

Review

Can a Regional Law Regulate End-of-Life Care in Italy? Ethical and Medico-Legal Perspectives

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Abstract

Recent Italian developments in end-of-life governance have intensified debate on self-determination, medically assisted suicide, and the constitutional limits of healthcare regulation. This article is a narrative review combined with doctrinal legal analysis and medico-legal commentary. It examines Tuscany's Regional Law No. 16 of 14 March 2025 within the broader Italian framework shaped by Law No. 219/2017, Constitutional Court Judgment No. 242/2019, and the subsequent constitutional review culminating in Judgment No. 204/2025. The article pursues three aims: to reconstruct the national legal framework governing end-of-life decision-making in Italy; to analyse the structure and constitutional implications of the Tuscan statute; and to assess the medico-legal relevance of the persistent uncertainty surrounding life-sustaining treatments as an eligibility criterion. The analysis highlights two distinct but interconnected issues: the constitutional boundary between regional healthcare organisation and matters requiring nationally uniform safeguards, and the unresolved interpretation of life-sustaining treatments in clinical and legal practice. In light of Judgment No. 204/2025, the article argues that regional procedural intervention may reduce administrative uncertainty, but cannot replace coherent parliamentary legislation capable of clarifying substantive criteria, limiting territorial variability, and reinforcing the role of palliative care within end-of-life pathways.

Keywords: medically assisted suicide; life-sustaining treatment; self-determination; constitutional law; regional competences; healthcare governance; palliative care



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1. Introduction

End-of-life decision-making in Italy has evolved through a complex interaction among legislation, constitutional adjudication, clinical practice, and ethical debate. In the absence of a comprehensive parliamentary framework on medically assisted suicide, much of the regulatory burden has shifted to the courts and to healthcare institutions, producing a landscape marked by legal uncertainty and territorial variability (Ciliberti et al. 2018; Ciliberti et al. 2025; Di Paolo et al. 2019; Montanari Vergallo et al. 2025; Veshi et al. 2019). This article is not an empirical study, but a doctrinal and medico-legal analysis of that evolving framework, with particular attention to the relationship between primary legal sources, constitutional case law, and the medical–bioethical literature.

A first major turning point was Law No. 219 of 22 December 2017, which strengthened informed consent, recognised the refusal or withdrawal of treatment, and regulated advance

treatment directives (Ciliberti et al. 2018; Di Paolo et al. 2019; Veshi et al. 2019). Although this statute significantly reinforced patient self-determination at the end of life, it did not establish a comprehensive statutory pathway for medically assisted suicide. The result was a structurally incomplete framework in which subsequent developments depended largely on constitutional jurisprudence, administrative implementation, and case-by-case litigation (Cecchi et al. 2024; Ciliberti et al. 2025; Montanari Vergallo et al. 2025; Turillazzi et al. 2025).

Against this background, several Italian Regions had already explored organisational responses to the national implementation gap, although Tuscany became the first to adopt a structured statutory framework (Signorella 2025). Tuscany's Regional Law No. 16 of 14 March 2025 is therefore of particular relevance. The law presented itself as an implementing measure rather than a source of new substantive entitlements, seeking to operationalise constitutional criteria already articulated at national level (Blandi et al. 2025; Camatti et al. 2025; Conti 2025; Montanari Vergallo and Gulino 2022; Regione Toscana 2025). At the same time, because it intervened in an area involving fundamental rights, healthcare safeguards, and the distribution of legislative competences under Article 117 of the Constitution, it immediately raised questions concerning the constitutional limits of regional action (Blandi et al. 2025; Camatti et al. 2025; Razzano 2025).

The Tuscan case highlights two analytically distinct issues. The first is constitutional: whether, and to what extent, a Region may regulate procedural pathways in a field that touches nationally uniform safeguards and civil-law protections. The second is substantive and medico-legal: the persistent uncertainty surrounding “life-sustaining treatments” (trattamenti di sostegno vitale, TSV), which remains one of the key eligibility criteria in Italian constitutional jurisprudence and one of the least stable in practical application (Cecchi et al. 2024; Turillazzi et al. 2025). These questions are closely related, but they should not be conflated. A regional law may be constitutionally problematic even if the eligibility criteria remain unchanged; conversely, uncertainty surrounding TSV may persist even within a procedurally well-structured framework.

