

**REGULATORY IMPACT ANALYSIS REPORT**  
**DRAFT DECREE REGULATING THE TECHNICAL AND HEALTH REQUIREMENTS**  
**FOR AESTHETIC MEDICINE HEALTHCARE CENTRES AND SERVICES IN THE**  
**REGION OF MURCIA.**

This report has been drawn up in accordance with Article 53(1) of Law 6/2004 of 28 December 2004 on the Statute of the President and the Governing Council of the Region of Murcia, following the structure laid down in the Resolution of 29 July 2022 of the Secretariat-General of the Regional Ministry of Women, Equality, LGBTI, Families, Social Policy and Transparency publishing the Agreement of the Governing Council approving the Methodological Guide for the preparation of a Regulatory Impact Analysis Report (MAIN) in the Region of Murcia, and the Methodological Guide on Regulatory Evaluation in the Region of Murcia, adopted at its meeting on 28 July 2022, and consisting of the following sections:

## CONTENTS

1. Executive summary.
2. Timeliness and technical reasoning for the regulatory proposal.
3. Content, legal analysis and description of the procedure for the regulatory proposal.
4. Study of administrative burdens.
5. Budgetary impact.
6. Economic impact.
7. Gender impact.
8. Impact on gender diversity.
9. Impact on children and adolescents.
10. Impact on the family.
11. Impact on the 2030 Agenda.
12. Impact on equal opportunities, non-discrimination and universal accessibility for persons with disabilities.
13. Other impacts.
14. Regulatory assessment.



## I. EXECUTIVE SUMMARY SHEET

<b>GENERAL INFORMATION</b>	
Initiating body/Proposing regional ministry	DIRECTORATE-GENERAL FOR PLANNING, PHARMACY AND HEALTH RESEARCH.  SECRETARY-GENERAL  REGIONAL MINISTRY OF HEALTH
Title of the regulation	Decree regulating the technical and health requirements for Aesthetic Medicine healthcare centres and services in the Region of Murcia
Type of report	ORDINARY
Date	20-02-2026
<b>TIMELINESS AND TECHNICAL REASONING</b>	
Subject	Determination of the technical and health requirements for Aesthetic Medicine healthcare centres and services in the Region of Murcia
Purpose of the Draft	It is considered necessary to approve a specific regulation governing the technical and health conditions and requirements applicable to clinical care units in Aesthetic Medicine healthcare centres and services, in order to ensure that they have the necessary means to carry out their intended activities and to safeguard the quality of healthcare and the safety of patients treated in these healthcare centres and services.
Main alternatives considered	This regulation can only be implemented through legislation, and specifically by means of a Decree, as there is no legal authorisation from the Health Minister and due to the requirements of legal certainty.
<b>CONTENT, LEGAL ANALYSIS AND PROCESSING</b>	
Type of regulation	Decree of the Governing Council, in accordance with Article 32(1) of the Statute of Autonomy, Articles 22(12) and 52(1) of Law 6/2004 on the Statute of the President



	and the Governing Council and Article 25(2) of Law 7/2004 on the Organisation and Legal Regime of the Public Administration of the Autonomous Community of the Region of Murcia
Competence of the Autonomous Community of the Region of Murcia	Legislative development and implementation in the areas of health, hygiene, pharmaceutical management and hospital coordination in general, including that of Social Security (Article 11(1) of the Statute of Autonomy)
Structure and content of the regulation	It consists of an explanatory part, 23 articles, within 6 chapters (Chapter I 'General provisions'; Chapter II 'Structure and requirements of installations and equipment'; Chapter III 'Documentary requirements'; Chapter IV 'Ownership. Personnel requirements'; Chapter V 'Inspection and control'; Chapter VI 'Penalty system and intervention measures'), 1 sole additional provision, 2 transitional provisions and 2 final provisions.
Inclusion of the proposal in the Annual Regulatory Plan	It has not been included in the 2025 Annual Regulatory Plan, but will be included in the 2026-2027 Annual Regulatory Plan.
New developments	It establishes the specific technical and health conditions and requirements of the Aesthetic Medicine Clinical care Units, in order to ensure that they have the necessary means to carry out the activities for which they are intended and to safeguard the quality of healthcare.
Provisions whose validity is affected	None
Public consultation procedure	<p>In order to complete the <b>Preliminary Public Consultation</b> procedure in accordance with Article 133(1) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of the Public Administrations, an Explanatory Memorandum to the draft legislation was published at the end of July 2025 on Citizen Participation web page of the CARM, so that citizens can provide input and suggestions.</p> <p>Prior to this, in April 2025, the Official Medical Association of the Region of Murcia was also notified of the Regional Ministry's intention to draft the said regulatory proposal, and was informed that a preliminary</p>



	<p>public consultation would be carried out on the Transparency Portal, should they wish to submit any contributions. A preliminary draft was also sent to them in case they wished to make any technical contributions or comments.</p> <p>Furthermore, as the regulation affects the legitimate rights and interests of citizens, it has been submitted to a <b>public consultation process</b>. As a result, it has been decided to publish the text and the initial Regulatory Impact Analysis Report (MAIN) on the Citizen Participation Portal of the CARM, on the 'MurciaSalud' health portal, and an announcement in the BORM.</p> <p>Individual consultations have also been held <b>with entities or organisations</b> recognised by law whose rights or legitimate interests are affected by the regulation and whose purposes are directly related to its object, such as professional associations, scientific societies, universities and consumer and user associations, through their representation on the Regional Consumer Advisory Council. To this end, the draft will also be sent to the Regional Ministry of Business, Employment and Social Economy.</p> <p>In response to this procedure, numerous contributions have been submitted that are being assessed in this Regulatory Impact Analysis Report (MAIN). It has also been submitted to, and received favourable opinions from, the following:</p> <ul style="list-style-type: none"><li>- Health Council of the Region of Murcia</li><li>- Regional Consumer Advisory Council.</li></ul>
Reports received	<p>Prior to its approval by the Governing Council, the mandatory report of the following bodies must be obtained:</p> <ul style="list-style-type: none"><li>- Legal report of the Deputy Secretary of the Regional Ministry of Health.</li><li>- Legal Services Directorate of the CARM.</li><li>- Legal Council of the Region of Murcia.</li></ul>
<b>STUDY OF ADMINISTRATIVE BURDENS</b>	
It entails a reduction in administrative burdens. Estimated quantification	No
It incorporates new	No



administrative burdens. Estimated quantification		
It does not affect the administrative burdens	It does not affect the administrative burdens	
<b>IMPACT ANALYSIS</b>		
<b>BUDGETARY IMPACT</b>		
Budgetary impact. Involves expenditure/revenue		<b>14.314,00</b>
In personnel resources	<b>TOTAL CHAPTER 1 – Personnel expenditure</b>	<b>12.190,00</b>
In material resources	<b>TOTAL – CHAPTER 2 – Current expenditure on goods and services</b>	<b>2.124,00</b>
<b>ECONOMIC IMPACT</b>		
General impact on the economy	<p>This draft generally complies with Law 20/2013 of 9 December 2013 on the guarantee of market unity.</p> <p>The draft does not have any relevant effects on prices and products, nor does it introduce any applicable tariffs or prices. In principle, the proposed draft does not have a direct impact on the productivity of workers and companies, as the technical and health requirements established do not differ greatly from those that aesthetic medicine centres and services already comply with and observe in the course of their activities. It also has no direct impact on the labour market, as it does not affect job creation or destruction, since aesthetic medicine centres and services are already required by law to employ staff with qualifications that meet the necessary requirements set out in the regulations governing the healthcare professions, represented by Law 44/2003. However, as a new requirement, it establishes the obligation for the Technical Director or substitute with equivalent qualifications to remain at the centre at all times while the healthcare centre is providing clinical care, in order to ensure that patient care is provided by a healthcare professional with the official qualifications and professional skills and competences appropriate to the clinical care provided,</p>	



	<p>in accordance with the definition of the care offered, thereby guaranteeing patient safety.</p> <p>As the measure establishes a new regulatory framework for technical and health requirements, it is considered that it may have an impact on innovation, both in production processes and in the organisational capacity of business.</p> <p>The proposed regulation is not only in the interest of healthcare professionals but also in the interest of citizens in general and society as a whole, as potential consumers of the services offered in those healthcare centres. As such they may enjoy and benefit from better services and products in this field, and may even be encouraged to adopt more appropriate, safer and more informed consumption practices.</p> <p>There are no effects on the economy of other States, and with regard to the effects on SMEs, the SME test is attached to this report.</p>
<b>IMPACT DUE TO GENDER</b>	
Negative/None/Positive	None
<b>IMPACT ON GENDER DIVERSITY</b>	
Negative/None/Positive	Positive
<b>IMPACT ON CHILDREN AND ADOLESCENTS</b>	
Negative/None/Positive	Positive
<b>IMPACT ON THE FAMILY</b>	
Negative/None/Positive	Positive
<b>IMPACT ON 2030 AGENDA</b>	
Related Sustainable Development Goal	Contributes to the achievement of Goal 3: Ensure healthy lives and promote well-being for all ages.
<b>OTHER IMPACTS</b>	
<b>REGULATORY ASSESSMENT</b>	YES
Time frame for assessment of the regulation	Total time frame: two years Periodic evaluations: Yes Time frame(s): initial, annual and bi-annual. .



Identification of objectives to be evaluated	Implementation of health requirements, functional and organisational conditions, as well as minimum structure, facilities and equipment that, according to the portfolio and clinical care services offered, must be met by Aesthetic Medicine centres or services in order to increase the quality and safety for patients at these healthcare centres.
Assessment tools for each objective or impact	<p>Number of Aesthetic Medicine centres and services at the time when the regulation enters into force</p> <p>Number of Aesthetic Medicine centres and services that have been adapted within the 1-year adaptation period from the entry into force.</p> <p>Number of new Aesthetic Medicine centres and services that have opened within 1 and 2 years of the entry into force.</p> <p>Number of inspections carried out in Aesthetic Medicine centres and services in the year prior to the regulation's entry into force, and at one and two years thereafter.</p>

## 2. TIMELINESS AND TECHNICAL REASONING.

### **Adaptation of the proposed regulation to the principles of good regulation set out in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations.**

To analyse the opportunity and technical motivation of this regulation, the first thing is to show that it complies with the principles of good regulation contained in Article 129 of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, in particular those of necessity, effectiveness, proportionality, legal certainty, transparency and efficiency.

