Integrated Agreed Programming (PPI);
To apply the risk classification criteria, prioritization of consultations and parameters of referrals, according to previous agreement between the actors involved;
To carry out the care process regulation, based on regulatory protocols.

ter according to their responsibilities and subordination are shown in Chart 2.

CRDF also constitutes a link between service users and providers and is responsible for the harmony between these two sides. Thus, to the same extent that all healthcare regions must guarantee the qualification of the requests to be sent to the Regulatory Complex CRs, the operating units should be responsible for the opportune availability of the services, respecting the governance rules of the supply.

Regionalization and Regulation Scenarios

The inherent characteristics of the Federal District organization and its health services led to the construction of a model of regulation to meet the logic of a territory that at the same time encompasses characteristics of a large municipality, as well as those of a state³⁰. Thus, the distribution of health services under regulation from the perspective of different scenarios was chosen, which were called "Regulatory Scenarios"³³.

Regulation Scenario or Regulation Model consists in the subdivision of specialized and hospital care services, according to the regional distribution, resulting in the formation of a supply list for these services. Therefore, according to these lists, the type of scenario to be carried out by the CRDF and its CR is established. It should be noted that the configuration of these scenarios is a dynamic one and should be continuously monitored, being constituted as follows:

Scenario 1 or Regional Regulation: It refers to the service supply structure that is present in all health regions of the Federal District, that is, it occurs when the health territory / region is capable of managing its own supply distribution and the allocation of patients' demands, according to their established capacity. Moreover, the health territory or region becomes responsible for the qualification of the requests (consultations / procedures / hospitalizations), according to the current flows and protocols.

Scenario 2 or Agreed Regulation (Interregional): It refers to the region offering the resource

Chart 2. CRDF Regulation Centers according to responsibilities and subordination.

Acronym	Regulatory Center	Scope and responsibilities	Subordination
CERIH	Hospitalization Regulation Center	Regulation of the hospital beds in health facilities linked to SUS, with regulation of ICU beds and general beds and clinical and surgical hospitalizations.	DIRAAH [†]
CERA	Ambulatorial Regulation Center	Responsible for the regulation of patients' access to specialized consultations, exams, as well as other outpatient procedures.	DIRAAH [†]
CERAC	Interstate and High Complexity Regulation Center	Regulation of patient access for patients who require high-complexity procedures outside their State of origin, such as Out-of-Home Treatment (OHT) and authorization for high-cost procedures performed within the SHS / DF network with the MoH.	DIRAAH [†]
CERCE	Elective Surgery Regulation Center	Regulation of access to elective surgical procedures in the entire SHS / DF network.	DIRAAH [†]
CERTS	Sanitary Transportation Regulation Center	Regulation of elective transportation of patients.	DIRAAH [†]
CERU	Urgency Regulation Center	Regulation of access to Mobile Pre-Hospital and Hospital urgency and emergency services.	SAMU Board of Directors 192
CEITAP	Toxicological Information and Psychosocial Care Center	Regulation of urgencies and emergencies in the areas of toxicology, psychosocial care and violence. Referral in Clinical Toxicology in SUS.	SAMU Board of Directors 192
CET	State Transplant Center	Regulation of access to transplants in agreement with the National Transplant Center of the Ministry of Health.	CET ^{**}

[†]Board of Directors for Ambulatory and Hospital Care Regulation and ^{**} Board of Directors for the State Transplant Center

that must be able to manage, in addition to its own demands, the demands of another territory/region, according to prior agreements (quotas of care). The territory must meet the risk classifications of its own region and those of the agreed regions. The waiting period for the scheduling of each specialty will follow the prioritization guidelines according to the risk and complexity classification of each specialty, in compliance with the protocols and guidelines adopted by the SHS-DF.

Scenario 3 or Central Regulation: It refers to resources that are not found in most territories, being concentrated in specific units that supply the entire SHS-DF network. These are scarce and strategic services that supply the population of the DF as a whole. The regulatory process for access to these services is performed by the CR of the CRDF itself, by managing the demands, evaluation and scheduling, according to the current flows and protocols. The model for the operationalization of access regulation according to the established scenario is shown in Figure 1.

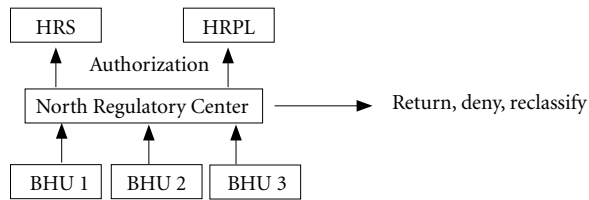
Challenges and perspectives

Within the SHS-DF, health regulation, through the CRDF, should promote the control of access to services from primary care and emergency care units to the other levels of care, considering the equity, integrality, available care resources the best care alternative to meet the needs of the population. However, some considerations based on perspectives and challenges must be made.

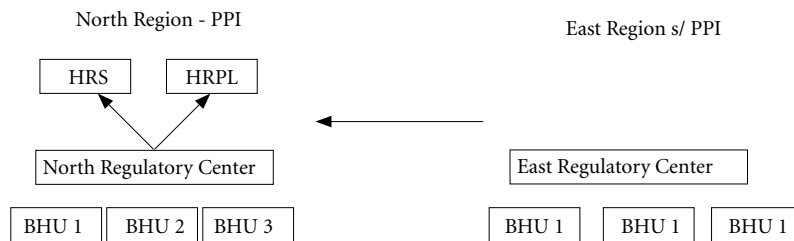
The CRDF became responsible for a group of strategies and actions defined in an assistance regulation plan directed at all levels of the system, aiming at the effective organization of a hierarchically articulated public network, with increasing technological levels of resolution, based on a regionally-articulated plan, through the CRs.

