
CONSOLIDATED LEGISLATION

Royal Decree 969/2025, of 28 October, establishing the criteria defining the irreversible and highly complex care conditions that fall within the scope of Law 3/2024, of 30 October, to improve the quality of life of people with Amyotrophic Lateral Sclerosis and other highly complex and irreversible diseases or conditions.

I

On 30 October 2024, Law 3/2024, for improving the quality of life of persons with Amyotrophic Lateral Sclerosis and other diseases or conditions of high complexity and irreversible course (hereinafter, ALS), was enacted. This law resulted from the efforts of individuals affected by ALS and the organizations representing them, as well as from the consensus of the various parliamentary groups. Its primary objective is to ensure an enhanced quality of life for persons with diseases or conditions of high complexity and irreversible course, by accelerating the administrative procedures required for the recognition of disability and dependency, and by promoting integrated care between social and healthcare systems.

Article 2 of Law 3/2024, of 30 October, establishes its scope of application, covering individuals diagnosed with ALS and those suffering from other irreversible and highly complex neurological diseases, provided that the following criteria are met (as defined in paragraph two of the Article):

- a) The condition is irreversible and significantly reduces life expectancy.
- b) There has been no meaningful response to treatment, or no therapeutic alternatives exist that would improve the individual's functional status or prognosis.
- c) The individual requires complex social and healthcare support, primarily in a home setting, with significant impact on their immediate environment.
- d) The condition progresses rapidly, necessitating accelerated administrative procedures for the assessment and recognition of disability or dependency.

Paragraph three of Article 2 allows the law to apply to other non-neurological diseases or conditions that meet all of the above criteria in their progression.

Paragraph four specifies that the precise criteria described above will be defined in accordance with Final Provision Seven of Law 3/2024, of 30 October.

This Final Provision Seven of Law 3/2024, of 30 October, empowers the Government to adopt a regulation establishing these criteria and including an annex listing the diseases and conditions to which this law applies.

II

On this basis, the purpose of this Royal Decree is to define the general and operational criteria that diseases and conditions of high complexity and irreversible course must meet in order to fall within the scope of Law 3/2024 of 30 October. The operational criteria aim to facilitate the identification of diseases and conditions that require the acceleration of administrative procedures due to the clinical course of the pathology itself, as the usual procedural timeframes could result in inadequate protection for affected persons.

The definition of these criteria is intended to enable public administrations to determine situations that require expedited action to prevent such gaps in protection. This objective must be pursued within the framework established by Law 39/2006 of 14 December, on the Promotion of Personal Autonomy and Care for Persons in a Situation of Dependency, utilizing existing mechanisms to provide greater security to potential beneficiaries, while adapting to the provisions of Law 3/2024, of 30 October.

As previously noted, the criteria set out in Article 2 of Law 3/2024, of 30 October, consider a series of clinical situations and social and healthcare needs that must be met collectively to fall within the scope of the law. Final Provision Seven of the law refers to the creation of a list of diseases and conditions to which the provisions of the law shall apply. However, the requirement that all the criteria of Article 2 be met simultaneously complicates, on the one hand, the possibility of establishing a list of diseases and conditions that automatically satisfy the criteria without assessment by a healthcare professional. The natural history and clinical course of diseases are dynamic processes which, depending on the timing of diagnosis and individual characteristics of the patient, can result in clinical severity that varies from case to case.

On the other hand, defining a closed list of diseases to establish the scope of application, without basing it on the fulfillment of specific criteria, could exclude diseases and conditions that, although not included in the list, might meet the criteria. This could generate situations of inadequate protection for affected persons and undermine the objectives of Law 3/2024, of 30 October, in seeking to

improve the quality of life of persons with diseases and conditions of high complexity and irreversible course other than ALS.

For all these reasons, this Royal Decree establishes a set of operational criteria that, beyond closed classifications of diseases, allow public administrations to identify situations of vulnerability that require rapid assessment and to prevent situations of inadequate protection in urgent cases. These criteria must be met, in accordance with the provisions of the Royal Decree, for a person to be considered as potentially falling within the scope of subjective application of Law 3/2024 of 30 October. The verification of the criteria may be carried out for any person suffering from a disease or condition of high complexity and irreversible course when there is suspicion that these criteria may apply. Therefore, the list of diseases included in the annex is indicative and consists of conditions in which there is a high probability of meeting the criteria set out in the Royal Decree, although it is specified that an assessment must be carried out to verify the degree of fulfillment of these criteria.

The Royal Decree is composed of an explanatory part and a dispositive part, divided into three articles, one additional provision, three final provisions, and three annexes.