In accordance with the principles of necessity and effectiveness, it pursues a general interest, namely to improve patient safety and the quality of healthcare in the procedures included in the portfolio of services offered by centres and services dedicated to Aesthetic Medicine, and is the most appropriate instrument for ensuring that this is achieved. It strictly contains the regulations essential for achieving the objectives pursued, after confirming that there are no other measures that are less

restrictive of rights or that impose fewer obligations on the recipients, and is therefore in accordance with the principle of proportionality.

The principle of legal certainty is also observed, as the legislative initiative shall be exercised in a manner consistent with the rest of the legal system, both national and European Union, to generate a stable, predictable, integrated, clear, and certain regulatory framework that facilitates its understanding and, consequently, the actions and decision-making of individuals and centres.

It also complies with the principle of transparency, since, prior to its processing, it was subject to a preliminary public consultation and, subsequently, to the appropriate public consultation and public information procedure. Similarly, the objectives of this initiative and its justification are set out in the explanatory part of the initiative.

With regard to the principle of efficiency, it only imposes the minimum technical and health requirements necessary to guarantee the suitability of the authorisations granted and the quality of clinical care provided in these centres.

### **2.1 Problems to be solved or situations expected to be improved with the application of the regulation.**

The draft regulation aims to establish specific regulations governing healthcare requirements, functional and organisational conditions, as well as minimum structure, facilities and equipment that, depending on the portfolio and clinical care services offered, must be met by Aesthetic Medicine centres or services located in the Autonomous Community of the Region of Murcia.

Aesthetic Medicine centres or services are defined as those healthcare centres or services that offer Aesthetic Medicine (U.48) clinical care, in which a doctor is responsible for carrying out non-surgical treatments aimed at improving the appearance of the body or face, in accordance with the definition set out in Annex II of Royal Decree 1277/2003 of 10 October 2003, which lays down the general principles governing the authorisation of healthcare centres, services and establishments, located in the Region of Murcia.

The treatments practised in Aesthetic Medicine (U.48) healthcare centres and services shall be in accordance with medical knowledge endorsed by the scientific community and adhere to clinical practice based on current scientific evidence.

In all cases, aesthetic medicine treatments offered at the healthcare centre or service may only require topical or local anaesthesia.

In accordance with Royal Decree 1277/2003 of 10 October 2003 laying down the general rules on the authorisation of healthcare centres, services and establishments and subsequently enacting Regional Decree no. 73/2004 of 2 July 2004 regulating the procedure for the authorisation of healthcare centres, establishments and services and the register of regional healthcare resources, the general requirements necessary for their establishment and operation were determined, all within the framework of the development of national basic legislation. In recent years, scientific and technical developments in the specific field of aesthetic medicine have made it advisable to specify the specific requirements and conditions necessary for the provision of services in Aesthetic Medicine clinical care units.

In the same vein, the regional legislation contains principles and mandates that require a review of the regional legal order, such as Law 12/2014 of 16 December 2014 on Transparency and Citizen Participation of the Autonomous Community of the Region of Murcia, which, in its second additional provision, on regulatory review and simplification, provides for the need to promote a process of review, simplification and, where appropriate, a regulatory consolidation of the regional legal order.

In short, there is a need for up-to-date regulation of the technical and health requirements to be met by these centres in the Region of Murcia, with a view to improving the quality of the health services provided by them, in order to provide greater safety and better quality of health for citizens. The draft will affect healthcare professionals in the field of aesthetic medicine and, of course, all users who demand the healthcare procedures offered by these healthcare centres and services.

## **2.2 Description of alternatives for resolving the problem or addressing the situation that the regulation seeks to resolve.**

There are no non-regulatory alternatives, as inaction would prevent the specification of the technical and human resource requirements that such healthcare centres and services must meet. This would mean that the intended objectives and purposes would not be achieved, nor could compliance be required, as this can only be achieved through the development of a general provision of a mandatory nature for a specific sector.

Moreover, as regards the regulatory status of the legislation, there are likewise no alternatives, since the establishment of those technical requirements requires the approval of a provision of a regulatory nature, the approval of which is the responsibility of the Governing Council through the adoption of a decree.

### **2.3 Reasons of general interest that justify the approval of the regulation.**

The reason of general interest stems from the need for specific regulations governing the technical and healthcare conditions and requirements that aesthetic medicine centres and services in the Region of Murcia must meet, in order to provide healthcare services that offer the highest possible level of quality, safety and guarantees for potential users.

Furthermore, the aim is to adapt the regional healthcare legislation on the requirements that these types of centres and healthcare services must meet to the general healthcare regulations to which they are subject.

### **2.4 Objectives pursued.**

The new regulations aim to achieve the following results and objectives:

To establish specific regulation of the means, conditions and facilities that these centres and services need to provide a healthcare service appropriate to the particular nature of the activities carried out therein.

- To adapt the regulation of their technical and healthcare requirements to new scientific practices and developments that have emerged in recent years, in order to provide potential users with healthcare of the highest possible quality, assurance and safety.

- To align with regulatory changes in healthcare regulation concerning the requirements applicable to healthcare centres, services and establishments in general, and, in particular, those relating to aesthetic medicine.

- To provide future and current owners of aesthetic medicine centres and services, as well as the general public, with a clearer understanding of the technical and health requirements they must meet.

## **3. CONTENTS, LEGAL ANALYSIS AND DESCRIPTION OF THE PROCEDURE.**

### **3.1 Contents.**

a) **Structure** of the legislative proposal, with an indication of the divisions of the proposal and the number of articles and the final part.

The draft regulations consist of an explanatory part, 23 articles, within 6 chapters (Chapter I 'General provisions'; Chapter II 'Structure and requirements of installations and equipment'; Chapter III 'Documentary requirements'; Chapter IV

'Ownership. Personnel requirements'; Chapter V 'Inspection and control'; Chapter VI 'Penalty system and intervention measures'), 1 sole additional provision, 2 transitional provisions and 2 final provisions.

b) Summary of the **main aspects** and the most important measures contained in the regulatory proposal.

From a substantive point of view, a unique, updated, harmonised and systematic regulation of the entire regime applicable to aesthetic medicine centres and services is established, both in technical and healthcare aspects, addressing general issues in the exercise of the activity; it also covers the ownership of healthcare centres and services, as well as personnel, premises, equipment, activities carried out, authorisation regime, healthcare documentation, quality, safety and working procedures, monitoring, inspection, control, sanctioning regime and intervention measures.

Detailed and specific rules are also laid down for certain technical elements relating to the premises and equipment that aesthetic medicine centres and services must have, in order to ensure that they are as adapted as possible to the advances, new technologies and scientific knowledge currently prevailing in the field of aesthetic medicine and that the quality of the procedures offered is adequately guaranteed.

c) **New elements**, and, where appropriate, differences from the previous regulations if any.

There is no previous regulation, since this draft regulation is intended to regulate this provision of clinical care for the first time. Within this framework, different health professionals, both graduates and members of regulated professions in a health sector, may provide services. However, as a new feature, these Aesthetic Medicine units must be headed by a technical director who is responsible for the responsibility, monitoring and control of the clinical care work carried out in the healthcare centre. All this is without prejudice to the competences attributed, in accordance with the applicable regulations, to the various healthcare professions.

They must hold a degree in Medicine and Surgery, and must also have specific training in aesthetic medicine, duly accredited by a university Master's degree which includes accredited in-person practice in Aesthetic Medicine or in capillary implantology or in those specific techniques related to the portfolio of services offered; alternatively, they may hold the degree of Specialist in Plastic, Aesthetic and Reconstructive Surgery or another surgical or medical-surgical speciality

whose official training programme certifies competencies in aesthetic medicine corresponding to the services included in the portfolio.

In short, the continuous and permanent physical presence of the Technical Director, or, where applicable, a substitute or deputy who meets the same training requirements as the Technical Director, will ensure that the clinical care activities and procedures provided at the healthcare centre or service are always carried out under their supervision and guidelines.

Currently, in the absence of specific regional regulations governing these centres, and in view of the actions taken by other Autonomous Communities, the possibility of authorising the provision of Aesthetic Medicine (U.48) clinical care as a healthcare service integrated into an organisation whose main activity was not health-related (C.3.1), but which could add healthcare value to the main activity of that organisation, has been accepted. Specifically, as of 9 May 2022, this type of healthcare service began to be authorised in the Region of Murcia in order to minimise the number of clandestine locations where medical-aesthetic treatments were being carried out. In such cases, the only health activity permitted in this type of centre would be that carried out by the aesthetic medical service, which would be considered complementary to the organisation's main activity and could not under any circumstances have commercial use as its purpose.

Experience during this time has led us to reconsider this interpretation, bearing in mind that Aesthetic Medicine should be considered a medical act that requires clinical conditions, qualified professionals and specific health authorisation. Allowing this practice in individual premises within hairdressing salons, beauty salons, etc., is causing a proliferation of these centres and a trivialisation of the medical act, where the population now trusts social networks as much as doctors when it comes to information. Furthermore, Royal Decree 1277/2003 of 10 October 2003, which establishes the general bases for the authorisation of healthcare centres, services and establishments, defines *Health services integrated into a non-health organisation C.3.1.* as services that perform health activities but are integrated into organisations whose main activity is not healthcare-related (prisons, companies, spas, retirement homes, etc.), and therefore do not fit the interpretation of a non-health organisation as defined by the Royal Decree.

