

Limits of the Substantive Scope of the Minister of Health's Decree on Accreditation Organizations: Delegation of Authority and Legality of Sanctions

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Abstract

Minister of Health Decree Number HK.01.07/MENKES/321/2026 designates health accreditation organizing institutions (LPA) while also containing obligations, supervision provisions, and four types of administrative sanctions. This combination raises the question of where an administrative designation ends and where norm-making that belongs in a regulation begins. Using normative juridical research with statutory, conceptual, and limited historical approaches, this article examines the legal character of the decree, its conformity with the delegation in Article 895 of Government Regulation Number 28 of 2024 and Law Number 17 of 2023, and its implications for legal certainty. The analysis finds that the core of the decree is an administrative designation grounded in Article 178 paragraph (5) of the Health Law and Article 895 paragraph (2) of the Government Regulation, whereas several obligations and sanctions require a firmer normative basis. Revocation of a designation can be traced to Minister of Health Regulations 12 of 2020 and 34 of 2022, but the basis for oral warnings, written warnings, and temporary suspension must be identified separately because Article 897 addresses health facilities, not LPAs. The article recommends an audit of legal bases, general provisions placed in a Ministerial Regulation, and sanction procedures that guarantee clarification and proportionality.

Keywords: *Administrative Sanctions, Delegation of Regulation, Health Accreditation, Legal Certainty, Ministerial Decree.*



A. INTRODUCTION

The accreditation of healthcare facilities has acquired a more explicit legal status following the enactment of Law Number 17 of 2023 on Health (Law 17/2023), which positions accreditation as part of the external assessment of service quality. Article 178 links accreditation to compliance with quality standards, guidance, service quality, and governance that is responsive, transparent, and accountable. Recognition of service quality through accreditation cannot be understood merely as a matter of technical assessment; the assessment results have implications for public trust, the standing of healthcare facilities, and the government's obligation to safeguard service quality. This legal framework requires clarity regarding who is authorized to conduct surveys, who establishes the standards, and how corrective measures are implemented when accreditation providers deviate from their responsibilities. Accordingly, the authority to regulate Accreditation Organizations (AOs) must be understood as part of the governance of public administration in the healthcare sector (Law 17/2023, Article 178 paragraphs (1)–(6)).

Minister of Health Decree Number HK.01.07/MENKES/321/2026 (Decree 321/2026), issued on 22 April 2026, provides a concrete basis for examining this legal issue. Operative Clause FIRST designates the accreditation organizations listed in its annexes, which are categorized according to the types of healthcare facilities they serve. The annexes classify accreditation providers for hospitals, primary clinics, specialist clinics, community health centers, laboratories, and blood management units. This designation identifies the recipients of a specific legal status and therefore initially exhibits the characteristics of an administrative decision. However, the decree does not merely list the organizations. Operative Clause SECOND sets out a broad range of obligations, Operative Clause THIRD governs guidance and supervision, while Operative Clauses FOURTH and FIFTH specify the grounds for and types of administrative sanctions. This combination warrants an examination of the boundary between the direct legal consequences of a designation and the establishment of operational norms that should properly be prescribed through regulations (Decree 321/2026, Operative Clauses FIRST, SECOND, and SEVENTH).

The obligations under Operative Clause SECOND include providing systems and resources, training surveyors, applying accreditation standards, complying with technical guidelines and survey instruments, implementing applicable tariffs, submitting reports, and achieving performance indicators. Another provision requires organizations to obtain accreditation from a national or international accreditation body periodically, no later than five years after their initial designation. These provisions are not uniform in nature. Some may be regarded as obligations inherent in the status of a designated organization, while others establish implementation criteria that require further definitions, benchmarks, and verification mechanisms. Measurable obligations may provide the government with a basis for conducting evaluations; however, such evaluations must remain grounded in procedures and standards that are accessible and ascertainable to the organizations being assessed (Decree 321/2026, Operative Clause SECOND letters a–l).

