JUSTIFICATION

GENERAL PART

The text of Decree No 296/2012 on requirements for equipping providers of medical transport services, providers of emergency medical services, and providers of urgent care patient transport with vehicles and on requirements for these vehicles (hereinafter the 'Decree'), which was drawn up between 2009 and 2012, no longer corresponds to the actual equipment and current needs of emergency medical services (hereinafter also 'EMS'). The Decree specifies only the basic types of vehicles for the provision of pre-hospital emergency care pursuant to Act No 372/2011 on health services and the conditions for their provision (the Health Services Act), as amended, and does not presuppose the use of special vehicles designed to deal with emergencies and perform tasks within the Integrated Rescue System (hereinafter also the 'IRS').

For purposes of purchasing vehicles from public funds and their subsequent operation, it is necessary to define and specify a framework for individual vehicles. For purposes of unambiguous identification of the specific IRS component at the scene of the emergency, better orientation of the response commander at the scene and overall facilitation of operation of the individual IRS components at the scene, it is necessary to lay down by decree how IRS vehicles are marked.

The need to amend the Decree was discussed within the Association of Emergency Medical Services of the Czech Republic (hereinafter the 'AEMS CR') and was also recommended by representatives of other IRS components.

1. Assessment of the current legal situation and justification of the need of its amendment

At present, the area of ambulance material and technical equipment is regulated by a decree at the level of implementing regulations to Act No 374/2011 on emergency medical services, as amended (hereinafter the 'EMS Act'). The current version of the Decree does not take into account changes in technical requirements for equipping emergency medical services vehicles, and in particular equipping emergency medical services with new categories of vehicles, designed in particular to deal with emergencies of various nature and intensity, which do not serve primarily to transport the sick and injured, but are intended for the transport of personnel and material for dealing with emergencies, including new risks and threats caused by civilizational and climatic factors. At the same time, it responds to legislative changes concerning road traffic and takes into account the constantly increasing requirements for the safety of ambulance crews and transported patients.

The proposed amendment to the Decree will bring about the unification of the visual design of EMS vehicles throughout the Czech Republic, similarly to the uniform visual design of the other basic components of the IRS, the Fire Rescue Service of the Czech Republic (hereinafter 'FRS CR') and the Police of the Czech Republic (hereinafter 'PCR'). According to the proposal of the AEMS CR, legislative anchoring is absolutely necessary for the uniform appearance and equipment of EMS transport vehicles throughout the Czech Republic,

especially since EMS are established not by one entity such as the FRS CR and the PCR, but rather by fourteen regions**.**

2. Explanation of the necessity of the draft legislation and justification of its main principles

The draft amendment to the Decree is being submitted primarily due to the expansion of the emergency medical services fleet to include special vehicles of various categories designed to address emergencies and enhance the safety of crews, patients, and other road users.

Another reason for the amendment is to take into account related legislative changes effective after the effective date of the Decree, such as Act No 193/2018 amending Act No 56/2001 on the conditions of operation of vehicles on roads and amending Act No 168/1999 on vehicle liability insurance and amending certain related acts (the Vehicle Liability Insurance Act), as amended by Act No 307/1999, as amended, and other related acts, regulating the colour and use of warning lights for the basic components of the integrated rescue system, introducing the possibility of combining blue and red colours in warning lights.[1] This provision of the Act was adopted on the basis of the requirement for increased safety and visibility of vehicles of the basic components of the IRS on roads and at the same time allows their unambiguous identification and differentiation from other vehicles equipped with warning lights (EMS vehicles have hitherto been equipped with blue warning lights).

Last but not least, the draft amendment to the Decree broadens the scope of the annexes by the indication of the colour scheme and markings of ambulances of all categories, in order to unify and unambiguously identify individual providers of health services under the Health Services Act, so as to avoid confusion between vehicles of these providers in road traffic. If the draft decree is adopted, it will not be possible to visually confuse EMS vehicles, which have high priority in traffic and drivers must allow it to pass unhindered, with a patient transport vehicle, used for simple transport of a patient who does not require acute health care.

The appearance of ambulances of the emergency medical service, as proposed, corresponds to the standard used in several European countries (for example Belgium, the Netherlands, Sweden, Norway, Denmark, the United Kingdom, Spain), allowing for the correct identification of these vehicles even by foreigners. The identical appearance of EMS vehicles and a clear distinction from other ambulances is also essential during response to an emergency that takes place in cooperation between several regions or in the context of cross-border cooperation. For providers of medical transport services, the decree stipulates a straightforward colour scheme with simple markings, preventing confusion with EMS vehicles and thereby protecting their personnel from inappropriate demands by the general public, while also preventing the misuse of warning devices in the context of medical transport.