On the other hand, it is important to note that this generalisation of Aesthetic Medicine units within non-healthcare organisations has led to a significant reduction in medical care in these centres in recent years, in many cases limited to the occasional hiring of a physician who was present only on a part-time basis and sometimes for just two or three hours a week. This undermines the significance and concept of Aesthetic Medicine units, which are configured as clinical care units in which a doctor is responsible for performing non-surgical medical treatments in accordance with basic state regulations.

In view of the above and in application of the principles of healthcare safety, protection of public health and quality assurance in the provision of healthcare, this regulation will establish that medico-aesthetic treatments must only be carried out in authorised healthcare centres, under the continuous responsibility of at least one medical professional who is responsible for and supervises the clinical care work carried out in a healthcare centre, thus excluding it from being carried out in hairdressing salons, beauty institutes, unauthorised aesthetic centres or any other establishment that does not have the corresponding health authorisation.

The total number of centres authorised under classification C.3.1 since 9 May 2022 has been 32, with a total of 29 centres having been reclassified in the renewals of previously authorised C.2.1 (medical consultation) centres. In view of the above, some 61 centres currently authorised would be subject to the transitional arrangements laid down in the first transitional provision in order to bring them into line with the provisions of the enacting terms of the legislation.

All of this is done with the aim of guaranteeing and strengthening the quality of clinical care provided in these healthcare centres, which must have their own identity and substance, separate from any other activity, and ensuring the continuity of the healthcare services provided, as well as the management and safekeeping of medical records.

Approval of the project does not entail the creation of new bodies or administrative units.

Furthermore, the draft does not contain any procedural regulations, as its content focuses on establishing technical requirements for materials and personnel, since the authorisations referred to are already required by current state and regional regulations. Consequently, there is no obligation to create or modify a procedure within the CARM's Guide to Procedures and Services.

### **3.2 Legal analysis.**

#### **1. Competence of the Autonomous Community of the Region of Murcia to approve the provision.**

The Region of Murcia has, by virtue of Article 11(1) of the Statute of Autonomy, approved by Organic Law 4/1982 of 9 June 1982, the power to develop legislation and implement measures in the areas of health, hygiene, pharmaceutical regulation and hospital coordination in general, including Social Security, without prejudice to the provisions of Article 149(1)(16) of the Constitution.

The Regional Ministry of Health is the department of the Autonomous Community of the Region of Murcia responsible for proposing, developing and implementing

the general guidelines of the Governing Council in the following areas: health, hygiene, pharmaceutical regulation and hospital coordination in general, including that of the Social Security system; drug addiction; the competence of execution in matters of pharmaceutical products and the management of clinical care provision legally attributed to the Autonomous Community of the Region of Murcia, and any other functions assigned to it by current legislation.

## 2. Relationship with **higher-ranking regulations**.

Article 6 of Law 4/1994 of 26 July 1994, on Health in the Region of Murcia, attributed to the head of the Regional Ministry of Health the granting of administrative authorisations of a health nature, as well as the cataloguing, accreditation and maintenance of the registers established by the legal provisions in force, and in its final provision, authorised the Governing Council to issue any provisions it deemed necessary for the execution and development thereof.

Government Council Decree No 349/2023 of 28 September 2023 establishing the governing bodies of the Regional Ministry of Health, determines that the General Secretariat shall, in turn, assume the powers and functions corresponding to the Health Services Inspectorate in relation to the inspection of healthcare centres, services and establishments.

For its part, the Directorate-General for Health Planning, Pharmacy and Research is responsible for the health management of clinical care resources, including the authorisation, registration and accreditation of healthcare centres, services and establishments, and also exercises responsibility for the organisation of healthcare professions, including the accreditation of professionals, entities and training activities.

In view of the above-mentioned competences in the field of health, Decree No 73/2004 of 2 July 2004 regulating the procedure for the health authorisation of healthcare centres, establishments and services and the register of regional healthcare resources was adopted. Likewise, Article 67 of Law 3/2009 on the rights and duties of users of the healthcare system in the Region of Murcia stipulates that the competent Regional Ministry for health must ensure that healthcare centres, services and establishments in the Region of Murcia meet the technical requirements demanded by state and regional regulations according to their classification, and must be authorised and registered in the Register of Regional Healthcare Resources.

3. **Consistency and alignment** with the rest of the legal system and rules from which it derives.

In compliance with the provisions of Article 29(1) of Law 14/1986 of 25 April 1986 on General Health, and Article 27(3) of Law 16/2003 of 28 May 2003 on the cohesion and quality of the National Health System, Royal Decree 1277/2003 of 10 October 2003 was approved, establishing the general bases for the authorisation of healthcare centres, services and establishments.

This Royal Decree regulates the general bases for authorising healthcare centres, services and establishments, and creates the General Register of Healthcare Centres, Services and Establishments, in which the authorisations, modifications, and notifications issued by the autonomous communities in matters of healthcare authorisation are recorded. Annex I sets out the classification of such health centres, services and establishments and Annex II sets out the definitions of health centres, clinical care units and establishments.

These regulations broadly define healthcare centres as organised sets of technical resources and facilities in which qualified professionals, by virtue of their official certification or professional authorisation, primarily carry out healthcare activities with the aim of improving people's health. Healthcare centres may comprise one or more healthcare services, which constitute their clinical care offering.

In turn, Royal Decree 1277/2003 of 10 October 2003 defines a health service as 'a clinical care unit, with a distinct organisation, equipped with the technical resources and qualified professionals, by virtue of their official qualification or professional authorisation, to carry out specific healthcare activities'. Annex II of the aforementioned Royal Decree defines the healthcare service or clinical care unit U.48 (Aesthetic Medicine) as the clinical care unit in which a doctor is responsible for carrying out non-surgical treatments aimed at improving bodily or facial appearance.

4. **Justification** of the formal status and competence of the body seeking to adopt the regulation and its relationship with the European Union.

The adoption of the proposed legislation is regulatory in nature and is therefore the responsibility of the Governing Council, in accordance with Article 32(1) of the Statute of Autonomy of the Region of Murcia and Article 22(12) and 52(1) of Law 6/2004 of 28 December 2004 on the Statute of the President and the Governing Council of the Region of Murcia.

As regards its regulatory status, the regulation takes the form of a Decree of the Governing Council, in accordance with the provisions of Article 25(2) of Law 7/2004 on the Organisation and Legal Regime of the Public Administration of the Autonomous Community of the Region of Murcia.

Although it is not based on, nor directly related to, EU legislation, by virtue of its content, the draft is considered to fall within the scope of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, which requires Member States to notify the Commission of draft technical regulations before their adoption.

Therefore, the draft regulation will be sent, through the Directorate-General responsible for European Union matters and the TRIS-TBT community platform, to the community bodies to enable them to review it and for Member States to submit their comments.

5. Planned **entry into force** of the regulation, justification of the period of ***vacatio legis***, and analysis of the **transitional regime**.

The second final provision establishes a *vacatio legis* of one month from the publication of the regulation in order to give interested parties sufficient time to familiarise themselves with it.

In addition, two transitional provisions have been introduced in order to guarantee the transitional regime and facilitate the implementation of this future regulatory draft. To this end, the first transitional provision, relating to procedures for opening and transferring cases pending at the time of the draft's entry into force, provides for the possibility of obtaining conditional authorisation, on the understanding that, at the end of the one-year general adaptation period provided for in the sole additional provision, all the requirements laid down in the regulations must be met.

Similarly, in the second transitional provision, concerning procedures for renewing health operating authorisations that are pending at the time of entry into force of this regulation as well as renewals that must be requested during the adaptation period provided for in the single additional provision, it is also possible to request conditional renewal.

6. **Temporary** nature of the legislative provision.

The draft is definitive in nature, so there is no limited provision for its duration.

7. List of **repeals**.

Given that the approval of this bill would entail the implementation of the first

regulations governing this type of Medicine centre and service, its entry into force would not imply the repeal of any current provisions, which is why no such provision has been included in the final part of the decree.

8. Subsequent implementation **instruments** that must be used, such as guidelines, instructions or action plans, where applicable.

It is likely that subsequently, if necessary, some type of instruction or service order may be issued, primarily aimed at civil servants, to clarify any aspect related to the application and enforcement of the regulation.

### **3.3 Description of the Procedure.**

a) **Drafting** process of the proposed regulation by the promoting governing body.

The draft was drawn up jointly by the competent units of the Directorate-General for Planning, Pharmacy and Health Research and the Secretariat-General, taking into account the respective competences of each of these management centres with regard to health planning and authorisation and with regard to the inspection of healthcare centres, services and establishments.

b) Inclusion of the proposal in the **Annual Regulatory Plan**.

The proposal has not been included in the 2025 Annual Regulatory Plan but has been included in the 2026-May 2027 regulatory plan, as it is expected to be approved in 2026 or early 2027.

c) **Public consultations** carried out.

In order to comply with the Preliminary Public Consultation procedure in accordance with the provisions of Article 133(1) of Law 39/2015 of 1 October 2015 on the Common Administrative Procedure of Public Administrations, the Explanatory Memorandum for the draft legislation was published on CARM's Citizen Participation website so that citizens could make contributions and suggestions during the period between 22 July and 22 August 2025.

Once the publication period had ended, the Transparency Office sent a report on the results to the Secretariat-General of the Regional Ministry of Health, showing that there had been 20 individual contributions and 3 contributions from institutions, with a total of 90 contributions. In this report, various positions of a general nature are highlighted depending on the sector concerned.

Some opinions consider it appropriate to approve a regulation governing the technical and health requirements of these healthcare centres and services, while

others, particularly in the field of nursing, argue that it should be the State that regulates this matter and that, in any event, nursing professionals are fully qualified to perform this aesthetic activity. Contributions have also been made by the Official College of Psychology, which also reflects the importance of regulations preventing practices that may contribute to body image disorders and suggest that it would be good to establish psychological assessment protocols prior to invasive or repeated procedures in vulnerable patients.