The relevant sectoral legal framework also establishes a clear division of authority. Article 178 paragraph (5) of the Health Law permits accreditation to be conducted by the Minister or by an organization designated by the Minister. Government Regulation Number 28 of 2024 (GR 28/2024) subsequently reaffirms this designation authority in Article 895 paragraph (2), while paragraph (6) of the same article requires further provisions concerning healthcare facility accreditation to be regulated by a Ministerial Regulation. A careful interpretation must distinguish between the authority to select or designate a particular organization and the authority to establish rules governing the implementation of accreditation. These two powers may be exercised by the same official without necessarily being embodied in the same type of legal instrument. A delegation provision does not, in itself, eliminate the scope for administrative decisions; rather, the relevant question is whether the decree exceeds the substantive limits of matters that should first be regulated through a regulatory instrument (GR 28/2024, Article 895 paragraphs (1)–(6)).

Minister of Health Regulation Number 12 of 2020 (Ministerial Regulation 12/2020) provides a legal basis for revoking the designation of independent hospital accreditation organizations when the designation requirements or their obligations are not fulfilled. Article 32 paragraph (3) of Minister of Health Regulation Number 34 of 2022 (Ministerial Regulation 34/2022) also allows the revocation of accreditation organization designations on specified grounds. The existence of these two provisions indicates that the authority to revoke a designation did not first emerge under Decree 321/2026. The issues requiring examination are whether the legal basis for revocation also extends to oral warnings, written warnings, and temporary suspension; whether the elements of each violation are proportionate to the corresponding sanction; and whether the procedures for imposing such sanctions are clearly established and expressly referenced. The analysis must distinguish the legal basis for imposing sanctions from the appropriateness of placing them within a designation decree (Ministerial Regulation 12/2020, Article 20; Ministerial Regulation 34/2022, Article 32).

Previous legal scholarship has examined the accountability of independent organizations responsible for hospital accreditation assessments. Nabella, Asmuni, and Pramono associate the regulation of accreditation organizations with administrative consequences, including the revocation of designation when assessment functions are not performed in accordance with applicable requirements. Their study helps explain the relationship between quality oversight and an organization's legal status, although its regulatory subject differs from that of Decree 321/2026, which was issued subsequently. Al-Fatih and Muluk conceptually distinguish among legal instruments in the form of administrative decisions, regulations, and policy rules, while Al-Fatih and other authors criticize the lack of clarity in the structuring of delegated regulations. Taken together, these three strands of literature raise a more specific question: how should the criteria for distinguishing between legal instruments be applied to the obligations and sanctions attached to the designation of accreditation organizations? (Nabella et al., 2024; Al-Fatih & Muluk, 2023; Al-Fatih et al., 2023).

The legal issues under examination are formulated into three research questions. First, what is the legal nature and status of Decree 321/2026 when distinguished between a government administrative decision and a legislative regulation? Second, are the substantive provisions concerning obligations, administrative sanctions, and referenced technical guidelines under the decree consistent with the limits of authority and delegated rulemaking established by Law 17/2023 and GR 28/2024? Third, how does the relationship between Decree 321/2026 and the prevailing accreditation regulations affect legal certainty for accreditation organizations and healthcare facilities, and what forms of regulatory improvement can be justified on legal grounds?

B. METHOD

The study adopts a normative juridical approach, treating statutory and regulatory texts, administrative decisions, and legal literature as the basis for legal

reasoning. The statutory approach is employed to trace the sources of authority and examine the vertical and horizontal relationships among Law 17/2023, GR 28/2024, provisions governing the formation of legislation, the Government Administration Law, several Minister of Health Regulations, and Decree 321/2026. A conceptual approach is necessary to distinguish between general and abstract norms, concrete and individual determinations, policy rules, delegated rulemaking, and the legality of sanctions. A historical approach is applied to a limited extent to examine changes in the legal basis for the designation of Accreditation Organizations (AOs) and the continuity of previous regulations following the entry into force of the new health regulatory regime. The use of these multiple approaches does not eliminate the need to interpret each provision in accordance with its wording and the scope of its legally defined subjects (Satory et al., 2024).

The analysis employs grammatical interpretation to examine the wording of obligations and sanctions, systematic interpretation to situate them within the broader regulatory framework, and conceptual reasoning to determine the most appropriate form of legal instrument. Each operative clause is assessed in terms of its intended subjects, the abstract or concrete nature of its directives, the repeatability of its application, the source of authority, the implementation procedures, and the legal consequences for the parties subject to the measures. Prescriptive conclusions are formulated after identifying provisions that already have a sufficient normative basis and those requiring further clarification. The assessment does not stop at the formal validity of the document, since the legality of sanctions also requires certainty regarding the relevant violations, the competent authority, the sequence of enforcement measures, the opportunity to remedy non-compliance, and access to legal protection (Satory et al., 2024).

