

THE GUARANTEE OF INDEPENDENCE IN THE REGULATION OF THE HEALTH SERVICE IN COLOMBIA

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1 Introduction

Organizations are essential to develop legal institutions such as the right to health. However, when regulatory decisions are made by political organizations, whose decisions are not consistent over time and depend on an electoral cycle, regulation becomes uncertain and non-technical. This problem of commitment and the technical nature of law require an equally qualified response: organizations that are more politically neutral and independent of the Executive, rational-deliberative and accountable to the public.

2 The institutional theory and the protection of rights

Talking about effectiveness of rights implies a progressive reduction of uncertainty and the predictability of regulator's decisions. According to North¹ it is the major role of institutions, by founding a stable structure to human interaction. Institutions define and limit the set of choices of individuals and create an institutional framework composed by the organizations developed as a consequence.

A distinction between institutions and organizations is imperative to understand the relation between a legal construct and the created organs and procedures that regulate their functioning and implementation. Thus, the protection of a concrete interest is configured by a legislative decision and subsequently 'organ-ized', it means, positivized through its own organs and procedures². From the economic neo-institutionalism, there is a clear difference between institutions and organizations, because "institutions are the rules" – a framework of objectives and means – "and organizations are the players" interacting to reach them³.

Institutions are possible through the establishment of organizations through a symbiotic relationship in which organizations are institutional change agents. They structure social life, reduce transactional and informational costs, and reduce uncertainty. Furthermore, organizational theories consider that effectiveness is a consequence of organizational

¹ North, 1990.

² Hauriou, 1968.

³ North, 1990, p. 4.

structure⁴. According to the Committee on Economic, Social and Cultural Rights⁵, ‘the highest attainable standard of health’ to every person is the aim of every health system, which is based on a minimum. It is possible if right-to-health legal organizations that regulate and enforce it, and at the same time become institutional determinants of its effectiveness.

In summary, effectiveness largely depends on the existence of organizations with regulatory powers, ruled by procedures to operationalize these institutional aims, which tend to be vague and open-ended. Therefore, procedures in regulatory organizations that protect fundamental rights reflect more specific and actual operations representing intermediate or supporting goals with an intrinsic value and substantial effects regarding the grant of rights and its guarantee.

3 The notion of effectiveness of a right

Organizations are essential to enforce legal institutions, but also the absence of unreasonable limitations to exercise them and the existence of procedures to protect them. This is the concept of effective protection of rights, the so-called “hard core” of rights against which any restriction can make the right inapplicable or void of content.

From a formal perspective, effectiveness is equivalent to the attainment of the Principal’ goals in a mandate relation⁶ – namely, constituencies, legislators, states, international organizations and the institutions engaged in the recognition of rights –, whose guarantor agent is in this case the regulator. As a result, a goal will be effectively accomplished if there are enough evidences of the enjoyment of the right in the health system. Effectiveness is associated to the capability of the regulatory system to produce the outcome of turning the human right into an enforced legal right. This goal-based approach departs from legally established goals following Principal’s preferences developed by regulation in the administrative level.

⁴ Scott, 2002.

⁵ Committee on Economic, Social and Cultural Rights, 2000.

⁶ Shany, 2014.

According to the international human rights doctrine, effectiveness is a principle according to which the substantive and procedural rules related to the objective obligation of protection of rights prevail over any restriction of the State⁷ under the effect utile premise.

Under these approaches, compliance is an indicator of the effectiveness of regulation and normative impact is its ultimate proxy⁸. Norm-compliance assesses the performance of an organization by reference to an objective measure, e.g., the number of solved *inter-partes* conflicts (in exercise of quasi-jurisdictional functions) or the number of regulations to guarantee the right. These proxies do not ignore that legal rules are used as regulatory tools that “may secure other ends in particular ‘best practice’ or indeed a ‘gold plating’ of the legal provisions”⁹, but they are useful to have a proxy measure to find correlations and facilitate the analysis.

This effectiveness assessment measures the absence of legal uncertainty derived from ambivalence, lack of clearness, ambiguity of legal precepts or the lack of ex-post implementation accountability¹⁰. Subsequently, the more explicit the goal, the easier will be measuring its accomplishment.