Similarly, through the electronic headquarters and also the specific corporate email address for health matters for the submission of comments during the public consultation phase, written contributions have also been received from the Spanish Society of Aesthetic Medicine, the Spanish Society of Dermo-Aesthetic Nursing, and some 15 individual contributions from professionals belonging to this Society in the field of nursing.

**d) Public consultation and public information procedure..**

Since the legislation affects the rights and legitimate interests of individuals, a general hearing process has been held over a period of 15 days, through the publication of a draft and this Regulatory Impact Analysis Report (MAIN) document on the CARM Citizens' Participation Portal on the MurciaSalud healthcare portal, as well as the corresponding announcement in the Official Journal of Murcia (BORM) published on 20 November 2020 informing them of the start of this procedure.

The opinions of entities or organisations recognised by law, whose rights or legitimate interests are affected by the legislation and whose aims are directly related to its subject matter, has also been sought on a case-by-case basis, specifically from the following stakeholders:

<b>ORAL SUBMISSIONS</b>	
<b>INTERESTED PARTIES</b>	<b>CONTRIBUTIONS</b>
Official College of Physicians	YES
Official College of Nursing	YES
Official College of Psychologists	
Order of Pharmacists	YES
Spanish Society of Dermo-aesthetic Nursing (SEED)	YES
Spanish Society of Aesthetic Medicine (SEME)	YES
Spanish Society of Plastic and Reconstructive Surgery (SECPRE)	
Spanish Society of Cosmetic Surgery (SECE)	

Spanish Society of Facial Plastic Surgery (SECPF)	
Murcia Union of Hospitals and Clinics	YES
Regional Confederation of Employers' Organisations of Murcia (CROEM)	
University of Murcia (UMU)	YES
Catholic University of Murcia (UCAM)	
<b>OTHER:</b>	
Official College of Dentists and others	YES
Madrid and National Society of Dermo-Aesthetic Nurses (SECUDEM)	YES
Individual submission of donation by CGM and two others	YES

**Analysis and brief assessment of the arguments presented during the public consultation procedure.**

Numerous written submissions containing comments and observations have been submitted by various stakeholders, as well as from private individuals. Next, a brief analysis of the comments made on the draft Decree is provided, along with a brief assessment of them, mentioning the submissions that are considered and included in the draft and those that are not, with an indication of the reason.

**1. University of Murcia.**

A drafting observation is made relating to Article 12(2), considering that, because of its content, it should be included in Article 11, which is the specific provision dedicated to minors. This contribution has been accepted and paragraph 2 has been incorporated into Article 11.

**2. Murcia Union of Hospitals and Clinics.**

They make a specific comment on Article 18(2) of the draft, concerning technical management, requesting that the following alternative wording be introduced: 'The Aesthetic Medicine activities and procedures carried out in the healthcare centre or service must be performed under the physical, continuous and permanent presence of the Technical Director...', considering that Aesthetic Medicine units may not practise this speciality during their entire opening hours, as they also carry out commercial or administrative activities. The important thing is that the technical director is present while these activities are carried out.

The proposed contribution is partially taken into account and, in view of it, the wording of Article 18(2) has been amended accordingly, by including at the beginning of the provision the expression 'Aesthetic Medicine activities and procedures' and also another specific clause to refer to the fact that the presence of the Technical Director will be required in the Aesthetic Medicine centre or service 'throughout the entire time during which clinical care activities and services are carried out'.

### 3. Official College of Physicians.

They submit a statement of comments in which they request only the inclusion of a second paragraph in Article 2, with the following wording:

'Procedures for Aesthetic Medicine, including those requiring medical devices, medicines, energy devices, invasive techniques or any intervention with a biological effect, are medical acts and must be carried out exclusively by medical professionals with accredited training in Aesthetic Medicine'.

All this is done with the aim of clearly defining medical acts, protecting patient health and safety, preventing unauthorised practice, and ensuring regulatory consistency.

This observation has not been accepted, since the proposed paragraph would entail the inclusion of a definition and precision of the aesthetic medicine procedures and, by extension, a delimitation of the competences attributed to these physicians, which in no way falls within the remit of this Regional Ministry of Health.

In this regard, it should be noted that neither the regulation of healthcare professions nor the definition of their competences or scope of activity can be established in this general provision. That definition or delimitation should, in any event, take the form of a legal provision and, moreover, could only be carried out by the General State Administration and not by the Autonomous Community of the Region of Murcia, which lacks competence in this matter.

### 4. Spanish Society of Aesthetic Medicine (SEME).

First, they express their gratitude for the initiative to regulate these healthcare centres, while also making certain specific comments on the provisions. With regard to the suggestion made in Article 3(3) to include a specific reference to Royal Decree 192/2023 of 21 March 2023, regulating medical devices, this suggestion has been accepted in order to complete the list of provisions whose application is required in these cases.

In relation to Article 4, they request the inclusion of an additional clause to add that 'Aesthetic Medicine treatments that penetrate beyond the corneal layer of the skin or that are intended to have a biological effect at a greater depth shall be included'. However, this will not be included; indeed there is even an intention to

remove the last paragraph of Article 4(1), for the reason explained in the previous justification, specifically that this decree cannot define or delimit the powers and competences corresponding to a particular profession.

As regards the facilities in the Clinical Area and in particular the examination and treatment area, it is proposed in Article 8(2)(e) that the disinfection system be provided by means of a sanitisation system or sinks, but not both. This proposal has been accepted and the wording of this paragraph has indeed been amended.

With regard to Article 18(7), which mentions other healthcare professionals, the SEME reaffirms that in U.48 units, the doctor is always responsible for performing these non-surgical treatments, with the aim of improving body or facial aesthetics, and therefore these treatments must always be carried out by a doctor. On this point, the decree clearly defines what is meant by Aesthetic Medicine centres or services, reproducing verbatim the definition contained in Annex II of Royal Decree 1277/2003 of 10 October 2003, which establishes the general bases for the authorisation of healthcare centres, services and establishments located in the Region of Murcia, but this does not prevent other healthcare or non-healthcare professionals from performing certain activities or tasks in these centres that are in accordance with their professional qualifications and training.

Furthermore, they consider that it would be appropriate for the change in technical direction to be communicated either by the outgoing technical director or by the owners, and that this should be published on the website for reasons of transparency. This request has been accepted.

Finally, with regard to additional training of medical staff, the inclusion of a third transitional provision is proposed, with the following wording:

'Medical staff of the Aesthetic Medicine centre or service who, at the time this Order enters into force, are working and do not have the additional specific training of a 'Master's degree in Aesthetic Medicine and/or Tricology' shall have a period of three years to obtain the training regulated in Article 18.

Notwithstanding the provisions of the preceding paragraph, the requirement for specific supplementary training shall not apply to medical personnel who have been working in authorised Aesthetic Medicine centres and registered in the registers of authorisation of health centres, services and establishments of the state or autonomous communities, continuously for at least the five years prior to the date of entry into force of this order.'

This provision has not been included because in recent years, such specific complementary training has already been required de facto for the authorisation of these health centres or services, meaning that there are currently no authorised health centres or services whose technical director does not have the training required under this draft.

## 5. Official College of Pharmacists.

This Professional Body proposes two specific amendments to the provisions. Specifically, in relation to Article 15(1), concerning botulinum toxin, they propose in paragraph d) the removal of the wording relating to the person responsible for the shipment, replacing it with the manager of the pharmacy. This suggestion has been accepted.

In paragraph (e) of the same article, they propose adding the following subparagraph at the end of this point: 'will always be available to the manager of the pharmacy to which the medicine storage facility is linked.'. This inclusion has also been accepted.

Finally, in relation to Article 22, concerning inspections, it is proposed to add a final clause and paragraph to refer to cases where the inspection affects medicine storage facilities, with the following wording: When the inspection concerns the medicine storage facility, the manager of the pharmacy linked to the storage facility in that clinic must be convened from the outset. Any incident detected, requirement or other matter concerning the storage of medicines must be notified simultaneously to the owner(s) of the Aesthetic Medicine centre and service and to the manager of the pharmacy, so that they can provide the necessary information or remedy the deficiency. This contribution has been accepted, albeit as a separate paragraph and with minor adjustments to the drafting.

## 6. General Council of Official Colleges of Nursing of Spain.

First, the statement of comments submitted, after indicating that the present draft is based on the General Health Law, the Law on cohesion and quality of the National Health System and Royal Decree 1277/2003 of 10 October 2003 which establishes the general bases on the authorisation of healthcare centres, services and establishments, focuses its presentation on analysing the scope of the provision that is intended to be approved and its regulatory value.

Specifically, it is stated that neither of the two laws cited, nor the Royal Decree, contains a delimitation or determination of the competences attributed to the various healthcare professions and, in that regard, they highlight the content of Article 36 of the Spanish Constitution, which provides that 'the law shall regulate the specific features of the legal regime of professional associations and the exercise of the regulated professions', which means that the attribution of competences to the various regulated professions must take the form of a provision of statutory rank. This has been endorsed both by the case-law of the Constitutional Court and the Supreme Court.

Therefore, this draft decree cannot under any circumstances attribute professional competences to any healthcare profession, nor exclude such competences from other healthcare professionals. Consequently, since the decree cannot affect limiting or restrictive aspects of professional practice and in order to avoid misinterpretations, it is considered necessary to include an explanatory paragraph in the explanatory memorandum stating that the provisions of the decree do not imply the attribution of professional competences in the healthcare field nor do they constitute a means of excluding other healthcare professions, since in that case the decree would be null and void.

In this sense, they must affirm that the draft regulation must respect the competences of nursing professionals. Therefore, its content must be understood as being limited to the regulation of U.48 Aesthetic Medicine, but without this precluding the existence and provision of authorisation for consultations by other healthcare professionals, under heading C.2.2 of Annex II of Royal Decree 1277/2003 of 10 October 2003, which covers the existence of nursing consultations and the authorisation of clinical care unit U.2, in which nursing staff are responsible for performing the functions and activities specific to their qualification in all areas covered by nursing care in accordance with the applicable regulations, including therefore the field of dermo-aesthetic care.