Against this background, this article pursues three aims: to reconstruct the national legal framework governing end-of-life decision-making in Italy; to analyse the structure and constitutional implications of Tuscany's Regional Law No. 16/2025; and to assess the medico-legal relevance of Constitutional Court Judgment No. 204/2025, especially in relation to regional competences and the unresolved interpretation of TSV. Read in this way, the Tuscan experience is not merely a regional episode, but a useful test case for examining the current limits of Italian end-of-life governance and the continuing need for coherent national legislation.

2. Methods

This article was designed as a narrative review combined with doctrinal legal analysis and medico-legal commentary. It is not an empirical study. Its purpose is to examine Tuscany's Regional Law No. 16/2025 within the broader Italian end-of-life framework by integrating primary legal sources with the relevant medical, bioethical, and medico-legal literature.

Primary sources included constitutional provisions, national statutes, regional legislation, judicial decisions, and other official legal materials relevant to medically assisted suicide and end-of-life decision-making in Italy. These sources were retrieved from institutional repositories and legal databases and were treated as the principal basis for interpretation. Secondary literature was used to contextualise doctrinal debates, organisational models, ethical tensions, and medico-legal implications.

A structured literature search was conducted in PubMed, Scopus, and Web of Science for publications in English and Italian from January 2017 to 31 January 2026. Search

terms combined legal, medico-legal, and clinical–bioethical expressions, including “medically assisted suicide”, “assisted suicide”, “end of life”, “informed consent”, “advance treatment directives”/“disposizioni anticipate di trattamento”, and “life-sustaining treatments”/“trattamenti di sostegno vitale”, together with terms related to regional regulation and Tuscany.

After removal of duplicates, records were screened for relevance to at least one of the following profiles: the Italian legal framework governing end-of-life decisions; constitutional or statutory safeguards; eligibility criteria for medically assisted suicide, including TSV; and the practical implementation of access pathways shaped by constitutional jurisprudence. Sources addressing the Italian context only marginally, or discussing end-of-life issues at too general a level to inform the present analysis, were not included in the substantive discussion.

This combined approach was adopted because the Tuscan statute cannot be adequately assessed through doctrinal analysis alone. Its significance depends not only on constitutional interpretation, but also on its implications for clinical evaluation, procedural safeguards, professional responsibility, and the operational meaning of key eligibility criteria.

3. The National Legal and Jurisprudential Framework of End-of-Life Decision-Making in Italy

3.1. From Law No. 219/2017 to Constitutional Court Judgment No. 242/2019

Italian end-of-life law has developed in the absence of a comprehensive statutory framework on medically assisted suicide. For many years, the legal system maintained a restrictive approach grounded in the protection of life, while ethical and political debate continued without producing an organic parliamentary response ([Constitutional Court \(Italy\) 2024, 2019](#)). In comparative perspective, this legislative inertia became increasingly visible as other European jurisdictions moved, through legislation or judicial intervention, towards more explicit forms of regulation ([Clin and Ferrant 2010](#); [Fullbrook 2007](#); [Jox et al. 2013](#); [McLean 1996](#); [Meñaca et al. 2012](#)).

A first major turning point was Law No. 219 of 22 December 2017, which strengthened informed consent, recognised the right to refuse or withdraw treatment, and regulated advance treatment directives. The statute marked a decisive shift in Italian medico-legal practice by consolidating therapeutic self-determination and by clarifying that even life-preserving interventions, including artificial nutrition and hydration, may be refused or discontinued ([Porteri et al. 2022](#)). Its importance was substantial, but limited: it redefined the legal framework of treatment refusal, not that of medically assisted suicide.

The constitutional turn was triggered by the Cappato case, arising from the prosecution under Article 580 of the Penal Code for aiding the suicide of Fabiano Antoniani (“DJ Fabo”) ([Montanari Vergallo 2019](#)). That litigation led to Constitutional Court Judgment No. 242/2019, which identified a narrow area of non-punishability for assistance in suicide under specific cumulative conditions—irreversible pathology, intolerable suffering subjectively perceived by the patient, full decision-making capacity, and dependence on life-sustaining treatments—within a pathway subject to verification by the public healthcare system and the competent ethics bodies ([Ciliberti et al. 2025](#)). The judgment did not recognise a general right to assisted suicide, but it opened a constitutionally delimited exception to criminal punishment.