3. Assessment of compliance of the proposed legislation with the constitutional order of the Czech Republic

[1] Cf. TUČEK, Jan. *Sanitky v Československu a Česku 1918-2018* [Ambulances in Czechoslovakia and the Czech Republic 1918-2018]. Prague: Grada Publishing, 2019. ISBN 978-80-247-5864-0. p. 290.

The draft amendment to the Decree is in compliance with the constitutional order of the Czech Republic. The proposal is fully in line with the EMS Act and § 11(7) of the Health Services Act, which this Decree is designed to implement.

4. Evaluation of the consistency of the draft legislation with EU legislation, EU case law and the general principles of EU law

The present proposal concerns Article 34 et seq. of the Treaty on the Functioning of the European Union and Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 on a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codified version).

The draft legislation is a technical regulation within the meaning of Directive (EU) 2015/1535, as it lays down requirements for vehicles, the regulation of which is the subject of the Decree, in particular to meet the conditions laid down in the relevant Czech technical standards, and will be notified to the European Commission in accordance with this Directive.

Also relevant to the draft is the Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval of motor vehicles and their trailers, as well as systems, components, and separate technical units intended for such vehicles, and on the market surveillance thereof, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC, as amended.

In the light of the above, the present draft complies with European Union law, European Union case law and the general principles of European Union law.

5. Assessment of compatibility with international treaties by which the Czech Republic is bound

This area of legislation is not the subject of any international agreement binding on the Czech Republic.

6. The expected economic and financial impact of the proposed legislation on the state budget, other public budgets, the business environment of the Czech Republic, as well as social impacts, including on specific groups of the population, in particular socially vulnerable people, persons with disabilities and national minorities, impacts on the protection of children's rights and environmental impacts

The draft legislation will not have a direct or indirect impact on the state budget or on other public budgets; most of the proposed measures are already being implemented by most of the entities concerned and are being financed from the investment funds of individual EMS. The mandatory medical and transport equipment remains unchanged, hence the price depends, as at present, on the type of equipment and the price resulting from the public contract. No increase is foreseen for providers of medical transport services and urgent care patient transport, as there is no increase in the stringency of requirements for equipment, vehicle colour or scope of retro-reflective marking. The new vehicle markings will not apply to vehicles already put into service and to vehicles undergoing a tendering procedure. The decree will apply only to vehicles registered in the Czech Republic from 1 January 2027.

The draft decree will have no impact on the business environment of the Czech Republic.

The proposed legislation will have no social impact, no impact on specific groups of the population (socially deprived persons, persons with disabilities, national minorities), no impact on the protection of children's rights, and no impact on the environment.

7. Assessment of the impacts of the proposed policy in relation to the prohibition of discrimination and in relation to gender equality

The draft legislation has no relation to the issue of discrimination and equality between men and women.

8. Impact assessment in relation to the protection of privacy and personal data

The draft new decree has no negative impact on the protection of privacy and personal data.

9. Assessment of corruption risks

As part of the preparation of the draft Decree, the level of corruption risks was comprehensively assessed. The assessment concludes that the proposal has no potential for corruption.

10. Assessment of impact on State security or defence

The draft amendment to the decree has no direct relation to the security or defence of the state. The inclusion of special vehicles in the Decree and the specification of a uniform method for marking them will increase the quality of cooperation between emergency medical service crews and other components of the integrated rescue system at the site of an emergency.

11. Assessment of the impact on families

The draft decree does not foresee any impact on families.

12. Evaluation of territorial impacts and impacts on territorial self-governing units.

The draft decree does not anticipate any impact on territorial self-governing units. The draft amendments are not expected to have an impact on regions and regional offices.

13. Evaluation of compliance with the principles for digitally friendly legislation (DFL)

1) Building digital by default as a matter of priority

The draft decree does not materially interfere with issues related to the principle of digital by default.

2) Maximum repeatability and reusability of data and services (once-only principle)

The draft decree does not incorporate the once-only principle into the issue.