Article 1 sets out the purpose of this Royal Decree, which is to establish the criteria contained in Article 2 of Law 3/2024, of 30 October, to define the scope of application of that law. Article 2 contains the general and operational definitions of the criteria that diseases and conditions of high complexity and irreversible course must meet. Article 3 establishes the procedure for requesting recognition that the criteria defined in Article 2 are met. The sole additional provision indicates that Annex I of the Royal Decree contains an indicative list of diseases and conditions of high complexity that, due to their clinical characteristics, are likely to meet the operational criteria and therefore may require a comprehensive assessment, without prejudice to the application of these criteria to other diseases or conditions not included in the list. Annex II contains a verification questionnaire for the operational criteria defined in the Royal Decree, to be used when assessing the degree of fulfillment of these criteria. Finally, Annex III provides the specific model application for requesting recognition that the disease or condition a person suffers from meets the operational criteria of high complexity and irreversible course.

III

The royal decree complies with the principles of good regulation contained in Article 129 of Law 39/2015, of October 1, on the Common Administrative

Procedure of Public Administrations: the principles of necessity, effectiveness, proportionality, legal certainty, transparency, and efficiency. The draft serves the general interest by specifying the criteria that define the scope of application of Law 3/2024, of 30 October, which will ensure the development of the rights recognized in that law. The regulation is consistent with the principle of proportionality, as it contains only the provisions essential to achieving the aforementioned objectives. Likewise, it complies with the principle of legal certainty, being coherent with the rest of the legal system, and establishing a stable, integrated, and clear regulatory framework. The principles of necessity and effectiveness are demonstrated insofar as the regulation is the most appropriate instrument to achieve the intended goals, in accordance with the provisions of Law 3/2024, of 30 October, enabling the establishment of criteria defining the scope of application of the law.

During the drafting process of this royal decree, consultations were held with entities including the autonomous communities, the cities of Ceuta and Melilla, and the Spanish Federation of Municipalities and Provinces, as well as the Interterritorial Council of the National Health System. Additionally, a prior public consultation and the corresponding public hearing and information procedures were carried out, in compliance with the principle of transparency, with the objectives pursued by this royal decree also set out in the preamble. Finally, in accordance with the principle of efficiency, the regulation introduces a specific administrative procedure to recognize compliance with the operational criteria regulated in Article 2 of Law 3/2024, of 30 October.

The royal decree is issued under the provisions of paragraph 16 of Article 149.1 of the Spanish Constitution, which grants the State authority over the “basis and general coordination of health matters.”

Furthermore, based on the above, this royal decree is issued pursuant to the regulatory authority set out in the seventh final provision of Law 3/2024, of 30 October, empowering the Government to carry out, within one year from its publication in the Official State Gazette, its regulatory development concerning the definition of the aforementioned criteria and the inclusion of an annex with a list of diseases and processes to which the law will apply.

Therefore, at the proposal of the Minister of Health, in accordance with the Council of State, and following deliberation by the Council of Ministers in its meeting of 28 October 2025,

I HEREBY ORDER:

Article 1. Purpose.

1. This Royal Decree aims to define the criteria referred to in Article 2 of Law 3/2024, of 30 October, for improving the quality of life of persons with Amyotrophic Lateral Sclerosis (ALS) and other diseases or conditions of high complexity and irreversible course.

2. The Royal Decree also includes an indicative list of diseases and conditions of high complexity and irreversible course which, due to their clinical characteristics, are likely to meet the operational criteria and, therefore, may require a comprehensive evaluation, without prejudice to the application of such criteria to other diseases or conditions not included in the list.

3. This Royal Decree shall not apply to persons diagnosed with ALS, who are already within the scope of Law 3/2024 pursuant to Article 2.1 of that law.

Article 2. General and Operational Criteria for Defining the Scope of Application of Law 3/2024, of 30 October.

1. Law 3/2024, of 30 October, shall apply to persons suffering from a disease or condition of high complexity and irreversible course, whether neurological or non-neurological, provided they cumulatively meet the criteria established in Article 2.2 of that law, in accordance with the general and operational criteria described below:

a) Having an irreversible condition with a significant reduction in life expectancy. A disease or condition shall be considered to meet this criterion when it is a chronic, non-reversible disease that progresses rapidly toward a functional status requiring intensive social and healthcare support for performing basic activities of daily living, and which directly affects life expectancy. To meet this general criterion, the following operational criterion must be met:

Severe structural and functional damage with no expectation of recovery under available treatments, leading to a significant reduction in life expectancy.

b) Having had no significant response to treatment, or when no therapeutic alternatives exist that could improve the functional status or prognosis of these persons. A disease or condition shall be considered to meet this criterion when there is no significant functional or prognostic response to available treatments, or when no therapeutic alternatives with proven efficacy exist: this criterion refers to chronic conditions in which, despite available treatment, there is no significant functional or prognostic improvement. To meet this general criterion, at least one of the following two operational criteria must be met:

1. No significant clinical response to authorized treatments with curative efficacy or substantial disease-modifying effect.