C. RESULT AND DISCUSSION

1. Legal Status and Nature of the Substantive Content of Decree 321/2026

The legal status of a government legal instrument cannot be determined solely by the hierarchical position of the official who issues it. A minister may issue regulations governing the implementation of governmental affairs, but may also issue decisions applying legal norms to specific subjects. These two forms of action have different legal bases, binding effects, and legal consequences. The hierarchy established under Article 7 of Law Number 12 of 2011 on the Formation of Laws and Regulations (Law 12/2011) does not list a Ministerial Decree as a separate level of legislation; Article 8, instead, recognizes regulations issued by ministers pursuant to mandates from higher-level norms or valid legal authority. These two articles must be interpreted without oversimplifying the issue by assuming that every Ministerial Decree automatically ranks below or at the same level as a Ministerial Regulation. The appropriate comparison concerns the normative function of the legal instrument under examination and the legal authority underlying its issuance (Ubaiyana & Fitriah, 2021; Pratama et al., 2022).

The theory of hierarchical norms helps explain why implementing regulations must derive their authority from higher-level norms. Each level of norm-making is constrained by the authority and substantive content established at the level above it; therefore, technical regulations must not implicitly alter the substantive elements of an obligation. Hans Kelsen's framework and Hans Nawiasky's development of the structure of legal norms are useful for explaining the relationship between validity and normative hierarchy, rather than serving as automatic formulas for classifying all ministerial legal instruments within a single hierarchical level. The assessment of Decree 321/2026 still requires an examination of its specific substantive provisions, since a norm implemented through a decision may take the form of an apparently general directive while actually being addressed to a specific group of designated recipients. This analytical approach ensures that hierarchy is not detached from the characteristics of the subjects and objects of administrative action (Purba et al., 2022).

Operative Clause FIRST has the characteristics most closely associated with an administrative determination. The government selects the organizations identified in the annexes according to the types of healthcare facilities they are authorized to serve. The designated organizations are identifiable, while the object of the decision is the conferment of status as accreditation providers. Although multiple organizations may receive the designation, the instrument does not thereby become a general regulation, provided that the identities of the organizations and the scope of their duties remain individually defined. A collective decision naming several recipients may still establish concrete legal consequences for each individual subject. This classification differs from a Ministerial Regulation, which establishes requirements, procedures, and criteria applicable to any organization seeking to enter the accreditation system (Al-Fatih & Muluk, 2023).

Operative Clause SECOND is more difficult to classify in a single category. The phrase "accreditation organizations as referred to in Operative Clause FIRST" restricts the subjects of the obligations to organizations that have already been designated. This restriction supports the view that the list of obligations constitutes additional conditions attached to administrative status. Nevertheless, several obligations do more than reaffirm requirements already fully established in higher-level regulations. Provisions concerning performance indicator targets, technical guidelines, and accreditation of the organizations themselves within five years contain regulatory elements that require examination of their normative basis. Restricting the recipients does not automatically justify the introduction of new substantive requirements merely because they are placed after the designation clause (Decree 321/2026, Operative Clause SECOND).

The legal consequences under Operative Clause FIFTH most clearly demonstrate the distinction between an administrative designation and rules governing the imposition of sanctions. Revocation of a designation is essentially a subsequent administrative action affecting a status that was previously granted. Warnings and temporary suspension, by contrast, may function as enforcement measures for obligations while the legal relationship remains in effect. Because these

measures differ in nature, each requires a legal basis and procedural safeguards that are not necessarily identical. The doctrine of administrative sanctions requires clarity regarding corrective objectives, the nature of the restriction, and the standards governing the appropriateness of government action. A decision may reaffirm the consequences of violations already established under existing legal norms, but it should not serve as the sole instrument through which entirely new legal consequences are introduced for the first time (Kartina et al., 2024).