However, effectiveness of rights depends also on several socio-legal factors. In the case of right to health, public health scholars establish some prerequisites for health (peace, shelter, education, food, income, a stable ecosystem, sustainable resources, social justice and equity), determinants of health (employment and working conditions, physical and social environments, biology and genetic endowment, health practices, healthy child development and health services) and social determinants of health (social-class health gradient, early life, social exclusion, work, transport and personal behavior), some overlapping the others¹¹. Education, sustainable resources, social justice, employment and working conditions, health services, etc., depend to a large extent on the existence of legal provisions that foster and protect them through institutions with specific characteristics that become determinants of the effectiveness of the right.

⁷ Cançado Trindade, 2003.

⁸ Shany, 2014.

⁹ Amodu, 2008, p. 5.

¹⁰ Baker, 2016.

¹¹ Raphael, 2003.

From the legal perspective, it is perhaps more useful to study the factors immediately controllable by law (institutions and norms) as causes of effectiveness of a right, rather than labelling other mediate factors not directly controllable by law (e.g., early life, biology or ecosystem aspects). This approach focuses on the determinants of health not object of the public health research, specifically the institutional determinants, namely, the functioning of the regulatory institutions, their legal design, nature, attributes, and regime of accountability.

From the institutional viewpoint, effectiveness of rights requires a partnership between the authorities to implement rights in their day-to-day decision-making¹². According to the Paris Principles, the pragmatic implementation of rights precepts depends on harmonization of national legislation and regulation, through a legal guarantee for the independence of the institutions that ensure human rights implementation¹³. This independence from the government and the regulatees has an impact on the legitimacy of the regulator, because although it appears to be a mere formal attribute, it has a substantial connotation regarding its capacity to guarantee the rule enforcement.

3.1 Effectiveness of rights and time-consistent regulation

It is possible to assert that the health care regulator's aim is the effectiveness of the right to health. It is technically different to state that the last aim of the system is to guarantee health as the 'right to not to be sick', which is a legally impossible objective. Under this approach, this right may be understood as (a) to access to healthcare services; (b) to obtain from the State certain measures to protect and promote public health, environment and safety, and (c) to not to be injured by any public or private person¹⁴.

Since the regulator's last aim is to protect health and finally realizing the right to health, the next step is to delimit its timeframe of accomplishment. It requires adopting a position concerning the nature of the right, between a fundamental right in its full scope, or a social right with time and budget constraints related to an alleged programmatic content. An increasing doctrinal agreement has been reached related to the nature of the right to health

¹² Feldman, 2002.

¹³ International Conference on Cataloguing Principles, 1963.

¹⁴ Lema Añón, 2010.

as a fundamental right – although Alexy prefers to call it a ‘social fundamental right’¹⁵. It settles and overcomes the limited conception of the right as a ‘reservation of the possible’ that commits State’s activities to protect the right, to budget availability, convenience, and political opportunism¹⁶. Considering the right to health a fundamental right has important consequences because it prevents that political discretion and electoral cycles condition its legal enforceability and availability. These factors undermine the legal right status of health and as far as the ultimate end of a ‘fundamental right’ category is to displace politics from Law¹⁷, and the timeframe for its accomplishment is not associated with public policy programs or social policy budgets dependent on political discretion. Contrary to a traditional social right perspective which has forced to divide the concept of legal enforceability in justiciability and political enforceability, the fundamental right conception binds the public powers to implement the right in all legislative, executive and judicial instances through concrete measures in a reasonably brief period.

In conclusion, the effectiveness of the right to health is determined by the existence of an institutional framework and an administrative regulatory organization, bound by a time-condition and a fixed telos. If regulatory decisions are coherent with the legally fixed goals, the regulator will be ‘time-consistent’ and not regressive or incoherent with the constitutional mandate. Time-consistency represents the execution of a prior decision taken in time $t1$ in a future time $t2$, evading other apparently favorable decisions in the present. It is theoretically a ‘perfectly rational’ decision because the agent’s preferences are congruent at any point in time¹⁸ and he has the incentive to not to change his preferences.