3) Building accessible and usable services for all, including persons with disabilities (the principle of governance accessibility)

The draft decree does not discriminate against persons with disabilities, and public administration systems and services will be fully accessible to them.

4) Shared public administration services

The draft decree does not in any way interfere with this principle.

5) **Consolidation and interconnection of public administration information systems**

The draft decree does not in any way interfere with this principle.

6) **International interoperability — building services that are interconnectable and usable in the European space**

The draft decree does not in any way interfere with this principle.

7) **Protection of personal data to the extent that it enables quality services (GDPR)**

The draft decree does not fully interfere with the elements of protection of these principles.

8) **Openness and transparency including open data and services (open government principle)**

The draft decree does not in any way interfere with this principle.

9) **Technological neutrality**

The draft decree does not in any way interfere with this principle.

10) **User-friendliness**

The draft decree does not create any barriers to the creation of user-friendly applications.

14. Regulatory impact assessment (RIA)

According to the Plan for the Preparation of Ordinances by Central Government Authorities for 2024, a regulatory impact assessment is not required for this proposal.

SPECIAL PART

Re: Article I

Re Point 1 [§ 2(2)]

The text has been amended, replacing the word ‘produced’ with ‘registered in the Czech Republic’, mainly because the date of manufacture is not unambiguously identifiable (in particular with regard to whether it is the date of manufacture of the base vehicle or the date of manufacture of the final vehicle) and at the same time it is difficult to credibly prove it.

Re Point 2 (§ 2a)

With regard to the specific requirements for the equipment of medical vehicles and the need to ensure a high level of safety and quality, the Decree uses exclusive references to Czech technical standards. In accordance with Article 45a(2) of the Legislative Rules of the Government, § 2a lays down the manner in which the technical standards referred to will be made available to the public, namely that the Czech technical standards used in the Decree will be published on the website of the Ministry of Health.

Re: Point 3 (§ 3)

The provision is repealed as the regulation contained therein is no longer relevant in view of the established temporal aspect.

Re point 4 (footnote 1)

This is an amendment to footnote 1, as it contains legislation that has already been repealed.

Re point 5 (Part I, Section A, paragraph 1, including footnote 2)

The specification of an ambulance vehicle pursuant to ČSN EN 1789 (842110) Medical vehicles and their equipment - Road ambulances, is added.

Re point 6 (Part I, Section A, paragraph 2, point 2.12)

The requirement that urine containers not to be of glass has been added due to the risk of breakage and injury from shards.

Re point 7 (Part I, Section A, paragraph 2, point 2.16)

This point is deleted as the driver of the transport health service does not have the competence to perform tasks that would require the use of sterile surgical gloves.

Re point 8 (Part I, Section A, paragraph 2, point 2.19)

The name spotlight is replaced by the more appropriate term work reflector, because transport service vehicles do not primarily respond in the field and the reflector is not used to search for people, but rather to illuminate the work area when loading patients.

Re point 9 (footnote 3)

This is an amendment to footnote 3, as it contains legislation that has already been repealed.

Re point 10 (Part I, Section A, paragraph 2, point 2.21)

An obligation to have a restraint system for the transport of wheelchairs for immobile persons who are existentially dependent on the assistive device is introduced.

Re point 11 (final part of Part I, Section A, paragraph 2)

This is a legislative and technical amendment to the reference to these provisions, as the draft renumbers them.

Re point 12 (Part I, Section A, paragraph 3)

The original text is replaced by a text reflecting the wide range of types of ambulances that can be used by a medical transport service, and the use of new technologies for ambulance markings, together with the definition of a minimum font size.

Re point 13 (Part I, Section B, paragraph 1 and Part II, Section B, paragraph 1)

The specification of an ambulance vehicle pursuant to ČSN EN 1789 (842110) Medical vehicles and their equipment - Road ambulances, is added.

Re point 14 (Part I, Section B, paragraph 2, point 2.2)

Radio transceivers are no longer mandatory, as the operational management of a medical transport service is usually carried out through mobile communication or data transmission, even in cases of cooperation with basic components of the IRS. Due to the disappearance of the original radio frequencies in the analogue network and the gradual transition to a digital network, it is not possible to establish a mandatory unified radio network and a unified radio frequency given the current number of providers.

Re point 15 (Part I, Section B, paragraph 4)

The original text is being replaced with a text reflecting the wide range of vehicle types that can be used by a medical transport service and the use of new wrap technologies for vehicles for the rapid transport of medical personnel and for the urgent transport of tissues, cells, and other biological material, medicinal products, and medical devices necessary for the provision of urgent care. The provisions of this part define the colours of markings and the minimum size of the markings and letters.