The mixed nature of the decree's substantive content can be addressed through a differentiated assessment. The designation clause may be considered valid if it is based on Article 895 paragraph (2) of Government Regulation Number 28 of 2024 (GR 28/2024) and satisfies the requirements of administrative law. The clauses concerning obligations and sanctions must still be assessed against the existence of an underlying legal norm and the nature of the obligations imposed. Examining the individual provisions separately is more precise than reaching an overall conclusion that treats the entire document as either a regulation or a purely administrative determination. This differentiated approach is also useful for regulatory reform: the designation elements may be retained, while provisions requiring a clearer normative basis can be transferred to, or reformulated through, the appropriate legal instrument. The quality of administrative lawmaking is measured by the suitability of each legal form for its intended function, not by the number of documents issued (Law 12/2011, as amended by Law 15/2019 and Law 13/2022, Articles 5, 7, and 8; Rokilah & Sulasno, 2021).

2. Compliance with Delegated Rulemaking and the Principle of Legality of Administrative Sanctions against Accreditation Organizations

The Minister's authority to designate accreditation organizations already has a legal basis at two regulatory levels. Article 178 paragraph (5) of Law 17/2023 allows accreditation to be conducted by the Minister or by organizations designated by the Minister. Article 895 paragraph (2) of GR 28/2024 reiterates this arrangement as an implementing provision. The designation authority is concrete in nature because its purpose is to select organizations authorized to perform specified functions.

However, the existence of this authority does not resolve the extent to which the Minister may impose additional substantive obligations and establish various types of sanctions through a designation instrument. The answer requires a parallel reading of Article 895 paragraph (6), which separately mandates that further provisions concerning the accreditation of healthcare facilities be stipulated in a Ministerial Regulation (GR 28/2024, Article 895). The delegation of rulemaking under Article 895 paragraph (6) of GR 28/2024 expressly identifies the required type of legal instrument: a Ministerial Regulation. This wording reflects the government's choice to place general provisions governing the implementation of accreditation within a ministerial regulatory instrument. A Ministerial Regulation is necessary when the subject matter applies to an open category of organizations, establishes eligibility requirements, prescribes recurring operational procedures, or determines rights and obligations in general terms. A Ministerial Decree remains necessary to apply those

criteria to organizations that successfully obtain designation. A problem arises when requirements or types of sanctions that should have been established as general rules can only be found in the annexes or operative clauses of an individual designation decision. This risk must be examined for each provision rather than presumed to affect the entire contents of the decree (Al-Fatih et al., 2023).

Minister of Health Regulation Number 12 of 2020 (Ministerial Regulation 12/2020) is a relevant part of the regulatory framework for hospitals. The requirements for accreditation organizations and their obligations are set out in Articles 5 and 6, while Article 20 authorizes the Minister to revoke a designation if those requirements or obligations are not fulfilled. These provisions demonstrate a direct relationship between general norms governing requirements and administrative decisions concerning an organization's status. The legal basis for revocation does not need to be recreated in a Ministerial Decree because the designation decision can, in principle, refer to existing legal norms. Revocation as a subsequent administrative measure is justified only after it has been established that the relevant statutory conditions have been satisfied. Accreditation assessments must not depend on a finding of a violation that is merely asserted unilaterally without the support of an examination procedure (Ministerial Regulation 12/2020, Articles 5, 6, and 20).

Minister of Health Regulation Number 34 of 2022 (Ministerial Regulation 34/2022) provides rules for other types of healthcare facilities, with an emphasis on guidance and supervision of accreditation organizations. Article 32 paragraph (3) links revocation of a designation to circumstances in which an organization no longer meets the requirements, is unable to perform its duties, neglects its obligations, lacks credibility, or engages in fraud. These provisions are substantively similar to the grounds specified in Operative Clause FOURTH of Decree 321/2026. This similarity is important because it indicates that a designation clause may restate or operationalize provisions that already exist. However, the legal basis for each sanction cannot be established merely by treating the regulatory scope for hospitals and other healthcare facilities as identical; the scope of application of each Ministerial Regulation must be examined. The authority to revoke a designation must be linked to the type of organization subject to the relevant provision (Ministerial Regulation 34/2022, Articles 30–32).