Endorsing all this, it lists a set of provisions, both legal and regulatory, as well as judgments, including those in the criminal field that protect nursing competence in different areas and their autonomy of action. Among these, particular mention should be made of Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022, which establishes common specifications for groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. Although it is not, strictly speaking, a regulation assigning professional competences, its provisions and annexes contain various requirements concerning certain products which, for safety reasons, are indicated as only to be used by doctors, while other products are referred to as being for use by other healthcare professionals in a safe healthcare environment. This includes certain products in the field of dermo-aesthetics that are listed in Annex XVI of the aforementioned EU Regulation, which includes a list of groups of medicines without an intended medical purpose, many of which are in the field of dermo-aesthetics.

For all of these reasons, it concludes its general position, stating that 'the draft Decree cannot seek or pursue a restrictive and exclusive approach, but must provide for and enable the offering of any nursing consultation in which nursing care is to be carried out in the field of dermo-aesthetics and well-being, as well as the obtaining of the corresponding administrative authorisation in accordance with Royal Decree 1277/2003 of 10 October 2003 establishing the general framework for the authorisation of healthcare centres, services and establishments'.

With regard to these general considerations, it should be noted that the draft regulation is limited to specifying the technical and healthcare requirements that healthcare centres or services offering U.48 must meet in order to obtain health authorisation and, in no way, enters into the realms of defining or delimiting the scope of competence and functions of the various health professions, nor does it specify the attribution of competence for the different treatments that may be carried out in the general field of aesthetics, because a regional regulatory provision certainly cannot regulate these issues.

In conclusion, the regulation of the healthcare requirements for a specific clinical care offering does not affect or predetermine the regulation of other healthcare services or the type of healthcare centres or services that, in accordance with Royal Decree 1277/2003 of 10 October 2003 which establishes the general bases for the authorisation of healthcare centres, services and establishments, may be subject to healthcare authorisation. Therefore, the draft does not affect nurses' competences, nor does it limit or restrict the possibility of authorising other types of healthcare consultations or centres listed in state regulations.

These statements must be understood as implicit in the content and context of the draft regulation. Notwithstanding the foregoing, in view of the interpretative doubts raised, an amendment is included in the explanatory section of the decree, as requested by the General Council and other stakeholders. Specifically, the wording of the penultimate paragraph of the preamble has been amended in order to clarify the scope of the decree to be approved, and now reads as follows:

'For all these reasons, it is considered necessary to approve specific regulations governing the technical and health-related conditions and requirements applicable to Aesthetic Medicine Clinical Care Units, with a view to clarifying and specifying the material and human resources that these clinical care units must possess in order to be authorised and to provide certain services or procedures, so as to safeguard the quality of healthcare and the safety of patients treated at these healthcare centres and services, without prejudice to the powers and responsibilities which, in accordance with the applicable regulations, correspond to the various healthcare professions.'

In addition to these general considerations, the statement of comments sets out a series of specific proposals for the articles that contribute to confirming the statements made in its general considerations.

1. Specifically, the inclusion of a specific paragraph in the explanatory memorandum of the draft is requested, with the following wording: 'The purpose of this Decree is not to establish or delimit professional competences or to exclude any healthcare group from the exercise of a profession, since its content is without prejudice to the professional functions and competences laid down by the legislation in force for the exercise of the healthcare professions and the pursuit of the corresponding professional activities.'

This provision has been incorporated in the explanatory memorandum with the alternative wording set out above.

2. Similarly, they propose including in Article 2 the wording 'within the scope of their competences' in order to reference the definition to the specific scope of medical competences.

This observation has not been accepted because Article 2 corresponds verbatim to the definition contained in Annex II of the Royal Decree, and it is therefore not possible to introduce modifications.

3. They also propose the deletion of Article 3(3) of the draft, since its content is completely alien to the purpose of the future Decree and has a direct impact on a matter reserved for legislation with the status of a law, since it deals with both the prescription and the indication or even the application of treatments of professional skills that are regulated.

The reference to the application of the set of rules in force regarding medicines and medical devices is included solely for the purpose of providing a guarantee for patients, it being obvious that in any case these rules will apply in all relevant cases. Therefore, the paragraph is maintained, although the introductory wording is modified slightly to limit the scope of application of the regulation to centres and services of Aesthetic Medicine.

4. In Article 4(1), they request the removal of the final paragraph referring to certain treatments, on the grounds that determining which types of treatments fall within the scope of Aesthetic Medicine constitutes a regulation of the profession and must therefore be verified by means of a provision of statutory rank.

The observation is noted and the final clause is deleted for the reasons stated above.

5. In Article 10, they also call for the inclusion of the following paragraph: 'In any event, the list of services and procedures included in this Article does not constitute any regulation conferring exclusive professional competences, but is limited to the establishment of specific requirements for the functioning of those services and procedures', with a view to clarifying and avoiding interpretations that would support exclusive competence in relation to certain treatments. The inclusion of this same provision is also requested in respect of Article 15 for the same reason.

The inclusion of this clause in Article 10 or 15 is not considered necessary, as the incorporation of a specific section in the explanatory memorandum sufficiently covers the intent of the draft's content, and it is not considered necessary to introduce specific clarifications throughout the article.

6. In Article 12(3), the replacement of the term 'physician' with that of 'doctor' is requested.

This request has been accepted.

7. In Article 17(1)(f) it is proposed to include in its wording the phrase '...and their respective professional competences recognised by the applicable regulations, not being able to', in order to refer to all professional competences.

This observation is taken into account.

8. Similarly, in section 4 of Article 18, they also request a clarification through the inclusion of various clauses, the final wording of which should be as follows: '4. The healthcare centres and services covered by this Decree must have sufficient healthcare personnel to ensure their proper functioning, who shall exercise the professional competences recognised by current regulations in relation to the services offered by the Aesthetic Medicine healthcare centre or service. These healthcare professionals must be registered as practising professionals and have professional liability insurance that covers their professional activities in the exercise of their duties.'

A reference to membership of a professional association is included.

Finally, they indicate that the mention of medical supervision for the use of laser equipment may be contrary to the provisions of Annex IV of the European Commission's Implementing Regulation (EU) 2022/2346 of 1 December 2022, which allows healthcare personnel such as nurses to use it with full autonomy, which is why the draft should be revised.

With regard to laser equipment, there is no mention of medical supervision, without prejudice to the fact that ultimately the technical director of these centres is responsible for the operation and development of the clinical care procedures offered by the centre.

#### 7. Madrid and National Society of Dermo-Aesthetic Nurses.

Firstly, they point out that the observations made are primarily in light of Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.

In this regard, they state that the regional draft, through its Article 4(1), seeks to regulate, limit or condition the professional competences specific to nursing. Thus, they understand that the definition contained in Article 4(1) may operate as an exclusionary criterion with respect to nursing competences, which would be unlawful as it would constitute a regulatory overreach into matters that must be governed by a provision of statutory rank. All of this goes beyond the purpose of the decree, which is to regulate the technical and health requirements of centres offering U.48 clinical care, and to support this, they refer to certain provisions of Law 44/2003 of 21 November 2003, on the regulation of healthcare professions and in Royal Decree 1277/2003 of 10 October 2003, which expressly states that its purpose is not to regulate healthcare professions or limit the activities of professionals. They also cite a number of judicial rulings that reaffirm the principle that the determination or restriction of professional competences is subject to a statutory reservation.

In line with this, they also state that nursing professionals are competent to administer hyaluronic acid injections as part of their professional practice, pointing

out that there is no criminal case law condemning this practice and that this position is primarily based on Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022, which lays down common specifications for groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council. In Annex IV of that Regulation, reference is made to these substances, indicating, among other aspects, that their administration is not restricted to medical practitioners but extends to other healthcare professionals, with specific mention of physicians only in cases where adverse effects occur and must be reported. This European Union law takes precedence over national legislation.

All of the above has been ratified by the Public Prosecutor's Office in a case of professional intrusion and also in a recent ruling by a criminal court in Madrid that acquitted professional nurses of professional intrusion for administering this substance. They also convey the opinion and position of the General Council of Nursing in defence of nursing competencies.

With regard to this statement of comments, which is essentially the same as those submitted by the General Council of Nursing and other scientific societies and professional healthcare bodies, it is only necessary to reiterate what has already been stated in the sense that it is not the intention of the draft legislation to delimit professional competences or to allocate competences for certain treatments to a specific health profession, since this would go beyond the remit of this Autonomous Community. For this reason, an express explanatory mention has been introduced in the explanatory memorandum, together with an amendment to the opening wording of Article 4(1) of the draft in order to delimit its content as well as the deletion of the definition contained in the final clause of this paragraph, as has been shown above in relation to the assessment of the comments submitted by the General Council of Official Colleges of Nursing.

#### **8. Official College of Nursing of the Region of Murcia.**

In its statement of comments, it is generally asserted that matters of such importance should be regulated by consensus at the state level. Furthermore, recognising that the purpose of the decree is unrelated to the nursing profession, we would point out below that the Ministry's intention is to exclude Dermo-aesthetic Nursing Consultations that fit into the U2 clinical care offering, which would be contrary to the legislation.

For all these reasons, they request, in a general and non-specific manner, the repeal or reform of a series of provisions in the draft, specifically Articles 4(1), 5(3), 10, 15(2) and 18(7), and, in turn, they point out the advisability of preparing another draft to regulate the powers and competences of nurses or a U2 nursing consultations.

In response to these requests, the assessments and considerations made in relation to the previous written submissions by the General Council of Official Colleges of Nursing are also deemed to have been reproduced, as they

substantially coincide with them.

#### 9. Official College of Dentists.

This Professional Body states that although the purpose of the submitted project does not directly affect the field of dental professionals, it does consider it appropriate that, in view of its content and in order to avoid misinterpretations, certain sections or clauses be included to clarify its scope and safeguard the professional powers of other healthcare professions, as recognised in the preamble to Royal Decree 1277/2003 of 10 October 2003, which establishes the general bases for the authorisation of healthcare centres, services and establishments.