2. No authorized therapeutic alternative exists with curative efficacy or substantial disease-modifying effect.

c) Requiring complex social and healthcare needs, focused on home care, with a high impact on the immediate environment of the affected persons. A disease or condition shall be considered to meet this criterion when the affected person requires comprehensive, continuous daily social and healthcare attention and the use of functional or life-support devices. To meet this general criterion, the following two operational criteria must be cumulatively satisfied:

1. Need for continuous assistance in basic activities of daily living, identified using validated instruments, when available, employed in social and healthcare practice.

2. Prolonged use of functional and/or life-support devices such as, among others, mechanical ventilation or respiratory support, percutaneous endoscopic gastrostomy, communication devices, and other equivalent support situations.

d) Experiencing rapid progression in some of these conditions that requires acceleration of administrative procedures for assessing and recognizing the degree of disability or dependency. A disease or condition shall be considered to meet this criterion when there is accelerated clinical deterioration that may require expedited assessment in accordance with Law 3/2024, of 30 October. To meet this general criterion, at least one of the following operational criteria must be met:

1. Clinically objective functional deterioration within less than six months, not related to a recent or reversible intercurrent process, with loss of autonomy in two or more basic activities of daily living.

2. Recurrent severe complications, not related to a recent or reversible intercurrent process, resulting in two or more unplanned urgent hospital admissions in the past six months.

2. The Ministry of Health and the Ministry of Social Rights, Consumer Affairs, and Agenda 2030, in collaboration with the autonomous communities and informing the plenary of the Interterritorial Council of the National Health System and the System for Autonomy and Care for Dependency, shall develop guidelines or manuals to ensure a homogeneous evaluation of the operational criteria.

Article 3. Procedure for Requesting Recognition of Compliance with the Operational Criteria.

1. The procedure by which compliance with the requirements indicated in Article 2 may be accredited shall be initiated at the request of the person who may be affected by an irreversible and highly complex disease or condition, or by their legal representative, through the initiation request described in Annex III. Its processing shall comply with the procedures established by the System for Autonomy and Care for Dependency as set by the autonomous communities, and with the provisions of Law 39/2015, of 1 October, on the Common Administrative Procedure of Public Administrations, including the specificities arising from the procedure regulated in Articles 28 and following of Law 39/2006, of December 14, on the Promotion of Personal Autonomy and Care for Persons in a Situation of Dependency, as well as the provisions of Law 3/2024, of 30 October. The entire procedure, including information, communication, forms, notifications, and resolutions, shall be accessible to all persons, incorporating formats suitable for the needs of persons with disabilities.

2. The evaluation of the degree of compliance with the criteria set out in Article 2.1 shall be carried out by a medical professional responsible for monitoring the disease affecting the person seeking recognition of compliance with the operational criteria. To conduct this evaluation, the medical professional shall apply the verification questionnaire of the operational criteria provided in Annex II.

3. The maximum period for issuing the report containing the evaluation by the responsible medical professional referred to in the preceding paragraph shall be one calendar month from the date of receipt of the request for recognition of compliance with the criteria defined in this Royal Decree, as set out in Annex III.

4. Recognition of compliance with the operational criteria regulated in Article 2 shall be made by resolution within a maximum period of three months, issued by the autonomous administration corresponding to the applicant's residence, and shall be valid throughout the territory of the State.

5. The resolution referred to in the preceding paragraph shall determine the services or benefits corresponding to the applicant in accordance with the provisions of Law 3/2024, of 30 October, and Law 39/2006, of 14 December.

6. In addition to the provisions of the sole additional provision, the criteria set out in Article 2.1 may be applied to any irreversible and highly complex disease or condition, neurological or non-neurological, that may be susceptible to meeting such criteria, respecting the procedure established in Article 28 of Law 39/2006, of 14 December, for the recognition of the right to benefits provided under Law 3/2024, of 30 October.

Sole Additional Provision. Indicative List of Highly Complex and Irreversible Diseases and Conditions Susceptible to Evaluation.

Annex I contains an indicative list of irreversible and highly complex diseases and conditions that, due to their clinical characteristics, may require an evaluation to determine the degree of compliance with the criteria set out in Article 2.1, without prejudice to the fact that these criteria may be evaluated for any highly complex and irreversible disease or condition not included in the list, if there is reason to suspect that such criteria may be met.

The diagnosis of a highly complex and irreversible disease or condition, without the fulfillment of the general and operational criteria as set out in Article 2.1 of this Royal Decree, shall not, by itself, be considered sufficient to define the scope of application of Law 3/2024, of 30 October.