Its impact was significant. The Court defined a framework of conditions and safeguards, yet Parliament did not enact a comprehensive implementing statute. The post-2019 phase has therefore been marked by administrative uncertainty, uneven local practice, and recurrent litigation, with access often depending less on a uniform legal framework than on

the interaction between constitutional case law, healthcare institutions, and local procedural responses (Cecchi et al. 2024; Ciliberti et al. 2025; Klesta 2025; Turillazzi et al. 2025).

3.2. Post-2019 Gaps and the Problem of Life-Sustaining Treatments

This fragmented post-2019 landscape made clear that the Italian model remained structurally incomplete. Although constitutional jurisprudence had identified the conditions under which assistance in suicide may escape criminal punishment, it had not resolved how those conditions should be translated into stable and homogeneous procedures across the national territory (Camatti et al. 2025; Ciliberti et al. 2025; Klesta 2025; Turillazzi et al. 2025). This implementation gap is central to understanding why regional initiatives, especially the Tuscan one, later assumed particular importance.

Within this unsettled framework, one criterion has proved especially problematic: the requirement of dependence on TSV. The criterion is central because it functions as one of the constitutional thresholds for access, yet it remains only partially defined in legal and clinical terms. Paradigmatic cases such as invasive mechanical ventilation, dialysis, or artificial nutrition and hydration are relatively clear, because the patient's survival is directly dependent on the continuation of the intervention (Porteri et al. 2022; Viafora 2023). More difficult are borderline situations in which treatment supports, rather than fully replaces, a vital function, or in which technological dependence is clinically significant but not readily amenable to binary classification (Cecchi et al. 2024; Turillazzi et al. 2025).

For this reason, the issue of TSV should be kept distinct from the separate question of the constitutional legitimacy of regional legislation. The former concerns the interpretation of an eligibility criterion within the national framework; the latter concerns the scope of regional procedural intervention under Article 117 of the Constitution. The two issues intersect in practice, but they are not the same. This distinction is essential for understanding the significance of Tuscany's Regional Law No. 16/2025: a regional statute may attempt to organise access pathways, yet it cannot by itself resolve the deeper uncertainty surrounding one of the key substantive thresholds governing eligibility.

4. Tuscany's Regional Law No. 16/2025 and the Path to Constitutional Review

4.1. Legislative Design, Eligibility Conditions, and Access Pathway

Tuscany's Regional Law No. 16 of 14 March 2025 was the first regional statute in Italy to establish a structured procedural framework for requests relating to medically assisted suicide within the regional health service (Regione Toscana 2025). The law did not purport to create a new substantive entitlement. Rather, it was framed as an implementing measure intended to render operational, at regional level, the constitutional conditions already identified by national jurisprudence (Blandi et al. 2025; Camatti et al. 2025; Conti 2025; Montanari Vergallo and Gulino 2022). Its declared objective was therefore organisational: to reduce uncertainty, identify competent bodies, and provide a traceable pathway for the assessment of requests.

The statute reproduced the four principal eligibility conditions derived from Constitutional Court case law: irreversible pathology, physical or psychological suffering regarded as intolerable by the patient, dependence on life-sustaining treatments, and full capacity to make free and informed decisions (Regione Toscana 2025; Constitutional Court (Italy) 2025). It also required that the patient be informed of available alternatives, including palliative care and the options already recognised under Law No. 219/2017, such as refusal or withdrawal of treatment and continuous deep palliative sedation (Porteri et al. 2022). In this way, the regional law sought to situate medically assisted suicide within the broader framework of end-of-life care rather than treating it as an isolated option.

Procedurally, the request was to be submitted to the competent Local Health Authority (AUSL), together with the relevant clinical documentation ([Regione Toscana 2025](#)). The law further provided for the involvement of a trusted physician and introduced defined timelines for the assessment process, with the apparent aim of reducing inertia and ensuring a more predictable institutional response ([Constitutional Court \(Italy\) 2025](#)). From a medico-legal perspective, this design was significant because it attempted to replace fragmented case-by-case management with a formal healthcare pathway characterised by documentation, traceability, and institutional accountability ([Blandi et al. 2025](#); [Camatti et al. 2025](#)).

4.2. Multidisciplinary Assessment and Constitutional Challenge

A central feature of the statute was the establishment of a Permanent Multidisciplinary Commission within each AUSL. The Commission was entrusted with evaluating requests and included several professional profiles, among them specialists in palliative care, psychiatry, anesthesiology, psychology, forensic medicine, and nursing; where necessary, a specialist in the patient's underlying pathology could also be involved ([Regione Toscana 2025](#)). This composition reflected an explicitly multidisciplinary understanding of end-of-life assessment, intended to integrate clinical, psychological, relational, and medico-legal considerations.