Re point 16 (Part II, Section A, paragraph 1)

The specification for the ambulance vehicle according to ČSN EN 1789 is added (842110) Medical transport vehicles and their equipment - Road ambulances.

Re point 17 (Part II, Section A, paragraph 2, point 2.8)

The obligation of data transmissions from an integrated device for monitoring vital functions has been added.

Re point 18 (Part II, Section A, paragraph 2, point 2.11)

The range of equipment for oxygen therapy has been supplemented with oxygen nasal cannulas.

Re point 19 (Part II, Section A, paragraph 2, point 2.13)

Intubation aids are supplemented with an intubation bougie and an invasive airway management kit.

Re point 20 (Part II, Section A, paragraph 2, point 2.31)

The type of emergency obstetric kit with material for the treatment of mother and child is specified.

Re point 21 (Part II, Section A, paragraph 2, point 2.32)

Sampling tubes for the collection of blood cultures are no longer required.

Re point 22 (Part II, Section A, paragraph 2, point 2.33)

Immobilisation aids are supplemented with extension splints.

Re point 23 (Part II, Section A, paragraph 2, point 2.37)

The requirement that urine containers not to be of glass has been added due to the risk of breakage and injury from shards.

Re point 24 (Part II, Section A, paragraph 2, point 2.43)

The range of equipment for extrication devices has been supplemented with optional alternative aids for a spinal board.

Re point 25 (Part II, Section A, paragraph 2, point 2.44)

The number of safety helmets in a vehicle is increased to include all members of the response team.

Re point 26 (Part II, Section A, paragraph 2, point 2.50)

Disinfectants for devices are deleted and surface disinfectants are added.

Re point 27 (Part II, Section A, paragraph 2, point 2.55)

Mandatory data transmission and data exchange for equipment used for navigation and communication with the Medical Operations Centre has been added.

Re point 28 (Part II, Section A, paragraph 2, point 2.56)

This is a fundamental requirement of professional associations with regard to increasing road safety to the exclusive use of a warning light with a combination of blue and red colours, in accordance with Act No 361/2000 on road traffic and amending certain acts (Road Traffic Act), as amended [cf. § 41(1) and (11)].

Re point 29 (final part of Part II, Section A, paragraph 2)

The final part of this provision is deleted, as currently all emergency medical service vehicles are equipped with a radio transceiver without alternative communication resources. The deletion of this provision does not represent, for providers of emergency medical services, a negative impact to a vehicle equipment.

Re points 30 and 31 (Part II, Section A, paragraphs 3 and 4)

The original text is replaced with a text reflecting the wide range of vehicle types that can be used in the provision of emergency medical services and the use of new wrap technologies for vehicles. At the same time, the unambiguous identification of the vehicles of the emergency medical services as a basic component of the IRS and their differentiation from the vehicles of providers of patient transport for urgent care and medical transport services are addressed. The provisions of these parts define colour markings and the minimum size of the markings and of letters.

Re point 32 (Part II, Section B, paragraph 3)

This is a legislative and technical amendment to the reference to these provisions, as the proposal renumbers them.

Re points 33 and 34 (Part II, Section B, paragraphs 5 and 6)

The original text is replaced with a text reflecting the wide range of vehicle types that can be used in the provision of emergency medical services and the use of new wrap technologies for vehicles. At the same time, the unambiguous identification of the vehicles of the emergency medical services as a basic component of the IRS and their differentiation from the vehicles of providers of patient transport for urgent care and medical transport services are addressed. The provisions of these parts define colour markings and the minimum size of the markings and of letters.

Re point 35 (Part II, Section C, paragraph 1)

The specification of an ambulance vehicle pursuant to ČSN EN 1789 (842110) Medical vehicles and their equipment - Road ambulances is added.

Re point 36 (Part II, Section C, paragraph 2)

This is a legislative and technical amendment to the reference to this provision.

Re point 37 (Part II, Section C, paragraph 3)

The provision defines the colour marking of emergency medical vehicles by reference to the colour marking of emergency medical vehicles provided for in Part II, Section A, more precisely in paragraphs 3 and 4 of this section.