The principal issue with Operative Clause FIFTH is that it establishes four types of sanctions with different degrees of restriction. The legal basis for revocation of a designation can be traced, with relative clarity, to the earlier regulations referenced in the legal considerations of the decree. Oral warnings, written warnings, and temporary suspension do not automatically acquire an identical legal basis simply because they appear alongside revocation in the same list. Each requires a separate examination of the provisions that specifically authorize its application to accreditation organizations. The closing phrase, “in accordance with the provisions of laws and regulations,” constitutes an open-ended reference rather than a substitute for identifying the rules governing the types of sanctions and their procedures. Such a reference may legitimately serve as a reminder of the obligation to comply with the

law, but it is inadequate if it is the sole link between restrictive sanctions imposed on an organization's activities and the legal norms authorizing them (Decree 321/2026, Operative Clauses FOURTH and FIFTH).

Temporary suspension of activities is the most sensitive sanction for the continuity of accreditation services, apart from revocation of designation. Such a restriction may halt scheduled surveys and affect healthcare facilities that are in the process of fulfilling their accreditation obligations. The duration of the suspension, the conditions for resuming activities, and the treatment of ongoing assignments are not fully clarified merely by naming the sanction in Operative Clause FIFTH. The absence of detailed provisions in the decree does not necessarily mean that the government will act arbitrarily; rather, it highlights the need to identify the applicable procedural basis in the relevant legal instruments. The government should provide written reasons linking the severity of the violation to the duration of the restriction. Quality supervision intended to protect patients must also take into account the consequences for healthcare facilities' access to valid accreditation assessments (Constitution of the Republic of Indonesia of 1945, Articles 1 paragraph (3), 28D paragraph (1), and 28H paragraph (1)).

The obligation for accreditation organizations themselves to obtain accreditation no later than five years after their initial designation presents another regulatory issue. This provision establishes a calculable time limit and requires assessment standards for the national or international accreditation body concerned. The phrase "from the date of initial designation" raises questions concerning organizations designated before 2026 and those whose status is renewed through a new decree. The five-year period must be interpreted consistently to prevent different deadlines from being applied to organizations designated under earlier and later decisions. An obligation that affects the continued status of an organization should be accompanied by transitional and evidentiary mechanisms that are known from the outset. If this provision is indeed a general condition for operating as an accreditation organization, its normative basis should be clearly established in a regulatory instrument applicable to all accreditation organizations (Decree 321/2026, Operative Clause SECOND).

The designation of technical guidelines and survey instruments by two director generals follows the division of healthcare facility categories established in the decree. From an organizational perspective, this separation may facilitate the use of standards tailored to primary and advanced healthcare services. Nevertheless, the legal status of these technical documents must be assessed in light of the mandate or authority held by the officials issuing them. Guidelines governing reporting formats, scheduling methods, verification procedures, and observation instruments generally fall within the operational domain. Provisions that expand the requirements for becoming an accreditation organization, create new types of sanctions, or extend the categories of parties subject to particular prohibitions enter the domain of substantive rulemaking. The label "technical guidelines" cannot be used to circumvent restrictions on the substantive content of delegated regulations. The decisive distinction lies in the legal

consequences for external parties, not in whether the provisions appear in an annex or in the complexity of the document (Director General of Health Services Decree HK.02.02/D/39212/2024).

The general principles of good governance strengthen the legality assessment once the source of authority has been established. Legal certainty requires norms whose consequences can be anticipated by the organizations concerned. The duty of care requires officials to examine the evidence before determining that a violation has occurred. Impartiality requires equal treatment of organizations in comparable circumstances. The prohibition against abuse of authority ensures that sanctions are not used for purposes unrelated to improving the quality and safety of healthcare services. Transparency enables interested parties to understand the reasons for a decision. Each principle has an operational role and need not be presented as an abstract list if it is not connected to a concrete process of supervision or sanctioning (Pamuji et al., 2023).

The general reference to “the provisions of laws and regulations” appears at the end of Operative Clause FIFTH. This drafting technique allows the issuer to avoid reproducing existing rules, but it creates uncertainty if readers cannot readily identify the legal basis for each sanction. Revocation of designation has a relatively clear reference in Ministerial Regulations 12/2020 and 34/2022. Oral warnings, written warnings, and temporary suspension require separate identification of the provisions applicable to accreditation organizations. If a detailed legal basis is not available, this uncertainty should be treated as a need for further regulation rather than resolved through an assumed analogy with sanctions imposed on healthcare facilities. The principle of clarity in drafting under the Law on the Formation of Laws and Regulations requires a structure that enables affected parties to understand the consequences of compliance and violations (Decree 321/2026, Operative Clauses FOURTH and FIFTH).