However, when the regulator has wide discretionary powers, its preferences may change according to convenience, political opportunism, and the electoral cycle. These may lead the politician to take non-popular – but necessary – measures at the beginning of its period and popular measures at the end, which appear to be favorable to its own interests but generates sub-optimal results contrary to the previously fixed objectives. This suggests that discretion and time-consistency cannot operate together unless the regulator accepted in advance his own weakness of will when electoral cycles or the political opportunity

¹⁵ Alexy, 1997.

¹⁶ Rodríguez-Arana, 2015.

¹⁷ Ferrajoli, 2001.

¹⁸ Elster, 2014.

emerge, based on the rational choice theory. This involves an ‘imperfect rationality’ theory that posits the necessity of the regulator to restrict itself regarding all the possible alternatives leading to sub-optimal decisions, as Ulysses decided to bound himself to the ship.

The solution for the temptation to unfollow the decisions taken at $t1$ in a subsequent $t2$ has been studied under the ‘delegation theory’ in the context of the so-called ‘rise of the regulatory state’. Majone considers the relationship between time and democratic process, concluding that the regular intervals of power incentive its arbitrary use¹⁹. A short-term alternation means that the effects of successful policies will come after the next election and will not be attributed to the current politician. Discretionary powers threaten the continuity of the policies and may subvert or even remove the optimal decisions taken at $t1$ by an opponent politician in a later moment $t2$. It creates uncertainty and ill-defined political property rights affecting credibility and generating a ‘commitment problem’, because “it is extremely difficult for democratic politicians to credibly commit themselves to a long-term policy”²⁰. Kydland and Prescott have summarized the credibility problem establishing that fixed rules are preferable instead of discretion because it leads to ‘time inconsistency’²¹.

However, the establishment of fixed rules is not enough if it is not accompanied by a change of the perverse incentives, because ‘short-termism’ derived from the political cycle generates the commitment problem. As a reaction, the regulatory state introduces an alternative to increase policy credibility through the delegation of policy-making powers to non-majoritarian organizations, i.e., non-democratically elected authorities whose decisions are not dependent on the political power in a given electoral cycle.

In summary, the effective enforcement of fundamental rights is determined by the existence of fixed objectives in a corresponding term. Nevertheless, as far as politicians have a commitment problem that generates time-inconsistency, a non-majoritarian regulatory organization would reduce the uncertainty of decisions, because it is in a better position to guarantee they will be non-regressive.

¹⁹ Majone, 1994.

²⁰ Majone, 1996, p. 2.

²¹ Kydland and Prescott, 1977.

3.2 Relationship between the administrative function of regulation and effectiveness

At this point, we can affirm that fundamental rights alone do not ensure their own effective enjoyment. They cannot be seen in isolation, but they need to be supported by an institutional and organizational network guided under the same protective objectives²², supported by a regulative pillar built to influence future behaviors through rule setting, monitoring and sanctioning activities. Institutions rest primarily on the regulatory pillar by constraining and regularizing behavior through regulatory processes reflected in the establishment of rules, the inspection of its accomplishment and the adjudication of rights.

This institutional framework is constituted by a normative-prescriptive function defined by objectives, valued ends, and the means to pursue them, a rule-setting, monitoring and sanctioning function and a cultural-cognitive function of creating stimuli, response, and compliance regarding those rules. These three pillars are accompanied by a transversal element that largely conditions the success of institutions: legitimacy²³. It is defined as the social acceptability and credibility of a certain decision or entity, or a generalized perception that the actions of an entity are desirable or appropriate within some socially constructed system of norms, values, beliefs and definitions²⁴, i. e., within an institutional framework. Legitimacy is a necessary component for the stability of the organizational activities that reflects the public support to the organization. Public administration's legitimacy increases according to accountability and transparency.

From the thesis advocated by Weber, the basis of the legitimacy of a system of authority is the probability that certain command will be obeyed for rational, traditional or charismatic grounds under a minimum of voluntary submission, which requires the control of an administrative staff, it means, the regulatory organization that exerts rule-setting, monitoring and sanction. Weber adds that rational criteria require the authority to be bound by a specialized training, because "only a person who has demonstrated an adequate technical training is qualified to be a member of the administrative staff of such

²² Tomuschat, 2008.

²³ Scott, 2008.

²⁴ Suchman, 1995.

an organized group, and hence only such persons are eligible for appointment”²⁵. Thus, legitimacy is supported on the public belief that the authority has a technical qualification.