Re point 38 (Part II, Section D, paragraph 1)

The specification of an ambulance vehicle pursuant to ČSN EN 1789 (842110) Medical vehicles and their equipment - Road ambulances is added.

Re point 39 (Part II, Section D, paragraph 2)

This is a legislative and technical amendment to the reference to these provisions, especially because the proposal renumbers them.

Re point 40 (Part II, Section D, paragraph 3)

The provision defines the colour marking of emergency medical vehicles for premature and pathological newborns by reference to the colour marking of emergency medical vehicles provided for in Part II, Section A, more precisely in paragraphs 3 and 4 of this section.

Re point 41 (Part II, Section E, paragraph 1, including footnote 5)

Helicopter specifications are added pursuant to ČSN EN 13718-1+A1 (842120) Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances and ČSN EN 13718-2+A1 (842120) Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances.

Re point 42 (Part II, Section E, paragraph 2)

This is a legislative and technical amendment to the reference to these provisions, especially because the proposal renumbers them.

Re point 43 (Part II, Sections F and G)

In the Annex, two completely new sections are added at the end of Part II. Section F defines other and special vehicles that may be used to provide emergency medical services under the Health Services Act, and special vehicles intended for performing emergency preparedness tasks under the Emergency Medical Services Act and the Integrated Rescue System Act. Section G, on the other hand, defines the designation of vessels used by EMS in the vicinity of large bodies of water.

Re point 44 (Part III, paragraph 1)

The specification of an ambulance vehicle pursuant to ČSN EN 1789 (842110) Medical vehicles and their equipment - Road ambulances, is added.

Re point 45 (Part III, paragraph 2)

This is a legislative and technical amendment to the reference to these provisions, in particular because the draft renumbers them and clarifies continuity with Act No 374/2011.

Re point 46 (final part of Part III, paragraph 2)

This is a legislative and technical adjustment of the reference.

Re points 47 and 48 (Part III, paragraphs 3 and 4)

The original text is replaced with a text reflecting the broad range of vehicle types that can be used to transport urgent care patients and the use of new wrap technologies for vehicles. At the same time, differentiation from vehicles of the emergency medical service as a basic component of the IRS, is addressed. The provisions of these parts define colour markings and the minimum size of the markings and of letters.

Re Article II – Transitional provisions

Re point 1

The transitional provision establishes the latest date for the registration of vehicles in the Czech Republic, the colour of which is specified in the Annex to Decree No 296/2012, as amended as of the effective date of the draft Decree. The requirements set out in the Annex to Decree No 296/2012, as amended as of the effective date of the draft Decree, do not apply to vehicles registered in the Czech Republic up to 31 December 2026.

Re Point 2

The provision stipulates that, by 31 December 2026, all requirements for material and technical equipment of a provider of medical transport services, a provider of medical emergency services, and a provider of transport of urgent care patients by vehicles set out in the Annex to Decree No 296/2012, as amended as of the effective date of this Decree, must be met.

The second part of the provision provides for an exception to the requirements laid down in Part I, Section A, paragraph 2, and Section B, paragraph 2, and Part II, Section A, paragraph 2, and Section B, paragraph 3 of the Annex to Decree No 296/2012, as amended as of the effective date of this Decree, which providers of medical transport services, providers of emergency medical services and providers of urgent care patient transport must comply with no later than 3 months from the effective date of this Decree. The above-mentioned parts of the Annex to Decree No 296/2012, as amended as of the effective date of the draft Decree, regulate requirements that these providers already meet to a greater extent. The proposed amendment clarifies their terminology and, in particular, reflects established practice.

Re Article III (Technical regulation)

As this is a technical regulation, given that the draft stipulates that the vehicles regulated by the Decree must comply with the conditions laid down by Czech technical standards, particularly with regard to their classification into specific categories of vehicles or requirements for the appearance of such vehicles, it must be notified to the European Commission in accordance with Directive (EU) 2015/1535.

RE: Article IV (Effective date)

In accordance with Article 53(1)(c)(6) and (3) of the Legislative Rules of the Government in conjunction with § 9(3) of Act No 222/2016 on the Collection of Laws and International Treaties and on the creation of legislation promulgated in the Collection of Laws and International Treaties (the Collection of Laws and International Treaties Act), as amended, it is proposed that this Decree shall take effect on the fifteenth day following its publication, on the grounds that it is not possible to stipulate its effective date on 1 January or 1 July due to the technical notification process under Directive (EU) 2015/1535.