Final Provision One. Basis of Jurisdiction.

This Royal Decree is issued under the provisions of Article 149.1.16 of the Spanish Constitution, which assigns to the State exclusive jurisdiction over the bases and general coordination of healthcare.

Final Provision Two. Power of Regulatory Development.

The holder of the Ministry of Health is authorized to issue the necessary provisions for the development of this Royal Decree, as well as to update the indicative list of diseases included in Annex I.

Final Provision Three. Entry into Force.

This Royal Decree shall enter into force twenty days after its publication in the *Boletín Oficial del Estado*.

Given on 28 October 2025.

FELIPE R.

The Minister of Health,
MÓNICA GARCÍA GÓMEZ

ANNEX I**Indicative List of Highly Complex and Irreversible Diseases and Conditions Susceptible to Evaluation**

This list is indicative and includes a set of diseases that, due to their clinical complexity and evolutionary course, present a high probability of meeting the criteria defined in this Royal Decree from the time of diagnosis.

Under no circumstances does this list limit the evaluation of criteria for persons with other diseases or conditions that, due to their evolutionary course, could meet such criteria.

The diseases included in the following list are also subject to the verification process according to the criteria established in the Royal Decree.

- Neurodegenerative motor neuron diseases other than ALS (Progressive muscular atrophy: ICD-10: G12.25. Primary lateral sclerosis ICD-10: G12.23).
- Transmissible spongiform encephalopathies (ICD-10: A81.0).
- Brainstem (pontine) infarction resulting in locked-in syndrome (ICD-10: I69.36 + G83.5)
- Spinal muscular atrophy type I (ICD-10: G12.0) and type II (ICD-10: G12.1) (non-responsive to treatment).

ANNEX II

Verification Questionnaire for the Operational Criteria Defining the Scope of Application of Law 3/2024, of 30 October, to Improve the Quality of Life of Persons with Amyotrophic Lateral Sclerosis and Other Highly Complex and Irreversible Diseases or Conditions

General and Operational Criteria	Yes/No
a) Having an irreversible condition with a significant reduction in survival. (The following operational criterion must be met).	
Is it a chronic, irreversible disease with severe structural and functional damage, with no expectation of recovery using available treatments, and with a significant reduction in survival? (Criterion met if “Yes” is marked).	
b) No significant response to treatment, or no available therapeutic alternatives that improve functional status or prognosis. (To meet this general criterion, at least one of the following operational criteria must be met:).	

General and Operational Criteria	Yes/No
Is there a lack of clinically significant response to currently authorized treatments? (Criterion met if “Yes” is marked).	
Are there any authorized treatments with curative potential or substantially modifying the course of the disease? (Criterion met if “No” is marked).	
c) Requiring complex social and healthcare support, primarily at home, with high impact on the patient’s close environment (Both of the following operational criteria must be met).	
Does the patient require continuous assistance for basic activities of daily living (ADLs)? (Criterion met if “Yes” is marked).	
Does the patient use prolonged functional and/or life-support devices? (Criterion met if “Yes” is marked).	
d) Rapid progression requiring accelerated administrative processes for assessment and recognition of disability or dependence (At least one of the following operational criteria must be met).	
Has there been an objectively observed, accelerated clinical deterioration, not related to a recent or reversible intercurrent condition, in the last six months? (Criterion met if “Yes” is marked).	
Has the patient experienced recurrent severe complications not related to a recent or reversible intercurrent condition in the last six months? (Criterion met if “Yes” is marked).	

ANNEX III

Application Form for Recognition of Compliance with Operational Criteria in Highly Complex and Irreversible Diseases or Conditions (In accordance with Royal Decree 969/2025, of 28 October, establishing the criteria defining irreversible and highly complex care processes that fall within the scope of Law 3/2024, of 30 October, to improve the quality of life of persons with Amyotrophic Lateral Sclerosis and other highly complex and irreversible diseases or conditions)

At the request of Mr./Ms. _____, with
NIF/NIE number _____, and, where applicable,
represented by Mr./Ms. _____,
with NIF/NIE number _____,

STATES:

That, in accordance with Royal Decree 969/2025, of 28 October, establishing the criteria defining irreversible and highly complex care processes that fall within the scope of Law 3/2024, of 30 October, to improve the quality of life of persons with Amyotrophic Lateral Sclerosis and other highly complex and irreversible diseases or conditions, they request recognition that the disease or condition they suffer meets the operational criteria of high complexity and irreversible course.

And for the record, this application is submitted to the competent body, center, or administrative unit _____, for the purposes of assessment and resolution.

Signature of the applicant or legal representative and date.

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