In this regard, it is requested that a section with the following wording be added to the explanatory memorandum of the draft: 'The purpose of this Decree is not to establish or delimit professional functions or to exclude any healthcare group from the exercise of a profession, since its content is without prejudice to the professional functions and competences laid down by the legislation in force for the exercise of the healthcare professions and the pursuit of the corresponding professional activities.'

Along the same lines, they also request the addition of a final paragraph to Article 10 to clarify that the list of services and procedures set out in the decree does not constitute an exclusive attribution of professional competences but the establishment of specific requirements for the operation of these healthcare centres.

Likewise, in Article 17(1)(f), they propose the inclusion of a further safeguarding clause, so that the provision would read as follows: '(f)... with the activity carried out and their respective professional competences as recognised by the applicable legislation, and may not have workers who carry out the activities specific to a profession without the corresponding healthcare qualification'.

Finally, it is also proposed that the wording of Article 18(4) be amended to read as follows: '4. The healthcare centres and services covered by this Decree must have sufficient healthcare personnel to ensure their proper functioning, who shall exercise the professional competences recognised by current regulations in relation to the services offered by the Aesthetic Medicine healthcare centre or service. These healthcare professionals must be registered as practising professionals and have professional liability insurance that covers their professional activities in the exercise of their duties.'

In relation to these observations, which essentially focus on the same line of argument put forward by the professional nursing sector, it is reiterated that the sole purpose of the draft decree is to specify the technical and health requirements for healthcare centres and services that intend to offer U.48 Aesthetic Medicine clinical care, as provided for in Royal Decree 1277/2003 of 10 October 2003, which establishes the general bases for the authorisation of healthcare centres, services and establishments, both for the purposes of their healthcare authorisation and

registration and for the provision of certain treatments or services. As previously stated with regard to the reports submitted by other professional groups, this does not in any way affect the definition or delimitation of the powers, functions and competences which, in accordance with the applicable regulations, correspond to the different healthcare professions, or the types of treatments that each of them may perform. For this reason, a clarifying clause has been included in the explanatory memorandum.

On the contrary, no such clause is included in Article 10, on the understanding that this provision is already sufficiently implicit in the wording added to the explanatory memorandum, but it is included in Article 18(1)(f) because it helps to complete and improve the paragraph. The requirement professional registration (membership of a professional body), where applicable, has also been accepted.

#### **10. Individual submissions.**

Finally, submissions have also been made by Mr. Carlos Martínez Galera, on behalf of himself and two other officials of the Inspection Service for Healthcare Centres, Services and Establishments of the Regional Ministry of Health, consisting of predominantly technical comments on certain provisions of the draft.

The comment made in relation to Article 5(4) has been taken into account and the name 'multipurpose centre' has therefore been corrected.

In relation to paragraphs 1 and 3 of Article 7 and Article 8, which are considered overly stringent in terms of 'separation from the rest', the requirement for 'smooth' surfaces and the dual hygiene system, the final subparagraph of Article 7(1) has been deleted, the word "rest" has been removed from Article 8, and the dual hygiene system requirement has been clarified. However, the requirement for smooth materials for floors and walls has been retained for reasons of public health. The substantive requirements of Articles 9 and 10 have also been maintained.

With regard to the observation concerning minors provided for in Articles 11 and 12, the previously stated intention regarding the inclusion of paragraph 2 of the latter Article in Article 11 is reiterated in order to ensure consistency.

With regard to medical records, a clarifying point is included in Article 13(1), but no specific regulation is made in this article regarding the destination and custody of medical records, as these aspects should not be regulated specifically and separately for a particular type of healthcare service. Rather, the regulatory development of medical records should be addressed in general terms for all healthcare centres and services.

The procedures relating to hyaluronidase contained in the draft decree have been reviewed and deemed appropriate and in accordance with the law.

Article 18 calls for a review of training but does not state how this should be done. Finally, Article 23(f) requests that the content of Decree 15/2008, which approves the regulations for the inspection of healthcare services, be reproduced. This is not accepted on the grounds that it would be an unnecessary reproduction,

since Article 22 of the draft contains an express reference to the application of said decree, which would, in any case, be applicable.

#### Other Procedures.

The text and the Regulatory Impact Analysis Report were also sent to the Regional Ministries of Economy, Finance, European Funds and Digital Transformation, the Presidency, Spokesperson, External Action and Emergencies; and Enterprise, Employment and the Social Economy.

Likewise, for the purposes of complying with Directive 2015/1535 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, the draft legislation, this Regulatory Impact Analysis Report (MAIN) and the necessary documentation are submitted to the Directorate-General of the European Union of the Regional Ministry of the Presidency, Spokesperson, External Action and Emergencies so that it is the subject of the corresponding notification at the level of the European Union through the TRIS-TBT platform, so that, where appropriate, the different Member States may examine the draft and submit comments.

#### **e) Mandatory and optional reports requested.**

Likewise, the draft regulations have been submitted to the following collegiate bodies, both of which have issued favourable reports:

- Health Council of the Region of Murcia (in accordance with the provisions of Article 11 of Law 4/1994 of 26 July 1994 on Health in the Region of Murcia).
- Regional Advisory Council for Consumer Affairs (Article 17 of Law 4/1996 of 14 June 1996 on the Statute for Consumers and Users of the Region of Murcia (as amended by Law 1/2008 and Law 10/2016)

Finally, the regulation must at least be subject to a mandatory report from the following bodies:

- Mandatory legal report from the Deputy Secretary of the Regional Ministry of Health (in accordance with Article 53(2) of Law 6/2004 of 28 December 2004, on the Statute of the President and Governing Council of the Region of Murcia).
- Directorate of Legal Services of the Autonomous Community of the Region of Murcia (in accordance with Article 7(1)(f) of Law 4/2004 of 22 October 2004 on legal assistance of the Autonomous Community of the Region of Murcia.)
- Legal Council of the Region of Murcia (in accordance with Article 12(5) of Law 2/1997 of 19 May 1997 on the Legal Council of the Region of Murcia)

#### **4. NOTIFICATION OF ADMINISTRATIVE BURDENS.**

The draft regulation aims to establish new technical and health requirements for optical establishments located in the Region of Murcia. The regulation does not entail any administrative burdens, as it is a draft regulation that does not regulate a specific procedure, even though it refers to the authorisation of these health centres, which is required under basic state legislation (General Health Law) and is regulated by state and regional provisions, specifically by Royal Decree 1277/2003 of 10 October 2003, which establishes the general bases for the authorisation of healthcare centres, services and establishments, and Regional Decree No 73/2004 of 2 July 2004, which regulates the procedure for the health authorisation of healthcare centres, establishments and services and the registration of regional resources.

#### **5. BUDGETARY IMPACT REPORT.**

##### **5.1. Impact of the draft regulation on the budget of the promoting department.**

- a) From a budgetary point of view, there is no additional economic impact or cost for the budget of the Regional Ministry of Health, the Directorate-General for Planning, Pharmacy and Health Research or the General Secretariat, since these Management Centres will comply with the provisions of the regulation as part of the exercise of their powers, using the financial and human resources currently available to them.
- b) Identification of Budgetary Items:
  - Programme 413E – Healthcare Management.
  - Programme 413G – ‘Inspection of Health Services’.
- (c) Quantification of income and expenditure or, failing that, justification of the impossibility of quantifying the impact.

The competent units of the Regional Ministry of Health have issued a budgetary report which states, inter alia, the following:

The Directorate-General for Planning, Pharmacy and Health Research has provided a forecast of income and expenditure for the implementation of the Decree regulating the technical and health requirements for Aesthetic Medicine healthcare centres and

services in the Region of Murcia, by means of a supporting report dated 23 September 2025 from the Head of the Department of Healthcare Planning, Accreditation and Quality of Clinical Care and the Head of the Inspection Service for Healthcare Centres, Services and Establishments.

In terms of revenue, this administrative procedure will primarily be subject to fees; however, other revenue is also expected from possible sanctioning proceedings arising from ex officio inspections.

	No of centres/year	Fee or sanction per centre	Total Revenue Forecast
Applications for healthcare authorisation	80	285,75 €	22.860,00 €
Applications for renewal of the healthcare authorisation	30	171,45 €	5.143,50 €
Possible sanctioning proceedings arising from ex officio inspections	20	Min 1.200 € - Max 9.000 €	Min 24.000 € - Max 180.000 €

Based on historical data and current amounts, the table above shows the possible number of applications and sanctioning proceedings, which would result in a total annual revenue forecast of between EUR 52 000 minimum and EUR 208 000 maximum.

In terms of costs, the forecast amounts to the following sum, with no additional financial impact on the Regional Ministry of Health, as compliance will be ensured using the existing financial and human resources currently available:

<b>Programme 413E – Healthcare Planning</b>	<b>Amount</b>
CHAPTER 1 – Personnel expenditure	1.290,00
CHAPTER 2 – Current expenditure on goods and services	344,00
<b>Programme 413G – Inspection of Health Services</b>	
CHAPTER 1 – Personnel expenditure	10.900,00
CHAPTER 2 – Current expenditure on goods and services	1.780,00
<b>APPROXIMATE EXPENDITURE SUMMARY BY CHAPTER</b>	
<b>TOTAL CHAPTER 1 – Personnel expenditure</b>	<b>12.190,00</b>
<b>TOTAL CHAPTER 2 – Current expenditure on goods and services</b>	<b>2.124,00</b>
<b>ESTIMATED EXPECTED COST</b>	<b>14.314,00</b>

**5.2. Impact of the draft regulation on the budgets of other departments, entities or agencies, other than the promoter.**

It does not affect other departments or public bodies.

### **5.3. Impact of the draft regulation on the budgets of local authorities within the scope of the CARM.**

It has no impact, since the legislation does not affect or regulate matters relating directly or indirectly to the administrative sphere of local authorities.