Accordingly, Weber considers ‘a matter of principle’ that the administrative staff should be completely separated from the ownership of the means of production or administration, to make the officials accountable regarding them. It means that the proprietor-regulator-supervisor tripod is not a legitimate model of public organization. It is not possible to hold an authority accountable whether it is the provider (proprietor), regulator and controller of the service at the same time.

Additionally, collegiality of bodies with rationally defined functions is important to preserve their objectivity and the absence of influences in their actions “because a monocratic position is more open to personal influence and is more easily swayed, making it more possible to influence the administration of justice and other governmental activity in favor of such powerful interests”²⁶. Thus, Weber formulates a theory of institutionalization of power under ‘a political separation of powers’ or a depersonalization of the Public Administration.

4 Towards an institutional theory of fundamental rights

C. Schmitt goes beyond Weber. Institutions are constitutional protections against the legislative, executive, or judicial suppression or distortion as far as a certain public and juridical normative ‘complex’ or a duly delimited and distinguishable organization becomes the prerequisite for the birth of an institutional guarantee. Thus, the recognition of legal rights is subject to the existence of a guarantee as objective protection derived from the inclusion of a right into the constitutional corpus²⁷. These regulations are a constitutional counterweight to the Legislator’s capacity of configuration. Accordingly, the German doctrine defines an institution as a juridical-organizational instrument of the Constitution configuring a structure to protect fundamental rights.

²⁵ Weber, 1947, p. 331.

²⁶ Ibid., p. 406.

²⁷ Parejo Alfonso, 1981.

This institutional scope is also widely developed by Häberle²⁸, who advocates a double constitutional content of fundamental rights as individual rights and institutional-objective constitutional guarantees that configure regulated and organized spheres in life according to freedom principles. He considers fundamental rights as “institutes” with both concurrent and reciprocal individual-subjective and objective-institutional aspects that enable individual and collective life. He advocates that the essence of individual and institutional aspects of rights is the set of rules that implement them, as health system is an objective expression of the right to health. The institutional aspect of fundamental rights reinforces the individual enjoyment of rights and their institutionalization through the objectified “status” of the right and the creation of procedures to protect rights. Subsequently, the theory of institution explains the effectiveness of rights through their administrative institutionalization. Finally, the status *activus processualis* inherent to every fundamental right is introduced as a procedural protection before any authority.

The institutional theory of rights is a significant element of the constitutional structure of the State. The recognition of the conflict as an inevitable element of the State leads to seek the management of it, instead of its elimination²⁹. Therefore, one of the ultimate ends of the institutional structure is the effective management of the conflict. The ontological legitimacy of the constitutional rights will be valued by people whilst the statement of principles and rights is reflected in State’s daily actions, assuring consistency in the practice of these values. This is the essence of the constitutional status that overrules uncertainty, overlooking of the fundamental rights and other constitutional norms by convenience or political influence rationales³⁰.

Consequently, the institutional framework build on the Constitution will be effective if it awakes a popular acquiescence founded on the belief of its social and legal binding force. The very cornerstone of legitimacy is the public acceptance of the substantive values of the constitution encouraged through its institutional employment and enforcement. The management of conflict implies enforcing the constitutional norms through an institutional framework, whose consistent public practice assures the gradual acceptance of the regulatory organization and the norm itself. However, the conflict is permanent and the unifying, stabilizing effects of the legal institution will always find some resistance

²⁸ Häberle, 1997.

²⁹ Waldron, 1999.

³⁰ Carolan, 2009.

and debate that must be welcomed by the institution through public interaction with dissidents³¹. Institutionalization of debate and public justification has legitimizing effects because it leads the dissent towards the institutional structures of the State. For Rawls³² the publicly reasoned application develops a sort of ‘public reason’, normative debate that mixes both publicity and rationality.

In summary, having norm-appropriate outcomes is not a measure of effectiveness, because the constitutional framework is not confined to the output achievement as an exercise of utility, but is beyond towards building the legitimacy of the institutions and organizations through a public reasoning. Finally, keeping the unifying force of the constitution in the long-term prevents politicians or private agents of having short-term interests.