Article 897 of GR 28/2024 cannot automatically serve as the legal basis for all sanctions under Operative Clause FIFTH. The subjects sanctioned under that provision are healthcare facilities that fail to fulfil their quality-improvement obligations, whereas the object of Decree 321/2026 is accreditation organizations acting as external assessors. These two categories of subjects are closely related within the quality assurance system, but they occupy different legal positions and perform different legal functions. Imposing administrative sanctions by analogy in a manner that expands the subjects liable for violations without an appropriate normative basis risks exceeding the limits of government authority. The legality assessment must establish that the cited provision actually applies to the organization subject to the measure, rather than merely sharing a general theme concerning accreditation or service quality (GR 28/2024, Article 897).

3. Implications for Legal Certainty and Proposed Regulatory Improvements for Accreditation Organizations

The relationship between earlier and newer regulations must be assessed in accordance with transitional provisions, rather than on the assumption that older regulations automatically cease to have legal effect. Article 453 of Law 17/2023 preserves implementing regulations issued under previous legislation insofar as they do not conflict with the new legal framework. This principle provides a basis for examining the continued applicability of Ministerial Regulations 12/2020 and 34/2022, but it does not eliminate the obligation to assess each provision against the Health Law and its implementing government regulation. Provisions concerning organizational requirements, obligations, accreditation procedures, and revocation of designation may remain applicable if they do not conflict with higher-level norms. Differences in the dates of issuance alone are insufficient to establish a normative conflict; the subjects, scope, directives, and legal consequences governed by the respective provisions must be examined (Law 17/2023, Article 453).

Minister of Health Regulation Number 6 of 2026 (Ministerial Regulation 6/2026) provides additional context for hospital governance following the issuance of Decree 321/2026. Article 69 retains accreditation as one of the mechanisms for external quality improvement, but adopts a general formulation directing its implementation to the applicable laws and regulations. This provision does not, by itself, revoke all technical provisions concerning hospital accreditation under Ministerial Regulation 12/2020. An assessment of the relationship between regulations must establish whether a particular provision governs accreditation organizations, healthcare facilities undergoing accreditation, or hospital service standards. These three areas are functionally interconnected but have different regulatory subjects. Conflating their scopes prematurely may lead to the conclusion that the regulations conflict when, in fact, each addresses a different stage or subject (Ministerial Regulation 6/2026, Article 69).

The revocation of Minister of Health Decree Number HK.01.07/MENKES/62/2026 (Decree 62/2026) by Decree 321/2026 constitutes a change to an administrative designation decision, not the revocation of the entire accreditation regulatory system. Operative Clause SEVENTH of the new decree specifically identifies the previous instrument and declares it no longer applicable. This relationship demonstrates that the list of accreditation organizations is established through a decision that can be updated when the scope of designated facilities or organizations changes. The latest decree serves as the reference point for determining organizational status from its effective date, namely the date of designation on 22 April 2026. Readers must distinguish changes to the list of organizations from changes to the substantive requirements applicable to every accreditation organization. If both types of changes are incorporated into the same document without sufficient explanation, the risk of misunderstanding when a particular obligation becomes binding will increase (Decree 62/2026; Decree 321/2026, Operative Clause SEVENTH).

The principle of legal certainty requires more than merely being able to locate a legal instrument on an official website. Obligations must be sufficiently clear for the parties subject to them to understand, while the consequences of violations must be foreseeable based on legal norms available before the relevant action is taken. Accreditation organizations need clarity regarding reporting documents, performance indicators, examination procedures, and criteria for successfully remedying deficiencies. Healthcare facilities need clarity regarding which organizations are authorized to conduct surveys, how temporary suspension affects accreditation schedules, and whether survey recommendations already issued remain valid. Certainty for both groups does not require eliminating the government's professional discretion, but it does require that such discretion be constrained by traceable criteria and procedures (Syaefuddin, 2024).