### **5.4 Is there community co-financing?**

It has no impact.

### **5.5 Is this a budgetary impact that affects the public deficit?**

It has no impact on the public deficit.

### **5.6 Repercussions and effects on budgetary stability and financial sustainability.**

There are none.

### **5.7 Does the regulatory draft generate revenue?**

As stated in section 1, the implementation of the draft involves certain regulation revenue-raising effects that are already routinely generated as a result of the fees charged for health authorisations and renewal of authorisations, as well as for official inspections carried out and possible penalties arising from control measures.

With regard to material and human resources, no additional resources are envisaged, so there is no need to assess their cost or to consider additional staffing.

## **6. ECONOMIC IMPACT REPORT.**

### **6.1 Impact or regulation of future legislation affecting an economic sector or activity. If not, indicate the indirect economic impact that the adoption of the regulation will have on the economy or on a sector of activity.**

The draft legislation regulates and specifies the healthcare requirements, functional and organisational conditions, as well as the minimum structure, facilities and equipment that, according to the portfolio and clinical care services offered, must be met by Aesthetic Medicine centres or services. In this sense, it is logical that its

approval will have a direct economic impact on the currently authorised healthcare centres and services that will have to comply with the requirements of the future regulation within the transitional period provided for in the transitional provisions of the regulation.

In relation to this point, it is not possible to make a theoretical forecast of what this cost might be, as the specific and concrete circumstances of each of the currently authorised healthcare centres may vary considerably. In this regard, it is foreseeable that some of them will require little or no adaptation in terms of facilities and equipment, while others will need to improve or adapt them, especially with regard to differentiation and separation from any other non-healthcare-related activity.

Apart from this, with regard to the human or personnel requirements, it should be noted that the qualification requirements for the appointment of Technical Director are not substantially different from those currently required, although it should be noted that their presence will be mandatory throughout the entire time that the healthcare centre is open, unlike the current situation where it was sufficient to hire a professional, even if only for a minimum number of hours per week.

In any case, as indicated above, the establishment of stricter conditions sought by this draft is considered essential to guarantee patient safety and the quality of clinical care offered at the centre or service, regardless of whether it actually complies with the definition of these Aesthetic Medicine Units (U.48).

## **6.2 Analyse the potential impact that the regulation may have on market unity, including whether limitations are placed on the exercise of activities or provision of services, and whether it complies with the Law on the Guarantee of Market Unity.**

The draft generally complies with Law 20/2013 of 9 December 2013 on the guarantee of market unity, although the draft contains requirements regarding the exercise of this economic activity which, in any case, are considered to be the minimum necessary and proportionate to the intended purpose of patient safety and security.

Furthermore, the provisions in the final part of the draft, specifically the transitional provisions, introduce flexibility mechanisms to enable companies to adapt to the requirements contained in the regulation within a reasonable period of time.

In any event, it should be noted that the limitations provided for do not in any way imply discrimination on grounds of establishment or residence. However, for the purposes of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 establishing a procedure for the provision of information in the field of technical regulations and of rules on information society



services, which requires Member States to notify the Commission of draft technical regulations prior to their adoption, there is no intention to submit the draft to the European Union for the purposes of any Member State being able to review it and make contributions.

### **6.3 Assess the impact on the prices of goods and services, where applicable.**

The proposed regulation has no relevant or direct effect on the prices of the services offered, nor does the draft introduce applicable tariffs or prices.

### **6.4 Analyse whether it affects the productivity of goods and services.**

In principle, the proposed draft does not have a direct impact on the productivity of services, although it must guarantee the quality and safety of the services and procedures offered.

### **6.5 Effects on employment.**

It has no direct impact on employment, as it does not affect job creation or job losses. However, the qualification requirements for the Technical Director and other healthcare professionals working in the centres will require all staff to undergo continuous training in line with the range of services offered by each healthcare centre.

### **6.6 Impact on innovation.**

In so far as it lays down new rules on the technical and healthcare requirements to be met by these centres and services, adapted to the new technologies and scientific knowledge in the field of Aesthetic Medicine, it is estimated that this could have a positive impact on innovation, both in the production process and in the organisational capacity of the business.

### **6.7 Impacts on consumers.**

Given that the draft regulation seeks to establish a new framework governing the technical and healthcare requirements for Aesthetic Medicine centres and services—setting out minimum requirements in terms of space and equipment that such establishments must comply with, in order to adapt to scientific, technological and technical advances and improvements in healthcare—it is not only of interest to healthcare professionals but also, and especially, to the general public and society as a whole, as they are potential consumers of these services and can therefore enjoy and benefit from better services and products provided in this field, while also promoting a more rational and appropriate use of Aesthetic Medicine services in a much more appropriate, safe and conscious manner.

### **6.8 Effects on the economy of other States.**

Do not exist.

### **6.9 Effects on free competition.**

It does not have an effect on free competition, in the sense of restricting a certain activity on the basis of territory or residence, nor does it limit access to new operators provided that the necessary conditions are met, which apply equally to all healthcare centres authorised or wishing to be authorised.

### **6.10 Effects on SMEs. (SME TEST)**

Annex I to Commission Regulation (EU) No 651/2014 of 17 June 2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty, establishes that an SME (acronym for small and medium-sized enterprise) is defined as any entity, regardless of its legal form, that carries out an economic activity.

In particular, entities engaged in craft or other activities on an individual or family basis, as well as partnerships or associations regularly engaged in an economic activity shall be regarded as undertakings.

In the SME category, a micro-enterprise is defined as an enterprise employing fewer than 10 persons and whose annual turnover or annual balance sheet does not exceed EUR 2 million.

However, the vast majority of the aesthetic medicine centres and services that exist in the Region of Murcia, and which are known from the data contained in the Register of Regional Healthcare Resources, have the character of a micro-enterprise, both because of the service provision activity they offer in the health sector, and because of the number of employees they have.

With the current data available in this Register, it is possible to ascertain, approximately, the size of each of the registered establishments in order to know the number of workers, given that the healthcare authorisation procedure for these establishments, regulated by Decree 73/2004 of 2 July 2004, provides that the Register shall contain data on these establishments concerning the list of healthcare personnel on their staff, and the documentation contained in the authorisation files also provides information on the specific professional categories, qualifications and working arrangements, as well as the professional qualifications or professional accreditation they have, and also the public or private nature of the establishment.

Given that the draft regulation aims to establish minimum regulations regarding the technical and health requirements that these centres and services must meet, regulating issues concerning the activities they carry out, the equipment they must have, staffing requirements, the areas or spaces they must have, and aspects relating to safety and working procedures, it is fair to say that this regulation may have a direct impact on SMEs.

For the purposes of complying with the SME Test, which is required by Article 46 of Law 6/2004 of 28 December 2004, on the Statute of the President and the Governing Council, as amended by Article 37 of Law 10/2018 of 9 November 2018, on Accelerating the Transformation of the Regional Economic Model for the Generation of Stable, Quality Employment, a questionnaire is provided below that reviews the principles defined in the Commission Communication "Think Small First" ("Small Business Act for Europe" - SBA), revised in 2011, to assess the agreement and impact of the regulations or plans on these small businesses.

Each section of the questionnaire reviews the ten principles' contained in the SBA and by assessing several questions related to those principles, the extent to which the regulation or initiative is favourable (1 at best), neutral (0) or unfavourable (-1 at worst) is assessed, subdivided according to the number of issues included in each section and the overall outcome is weighted.

#### QUESTIONNAIRE:

**1. Entrepreneurship** (Developing a favourable environment for entrepreneurs, particularly women; promoting the transfer of businesses, including family businesses; entrepreneurial culture; business networking; exchange of experiences): maximum 1 point.

- Does it favour the creation of companies or self-employment? Scoring: 1

The aim of the regulation is not, of course, to promote the creation of businesses or employment, but to lay down technical and healthcare requirements that optical establishments must meet and to enable the Administration, subsequently, to know whether they comply with those requirements, through inspection and control functions. Scoring: 0

- Does it promote the continuity of family businesses? The impact of the regulation on this aspect is nil. Scoring: 0

- Does it disseminate and promote entrepreneurship? The impact of the regulation on this aspect is nil. Scoring: 0

**2. Second chance** (Rapid closure processes and feedback on starting over) maximum 1 point:

- Does it speed up the closing process for a business? Scoring: 0.
- Does it reduce the costs of closing a business? Scoring: 0
- Does it support second chances? Scoring: 0

The impact of the regulation on these aspects is nil

**3. Think small first** (so that the design of the measures does not put SMEs at a particular disadvantage compared to large businesses) maximum 1 point:

- Are regulations and processes communicated and simplified? Scoring: 0.33
- Is the regulation burdensome for SMEs? Scoring: 0.33

The technical and health requirements established in the regulation facilitate their identification and compliance by these establishments, thereby streamlining the administrative and technical management they must comply with and providing legal certainty for the operation and development of their activities. It facilitates the accreditation and submission of documentation supporting the requirements that must be met in order to be able to carry out their business activity.

**4. Responsive administration** (adaptation to the needs of SMEs and removal of administrative obstacles):

Are the time limits reduced and the company's management with the public administrations streamlined? Scoring: 0.33

Although the regulation does not regulate or set deadlines, it does lay down a series of requirements and conditions that businesses must comply with in the exercise of their activity, thereby facilitating compliance for the purposes of subsequent review and control by the Administration.

- Are the costs reduced in relations between businesses and public administrations? Scoring: 0

The regulation does not specify specific time limits or involve the use of electronic means or administrative burdens directly affecting costs incurred by businesses in their dealings with the Administration, so its impact in this respect is nil.

- Does the regulation respond to a need of the SME? Scoring: 0.5



The new regulation will allow Aesthetic Medicine healthcare centres and services to know which are the technical and health requirements that must be adhered to in accordance with the provisions of the regulatory framework of this type of company, thereby providing greater certainty in carrying out their activities and enabling them to offer improved services and clinical care to users.