The law thus sought to address a concrete implementation gap left open after Judgment No. 242/2019. In the absence of national legislation, it offered a regional procedural response to a constitutionally recognised but operationally unstable pathway. Yet that same ambition exposed the statute to constitutional challenge. The more detailed the regional procedural model became, the more difficult it was to maintain a clear distinction between healthcare organisation and the indirect shaping of access in a field involving nationally uniform safeguards and civil-law protections ([Blandi et al. 2025](#); [Camatti et al. 2025](#); [Caputo 2025](#); [Razzano 2025](#)).

In May 2025, the President of the Council of Ministers challenged the law before the Constitutional Court, alleging that it exceeded the limits of regional competence. The ensuing Judgment No. 204/2025 did not strike down the law in its entirety, but clarified that regional intervention is permissible only within the boundaries of organisational and procedural regulation falling under the protection of health. Where regional provisions affect access criteria, nationally uniform safeguards, or equality-sensitive obligations, they risk encroaching on matters reserved to the State ([Constitutional Court \(Italy\) 2025](#)). Tuscany's law thus became the first concrete occasion for the Court to define the constitutional limits of regional proceduralisation in medically assisted suicide.

5. Discussion

5.1. Regional Competences, Article 117, and Judgment No. 204/2025

Tuscany's Regional Law No. 16/2025 brought to the forefront a central constitutional question: whether a Region may regulate the procedural pathway for medically assisted suicide in the absence of a comprehensive national implementing statute. Under Article 117 of the Constitution, the difficulty lies in distinguishing legitimate healthcare organisation from impermissible interference with matters requiring nationally uniform safeguards. In this field, procedural choices are not neutral, because they may affect access to a legally exceptional pathway involving fundamental rights, equality-sensitive protections, and civil-law implications ([Caputo 2025](#); [Council of State \(Italy\) 2024](#)).

Supporters of the Tuscan statute argued that the Region did not create a new substantive entitlement, but merely sought to render operational within the regional health service a pathway already delimited by constitutional jurisprudence ([Caputo 2025](#)). Critics, by

contrast, maintained that a regional law cannot transform constitutional case law into a detailed access model where Parliament has remained silent, because this risks territorial differentiation in a domain that requires national uniformity (Blandi et al. 2025; Camatti et al. 2025; Caputo 2025; Razzano 2025). The argument based on *cedevolezza inversa* partly explains the logic of the regional initiative, but does not eliminate the constitutional problem: in end-of-life governance, procedural architecture may indirectly shape the substance of access.

Judgment No. 204/2025 clarified this boundary. The Constitutional Court did not exclude all regional intervention, but confirmed that Regions may act only within the limits of organisational and procedural regulation falling under health protection (Constitutional Court (Italy) 2025). Regional provisions become constitutionally problematic when they crystallise access criteria, alter nationally uniform safeguards, or impose equality-sensitive obligations reserved to the State. This explains why the Court did not strike down the Tuscan law in its entirety, but selectively censured those provisions that exceeded the organisational sphere, including delegated submission of the request, rigid procedural deadlines, and organisational obligations extending beyond legitimate regional competence (Porteri et al. 2022; Constitutional Court (Italy) 2025). The ruling therefore confirms that regional proceduralisation may mitigate administrative uncertainty, but cannot serve as a substitute for national legislation.

5.2. Life-Sustaining Treatments as an Unstable Eligibility Criterion

Separate from the question of constitutional competence is the persistent uncertainty surrounding TSV, one of the key eligibility criteria in Italian constitutional jurisprudence (Delogu et al. 2024; Pucci et al. 2025; Viafora 2023). This criterion is relatively clear in paradigmatic cases such as invasive mechanical ventilation, dialysis, and artificial nutrition or hydration, where the patient's survival is directly dependent on the continuation of the intervention (Porteri et al. 2022; Viafora 2023). It is much less clear in borderline situations involving technologically complex support that does not fully replace a vital function or does so only indirectly (Cecchi et al. 2024; Turillazzi et al. 2025). For example, invasive mechanical ventilation would ordinarily fall within TSV, whereas home oxygen therapy alone would not necessarily satisfy that criterion.