5 Changing the paradigm: towards more technical decisions

5.1 Technical reasoning leads to rational deliberation, but its implementation needs democratic participation

The dialectic between technical and legal rationalities in health regulation raises a paradigm shift: the ministerial regulator is partially or totally replaced by the technical regulator. Most of the time the politician lacks the technical capacity to undertake an administrative function according to technical criteria. Therefore, the regulator increasingly relies on scientific committees who base their concepts on clinical effectiveness, scientific efficiency, or evidence-based conclusions.

The application of this type of reasoning develops a technical discretion, characterized by using scientific criteria within a minimum frame of results disputable by grade, not by reference to chance or convenience³³. This margin of appreciation is smaller, because it involves the interpretation of economic concepts offering mathematical and / or empirical

³¹ Ibid., p. 10.

³² Rawls, 2001.

³³ Desdentado, 1997.

alternatives and in the case of health sector, it includes medical concepts derived of natural science based in an empirical and scientific method founded on evidence.

Since the subject matter of regulation follows technical parameters, the assessment of the facts is based on reality judgments rather than value judgments. Medicine uses empirical, scientific, or evidential methods to apply the available evidence from clinical trials, ensuring the efficiency of the use of resources by standardizing cost-effective therapies of proven benefit. On another hand, economy gathers economic facts from the observation of social reality, which despite being non-experimental data, are phenomena increasingly treated from a probabilistic approach by statistical inference.

This tendency to seek more technical arguments in the justification of regulatory decisions is the result of the influence of technical reasoning in law and in the “rationality” of public policies, not only in the economic sense or in cost-effectiveness terms, but in objectivity as a means to avoid arbitrariness. When the regulator is legally constrained to use technical mechanisms – e.g., decisions based on clinical evidence –, law seeks to ensure optimal and measurable results to achieve the level of health proposed by the fundamental right. Thus, the nature of the regulated object determines the form and method of regulation, which subjects it to technical reasoning and transmits to law a specific way of acting.

This symbiotic relationship between technical reasoning and law makes the former dependent on the latter as a feedback structure that regulates and controls itself, which leads to seek the expertise of those who are responsible for the regulated object. However, recognizing the existence of a fundamental right in the basis of the health sector leads democracy to play a major role that requires incorporating deliberation and social participation to the decision-making procedure. Otherwise, decisions would lack democratic legitimacy and even if they are based on rational-technical argumentation, they would not be socially embedded neither accepted by the majority.

Hence, technical reasoning – understood as the application of knowledge and methods concerning science – is one of the inputs of the argumentation of regulatory decisions, which also gives them legitimacy, while the implementation of these measures requires the citizen participation to achieve its successful incorporation and acceptance. As a consequence, democratic rational deliberation is the scenario in which technical reasoning and law converge. However, deliberation reaches decisions compatible with

democracy and technical reasoning when there is a guarantor who knows both fields and is not directly influenced by actors either side, preventing to ignore the democratic consensus or rational-technical justifications because of certain interests of groups. This would be an arbitrator and guarantor whose function would be to moderate the discussion, surveil and decide based on the content of deliberation as a neutral party.

However, the regulatory agency not only serves the purpose of reconciling both positions, but also to consider aspects of equitable and social justice distribution in addition to technical reasoning, to use deliberation beyond a mere instrument to reach an agreement. As a result, the regulatory exercise is situated between technical effectiveness and social equity, which could label it as a regulation for the effectiveness and protection of the right, considering the nature of the regulated object and the agents concurring to this purpose.

6 Conclusion

After the explained notions, effectiveness of the right to health can be understood as (i) the achievement of a progressively better health based on a minimum (ii) in a reasonable brief and time consistent period of employment and enforcing of the right (iii) under a public reasoning in terms of deliberation and accountability.

Therefore, the effectiveness assessment will depend on the achievement of the objectives pursued by the institutional framework of the right to health can be attributed to health regulator's independence and accountability. The object of analysis is the organization that develops and executes the institution of the right to health through regulations to become health into a subjective and legal right, under the framework and aims (telos) designed by Constitution and Law.

Accordingly, the concept of effectiveness is based in a goal-based approach or a rational system measured by reference to desired outcomes that the institution of the right to health seeks, and the timeframe in which it is reasonable to meet these goals. It means, the indicators to assess effectiveness are aim fulfillment and a timeframe.

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