**5. Public procurement and State aid** (Adaptation of instruments for SMEs): maximum 1 point

- Is public procurement with SMEs encouraged? Scoring: 0
- Does the planned aid favour SMEs? Scoring: 0
- Are the payment deadlines for contracts and/or subsidies being improved? Scoring: 0
- Are European funds being channelled to co-finance actions by SMEs? Scoring: 0
- Are the required guarantees suitable for SMEs? Scoring: 0

This regulation has no impact on public procurement, nor on the granting of public aid or subsidies, so its impact in this regard is nil. Scoring: 0

**6. Access to finance** (Resources from diversified types of finance covering the different stages of the business's life cycle) maximum 1 point:

- Does it facilitate access to finance for SMEs? Scoring: 0
- Does it provide financing for SME innovation? Scoring: 0

This regulation also has no impact on business's access to financing.

**7. Single market** (Ensuring that SMEs have access to the opportunities offered by the internal market, patent system and Community trademark, mutual recognition, etc.) maximum 1 point:

- Does it promote the growth of the SMEs' target market? This regulation has no impact in these respects. Scoring: 0
- Is the regulation related to the transposition of directives aimed at the internal market? This regulation has no impact in these respects. Scoring: 0
  
- Does it promote SMEs' access to the intra-EU market, both on the supply and demand side? Scoring: 0.50

The regulation, insofar as it establishes innovative rules on the technical and healthcare requirements that such establishments must meet, adapted to new technologies and scientific knowledge, is considered to facilitate companies' access to the market and to the supply and demand for this type of healthcare service.

**8. Skills and Innovation:** maximum 1 point.

- Does it promote cooperation between SMEs and/or the increase of their size and capabilities, as well as continuous training of personnel? Scoring: 0.5
- Are product and/or process and marketing innovations favoured over research or the incorporation of ICTs in SMEs? Scoring: 0.5

The regulation establishes certain requirements for personnel working in these healthcare centres, particularly with regard to the qualifications and certifications they must possess, which must also be adapted to new scientific or technological knowledge about the instruments, materials, or tools used in the performance of their duties. This has an impact on both training and innovations in products or work processes carried out in these establishments.

**9. Environment** (Transforming environmental challenges into opportunities, new goods and services): maximum 1 point.

- Is environmental and energy efficiency promoted among SMEs? Scoring: 0.5

The regulation, which establishes requirements relating to the maintenance of premises, facilities, instruments and technical equipment, regulating aspects such as cleaning, conservation, waste disposal, pollution, noise pollution, etc., has an impact on environmental and energy efficiency.

- Is the production of environmentally sustainable services and products encouraged? This regulation has no impact in these respects. Scoring: 0
- Is access to and/or increased presence in green markets encouraged? This regulation has no impact in these respects. Scoring: 0

**10. Internationalisation** (Overcoming barriers to trade with third countries) maximum 1 point:

- Is the internationalisation strategy of SMEs being promoted? This regulation has no impact in these respects. Scoring: 0

- Are exports and their processing in the EU and third countries promoted?  
This regulation has no impact in these respects. Scoring: 0

Scoring:

1-Entrepreneurship	1.00	(-1 to 1)
2-Second Chance	0.00	
3-Think small first	0.66	
4-Responsive administration	0.83	
5-Public procurement and State aid	0.00	
6-Access to financing	0.00	
7-Single market	0.50	
8-Skills and innovation	1	
9-Environment	0.50	
10-Internationalisation	0.00	

Overall score 4,49 (-10 to 10)

The result of this test shows that the impact of the regulatory draft is moderate with regard to whether or not it has a favourable impact on SMEs, since in most sections the result is 0 but in some sections the score is high which makes it possible to achieve a moderately satisfactory outcome in this regard.

## 7. GENDER IMPACT REPORT.

The gender impact of the project is nil or neutral, as there are no initial inequalities in terms of equal opportunities and treatment between men and women. Therefore, the application of the regulation does not affect gender policies, although the approval of a regulation that promotes patient safety and quality of clinical care may indirectly have a positive impact on women, as women tend to be the majority of users of these aesthetic medicine services, even though men are also increasingly accessing them.



## **8. REPORT ON THE IMPACT ON GENDER DIVERSITY OF THE MEASURES SET OUT THEREIN.**

With regard to the impact on gender diversity of the measures established in the draft, and having regard to Law 8/2016 of 27 May 2016, on the social equality of lesbian, gay, bisexual, transsexual, transgender and intersex persons and on public policies against discrimination based on sexual orientation and gender identity in the Autonomous Community of the Region of Murcia, the draft regulation has no direct effect on sexual orientation and gender identity, although the approval of a regulation that promotes patient safety and quality of clinical care may indirectly have a positive impact on these groups, many of whom may seek cosmetic medicine services as an aid to affirming their gender identity.

With regard to other possible impacts that this regulation may have, the following should be noted:

## **9. IMPACT REPORT ON CHILDREN AND ADOLESCENTS.**

In accordance with Article 22(d) of Organic Law 1/1996 of 15 January 1996 on the legal protection of minors, partial amendment of the Civil Code and the Law of 7 January 1996, on Civil Procedure, it is mandatory to include this impact in the Regulatory Impact Assessment (MAIN). In compliance with these legal mandates, it is hereby stated that, in general terms, the impact of this regulatory initiative on children and adolescents is positive.

In this regard, it is important to note that in recent years there has been an exponential increase in the use and consumption of Aesthetic Medicine services by minors, perhaps due to a misperception and trivialisation of these services, which are not always advisable for this sector of the population, except in specific cases where medical professionals deem them appropriate.

In this regard, Article 12 of the draft introduces certain precautions and requirements regarding the prior information that must be provided to patients about treatments, especially in the case of minors and their families, as well as on safeguarding the autonomy and will of patients in accordance with the terms of Law 41/2002 of 14 November 2002, which regulates patient autonomy and rights and obligations in relation to clinical information and documentation.

## **10. IMPACT REPORT ON THE FAMILY.**

In accordance with the tenth additional provision of Law 40/2003 of 18 November 2003 on the Protection of Large Families, it is mandatory to include this impact in the Regulatory Impact Assessment (MAIN). In compliance with the provisions of these legal mandates, it is noted that the impact of this regulatory initiative on the

family is positive for the same reasons as those set out in the previous section of this report. Logically, the safeguards and precautions taken with regard to children and adolescents should have a positive impact on the welfare and safety of all the families concerned.

#### **11. IMPACT ON THE 2030 AGENDA.**

This impact should be included under the Governing Council Agreement approving the Regulatory Improvement and Regulatory Quality Plan of the Autonomous Community of the Region of Murcia, adopted at its session of 1 July 2021, and the Action Plan for the implementation of the 2030 Agenda in the Region of Murcia, approved by the Governing Council at its session of 29 December 2020.

The impact in this area is positive as it contributes to the achievement of sustainable development objective 3: Ensuring healthy lives and promoting well-being at all ages and helping to remove obstacles to its full attainment.

#### **12. IMPACT ON EQUAL OPPORTUNITIES, NON-DISCRIMINATION AND UNIVERSAL ACCESSIBILITY FOR PERSONS WITH DISABILITIES.**

For the purposes of applying Royal Legislative Decree 1/2013 of 29 November 2013, approving the Consolidated Text of the General Law on the Rights of Persons with Disabilities and their Social Inclusion, the draft provision will have no impact.

#### **13. OTHER IMPACTS.**

In accordance with the provisions of Article 35 of General Law 33/2011 of 4 October 2011, on Public Health, the assessment that may result from the implementation of this project from the perspective of its impact on health is expected to have favourable and positive effects on citizens' health.

This provides the healthcare services offered by these centres and services with the highest possible level of quality, safety and guarantees for potential users, so that they can sufficiently satisfy their health improvement needs.

#### **14. REGULATORY ASSESSMENT.**

##### **14.1 Subject of the assessment.**

The objectives of the regulation are those outlined in the section on opportunity and technical motivation of the regulation, namely that the draft regulation aims to establish specific regulations on health requirements, functional and organisational conditions, as well as minimum structure, facilities and equipment that, according to the portfolio and healthcare activities offered, must be met by Aesthetic Medicine

centres or services located in the Autonomous Community of the Region of Murcia. All of this has the aim of improving the quality of care and patient safety in access to healthcare services for Aesthetic Medicine. To this end, the impact that the adoption of this regulation will have on Aesthetic Medicine healthcare centres and services should also be assessed compared to the current situation. Among the objectives to be achieved with the approval of the regulation in the medium and long term are:

- Improvement of the current technical conditions and requirements.
- Reduction of incidents and deficiencies in the activity carried out.
- Reduction in the number of penalties imposed on these healthcare centres and services.

#### **14.2 Assessment methodology.**

Both specific indicators and certain stages or milestones will be used for the assessment of the future application of the regulation.

##### **1. The following indicators will be used:**

Number of Aesthetic Medicine centres and services at the time when the regulation enters into force

Number of new Aesthetic Medicine centres and services to be opened during the first year following the entry into force of the regulation.

Number of new Aesthetic Medicine centres and services to be opened during the second year of application of the regulation. Number of inspections carried out at Aesthetic Medicine centres and services in the first six months, after one year, after one and a half years and after two years, and number of penalties imposed during these periods.

Number of centres and services with a valid authorisation that have adapted to the regulation within one year.

##### **2. Phases or milestones.**

Deadline for adaptation of centres and services with valid authorisation: 1 year

Assessment period of 2 years from the entry into force of the Decree for the assessment of objectives and impacts.



### **3. Deadline for completing the assessment.**

Assessments of the regulation shall be carried out at the time of its entry into force, and subsequently after one year and after two years, in order to prepare an assessment report enabling verification of the effectiveness of the Regulation as applied and, where appropriate, to propose any corrective measures that may prove necessary in the future in order to guarantee the achievement of its fundamental objective.