This uncertainty is not merely terminological. It has concrete implications for eligibility assessment, for the work of multidisciplinary commissions, and for equality of access across different territories. For that reason, a functional approach is preferable to a purely formal one. The key questions are whether the intervention substitutes an essential physiological function, whether dependence is continuous and technologically mediated, and whether withdrawal bears a sufficiently direct causal relationship to death. Such an approach cannot eliminate all borderline disputes, but it better reflects the medico-legal reality of end-of-life assessment (Cecchi et al. 2024; Delogu et al. 2024; Pucci et al. 2025; Viafora 2023).

The Tuscan case shows why this issue matters. Even a procedurally well-structured regional pathway cannot stabilise access if one of its main eligibility criteria remains conceptually unsettled. The problem is therefore not only institutional but also doctrinal. This is one of the strongest reasons why regional initiatives, however useful, cannot replace a coherent parliamentary framework capable of clarifying the substantive thresholds governing access.

5.3. Clinical, Ethical, and Deontological Implications

The legal issues discussed above also have direct consequences for clinicians. In Italy, the Code of Medical Deontology continues to prohibit physician participation in acts directly intended to cause death, preserving a normative distinction between care and

intentional life-ending conduct ([National Federation of Orders of Surgeons and Dentists 2014](#)). At the same time, Law No. 219/2017 strengthened informed consent, refusal of treatment, and withdrawal of treatment, thereby consolidating an autonomy-based model of end-of-life decision-making ([Porteri et al. 2022](#); [Spasari 2003](#)). The resulting tension is evident: clinicians are required to respect self-determination, yet they operate within a professional and ethical framework that remains cautious toward medically assisted suicide.

This tension is particularly important in pathways such as the Tuscan one, where clinicians are not the direct authors of the final act, but remain deeply involved in assessing eligibility, documenting decisional capacity, presenting alternatives, and preserving the integrity of the therapeutic relationship. From this perspective, palliative care cannot be treated as a merely formal step preceding access. It is an effective safeguard, both clinically and ethically, and one that Judgment No. 204/2025 indirectly reaffirmed by striking down rigid timelines that might compress multidisciplinary assessment and limit the authentic exploration of alternatives ([Constitutional Court \(Italy\) 2025](#); [World Medical Association 2019](#); [Spasari 2003](#); [Marisei et al. 2025](#)).

The broader implication is that end-of-life governance cannot be assessed only in terms of access. It must also be evaluated in light of its effects on clinical responsibility, professional integrity, and the effective availability of palliative and psychological support. Tuscany's experience is important precisely because it shows both sides of the problem: procedural organisation may improve traceability and reduce inertia, but it cannot by itself resolve the ethical burden placed on professionals or the conceptual instability of the legal criteria they are asked to apply.

6. Conclusions

The Tuscan case confirms that end-of-life governance in Italy is shaped by two distinct but interconnected problems: the constitutional limits of regional procedural intervention and the unresolved interpretation of life-sustaining treatments as an eligibility criterion. One of the main contributions of this article is to keep these issues analytically separate. The first concerns the boundary between regional healthcare organisation and matters requiring nationally uniform safeguards under Article 117 of the Constitution. The second concerns the substantive and medico-legal uncertainty that continues to affect access even within procedurally structured pathways.

From this perspective, Tuscany's Regional Law No. 16/2025 was significant not because it created a new right, but because it attempted to translate a constitutionally delimited and operationally unstable pathway into a formal healthcare process. Judgment No. 204/2025 clarified that such regional intervention is not wholly precluded, but remains constitutionally legitimate only so long as it does not alter access criteria, weaken nationally uniform safeguards, or impose obligations that exceed the organisational sphere.

At the same time, the Tuscan experience shows that the deeper instability of the Italian model lies not only in the distribution of competences, but also in the lack of a sufficiently clear legal taxonomy of life-sustaining treatments. As long as one of the central eligibility thresholds remains uncertain, procedural solutions alone cannot guarantee homogeneous application.

For this reason, the Italian framework still requires coherent parliamentary legislation capable of clarifying substantive criteria, defining the permissible scope of regional organisation, and reinforcing the role of palliative care within end-of-life pathways. Read in this light, the Tuscan law and the Constitutional Court's response to it are not merely a regional episode, but a revealing test of the current limits of end-of-life governance in Italy.

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Abbreviations

The following abbreviations are used in this manuscript:

AUSL	Local Health Authority (Azienda Unità Sanitaria Locale)
TSV	Life-sustaining treatments (Trattamenti di sostegno vitale)

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