Thus, these processes should be reinforced as a health care instrument and not just a bureaucratic normative act. Health care regulation should be a living mechanism inside the health system and not just a cluster of health profession-

Scenario 1: Ex: North Region



Scenario 2: Ex: North Region and East Region



Scenario 3

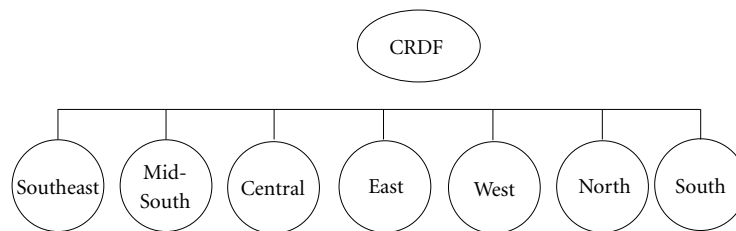


Figure 1. Example of operationalization of the regulatory scenarios. Health Regulatory Complex, SHS-DE, 2018.

Hospital Regional de Sobradinho (HRS), Hospital Regional de Planaltina (HRPL), Basic Health Unit (BHU), Integrated Programmed Agreement (PPI), Health Regulatory Complex of the Federal District (CRD).

als that allows patient access to a specialized outpatient or hospital service, or not, based solely on clinical protocols¹⁵. To carry out, monitor and evaluate the possibility of dialogue between the traditional method of regulation, which is often very focused on regulations with little or no flexibility and innovative forms of regulation, centered on the user and their health needs, is one of the biggest challenges of the CRDE.

As there was little tradition of regulation of services (only prehospital urgencies, ICU beds

and a part of the hospital consultations and procedures), it was decided to restructure the CRDF through standardization and, subsequently, to add more quality to the “live” process of regulation. Although with a normative and sometimes bureaucratic characteristic, the organization/restructuring of the CRDF through its CRs plays an important role in the organization of health care. First, because it establishes the role of the sanitary authority, performing schedules / giving directions as equanimous as possible, with no oth-

er form of access to services. Secondly, it makes it possible to adopt regulatory protocols with clear criteria for all citizens, thus bringing transparency to the entire process. Even though they contain very normative criteria, these protocols aim at standardizing parameters within a network as extensive as that of SHS-DF. In a complementary way, it is suggested that the construction of these protocols be carried out collectively (professionals and managers), mainly because they help in the broadcasting of the supply and how to access it.

Also from this perspective, we suggest that the legal framework governing regulation should be in continuous integration with other health policies. Such action, albeit simple in nature, can contribute greatly to the organization of more integrated processes, thus adding more quality to the care process. Another challenge faced for the consolidation of the CRDF and its regulatory processes within the SHS-DF structure is the adoption of technological incorporation mechanisms. Reinforcing processes for the development of technology, especially those related to artificial intelligence, can bring great benefit to the process. Considering that, in 2018, the CRDF, through the *Regula+Brasil* Project, initiated the implementation of the Federal District Telehealth Center. It is a project developed in partnership with the Institute of Education and Research of Hospital SírioLibanês and the Ministry of Health, aiming to reduce the waiting time for specialized consultation, prioritize the care of more severely-ill patients and provide support to PHC physicians for the most common health problems. The entire process is based on the adoption of regulatory protocols and counts on the technical contribution of the Telehealth Center of Rio Grande do Sul. This first phase encompasses waiting time for the following specialties: cardiology, endocrinology, pulmonology and dermatology³⁴. The implementation of the Tele-

health Center in Federal District is an important beginning, but actions aimed at its sustainability should be planned. From this point of view, more time could be devoted to educational processes aimed at health professionals, thus enhancing the quality of the health care network³⁵.

However, it is noteworthy, even though it is not the object of this article, the association between the Federal District and the Interfederative Development Network (RIDE)³⁶. This process has been the subject of meetings of the SHS-DF, but it needs, mostly, definitions of the Ministry of Health for its design.

The Federal District is an important health provider, especially in medium and high-complexity cases, for the other 33 municipalities of RIDE. Although it has existed for some time, there is a need for a detailed discussion of the agreements of these municipalities and their respective states with the Federal District. In all, RIDE contemplates a quantitative population of 4.4 million people, making it the fourth most populous region in the country³⁷.

Nevertheless, the PHC deserves due recognition and the strengthening of its flows and improvement of the practices of matrix support, stimulating contextualized interventions in the territories, resulting in an impact in the entire care network. It must be seen as the true front-runner of the line of care within a health care network, and only by starting with it can one break the current hegemony of the fragmentation of the care that is so present in our services.

Finally, we believe that regulatory processes need to and should be ruled by the constitutional aegis that guarantees not only the right to health, but the right to life. This “gives us the opportunity to move from the orderly, normative and exclusionary place to another, a new one, which brings us closer to the pain, to the waiting, to the care”¹⁵. Thus, regulation becomes, in fact, centered on the users and their real needs.

Collaborations

SR Batista worked on article conception and design, data research and organization, final writing of the manuscript, critical review, and manuscript approval for submission to publication. GCM Vilarins worked on article conception and design, in the final writing of the manuscript and its critical review. MG Lima worked on the final writing of the manuscript and its critical review. TB Silveira worked on data research and organization, final writing of the manuscript and its critical review.

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