Legal certainty for healthcare facilities must be assessed separately from legal certainty for accreditation organizations. Hospitals or community health centers that have undergone surveys need clarity on whether the temporary suspension of an accreditation organization's activities affects the validity of surveys conducted before the sanction was imposed. Facilities that have not yet received a survey schedule require a mechanism for rescheduling their assessments so that their external quality-assessment obligations can still be fulfilled. A designation decision containing a list of organizations can serve as an initial source of information, but it is insufficient to regulate all subsequent consequences when an organization is no longer authorized to operate. This issue is directly related to the objective of Article 178 of Law 17/2023, which emphasizes continuous quality improvement. A sanctions system for external quality assessors should be designed without undermining the certainty of accreditation processes for facilities that have not participated in any violation (Decree 321/2026, Operative Clauses FOURTH and FIFTH).

The adoption of a dedicated Ministerial Regulation on accreditation organizations should be considered if the provisions currently distributed across several Ministerial Regulations make it difficult to obtain a coherent understanding of organizational requirements, obligations, supervision, and sanctions. A dedicated instrument could consolidate the definition of accreditation organizations, designation status, the division of supervisory responsibilities, the classification of violations, the types of sanctions, and the consequences of suspension or revocation for ongoing accreditation processes. Its preparation must remain consistent with GR 28/2024 and avoid duplicative provisions that conflict with sector-specific regulations. However, adopting a new instrument is not the only available option. Amending existing accreditation-related Ministerial Regulations may be more appropriate if the substantive framework is already in place and only certain provisions require alignment. The choice should be based on the extent of the regulatory gaps that have actually been identified (Ministerial Regulation 34/2022, Articles 30–32).

The formulation of sanction procedures requires at least five interconnected components. The government must document and verify findings, notify the organization of the alleged violation, receive its clarification and supporting evidence,

select a measure proportionate to the circumstances, and issue a decision stating the reasons and explaining how legal remedies may be pursued. These components do not necessarily require lengthy procedures for every violation, but any exceptions must be expressly established. Revocation, as the most severe sanction, requires closer examination of whether the objective of protecting service quality could still be achieved through a less restrictive measure that does not terminate the organization's status. Establishing such procedures strengthens the legitimacy of supervisory authorities while reducing the risk of disputes arising from unclear reasoning or administrative negligence (Sulistiyowati, 2026).

The most legally defensible reconstruction is to preserve the function of the Ministerial Decree as an instrument designating accreditation organizations while strengthening the normative framework at the Ministerial Regulation level. Obligations that already have a legal basis may be referenced concisely in the decree, whereas provisions that introduce genuinely new requirements or expand the range of sanctions must be aligned with the delegation under GR 28/2024. The classification of violations, examination procedures, imposition of sanctions, and transitional arrangements should be set out in a form that accreditation organizations and healthcare facilities can readily access. These changes may be implemented through a new regulation or amendments to existing regulations after examining their scope and potential conflicts. The central concern is not the renaming of legal documents, but ensuring that the appropriate legal instruments are used to establish valid and foreseeable legal consequences (Decree 321/2026, Operative Clauses FOURTH and FIFTH).

D. CONCLUSION

Decree 321/2026 has a mixed character, but its core function is that of an administrative determination because Operative Clause FIRST designates specific accreditation organizations on the basis of Article 178 paragraph (5) of Law 17/2023 and Article 895 paragraph (2) of GR 28/2024. The inclusion of obligations, grounds for violations, and sanctions in other operative clauses does not automatically transform the entire decree into a legislative regulation. A differentiated examination indicates that the legal basis for revocation of designation can be traced to Ministerial Regulations 12/2020 and 34/2022, whereas oral warnings, written warnings, and temporary suspension require separately identified legal bases applicable to accreditation organizations, because Article 897 of GR 28/2024 applies only to healthcare facilities. Obligations introducing substantive requirements or new types of sanctions should be regulated through a Ministerial Regulation, as directed by Article 895 paragraph (6) of GR 28/2024. Furthermore, earlier accreditation regulations cannot be considered conflicting merely because they were issued earlier, since Article 453 of Law 17/2023 preserves them insofar as they do not conflict with the new legal framework. The Ministry of Health is advised to audit the legal basis for each obligation and sanction; establish general provisions—including definitions of violations, examination procedures, the right to provide clarification, time limits for

temporary suspension, and the treatment of ongoing accreditation processes—through a new Ministerial Regulation or amendments to existing Ministerial Regulations; and limit the Ministerial Decree to identifying accreditation organizations and defining their scope of authority, accompanied by orderly updates to their designation status.

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