

EMERGENCY ORDINANCE no. 23 of 13 May 2014 for amendment of Law 95/2006 on healthcare reform and amendment of certain legislation

ISSUED BY: THE ROMANIAN GOVERNMENT

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Considering Romania's duty as a full EU Member State to transpose and implement Directives adopted by the European Union, and taking into account negative consequences of failure to urgently promote this legislation ensuring the primary framework for transposition of Directive 89/105/EEC of the Council of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of the public health insurance system,

taking into consideration the need to avoid opening the infringement procedure and enforcement of monetary sanctions against Romania, in accordance with provisions of Article 260 (3) of the Treaty on the Functioning of the European Union, accelerating the mechanism for imposition of financial penalties on notification of the Court of Justice by the European Commission, on non-compliance with a Member State's responsibilities concerning notification of measures for transposition of a directive approved in accordance with a legislative procedure,

to avoid opening of action against Romania's failure to comply with its duties as an EU member state, in light of the European Commission request leading to commitment of Romanian authorities to compliance with national provisions concerning transparency of measures regulating inclusion of medicinal products into the scope of national health insurance systems, with provisions of Directive 89/105/EEC,

considering that, after notification by the European Commission, Romania has undertaken to propose, before the end of April 2014, legislation for resolution of the issue of transparency of measures concerning compensation of medicinal products prices, to its avoid progress to infringement level,

considering the Minister's of Foreign Affairs request to the Minister of Health, on taking notice of the non-compliance with European Commission requirements, for accelerated adoption of regulations for transposition of European legislation in that respect,

having in mind that Romania's obligation as a Member State to ensure full transposition of provisions of this Directive can only be considered fulfilled on notification of all measures for transposition of this Directive, thus avoiding opening of the infringement procedure,

considering the Zero Tolerance Policy adopted by the Commission for cases of non-transposition, according to COM (2012) 259 (Communication on Better Governance for the Single Market), requiring Member States to undertake

a zero-tolerance objective concerning respecting a transposition deficit target and a conformity deficit target of 0%.

,taking into account that absence of these regulations precludes Romanian patients' access to novel treatments, vital for their life and health, urgent measures are mandatory for elimination of irregularities potentially arising from non-implementation of this directive,

to prevent deterioration or even irrecoverable damage to the health condition, particularly of patients depending on access to new medicinal products, it is necessary to limit detrimental effects upon the population's overall health condition,

considering the need for emergency adoption of the organisational framework of the healthcare system, so as not to affect the quality of medical assistance and public health,

considering the need for regulation of the framework for implementation of systems included in the healthcare insurance information platform – the patient electronic healthcare dossier and the national system of the social health insurance card, as well as for observance of their deadlines for implementation agreed upon with international financial bodies,

considering that introduction of a new electronic system for collection of personal and medical data, namely the patient electronic healthcare dossier, the role of the social health insurance card is considered a single document attesting the status as “insured person” of citizens, ensuring access of authorised persons to data available on the patient electronic healthcare dossier, taking into account that introduction of this electronic device leads to increased quality of medical services granted to patients, by decreasing time allocated to bureaucratic activities, thus increasing time available for actual patient care,

considering that providing for the operational character of the social health insurance card leads to provision of medical services to insured persons, depending on their health condition and medical history as recorded on the patient electronic health dossier, fully available to the respective medical service provider not requiring supply by the insured person of current medical records provided by other medical service providers,

taking into consideration that the two electronic devices (the patient electronic health dossier and the social health insurance card) improve access to medical services for insured persons, eliminating bureaucratic activities in that respect, whereas providing for a mechanism for elimination of services not performed but reported for reimbursement,

considering that, as of May 2014, the National Health Insurance House commences distribution of cards for a determined patient sample group, namely persons diagnosed with acute renal impairment on dialysis,

considering the need for harmonisation of data available on the social health insurance card with that provided in the patient electronic health dossier,

taking into account that failure to adopt these immediate measures and their implementation rules, through Emergency Ordinance, would generate major irregularities with negative impact upon the population's health condition as well as on efficient use of human and financial resources of the healthcare system, and that any delay by Romanian authorities may result in action against failure to fulfil its obligations as a Member State, in accordance with Article 258 of the Treaty on the Functioning of the European Union,

considering the impending need of removal of legislative barriers, namely elimination of discrimination concerning the possibility provided to general medical assistants/nurses, midwives and medical assistants to retire upon request, in line with Law 263/2010 regarding the integrated public pension system, as amended,

taking into account that the issue of under-financing of the Romanian medical system and thereby of healthcare professionals requires identification of immediate alternative solutions to ensure sufficient and fully trained working force nationally,

having in mind one of the Ministry of Health general targets to permanently improve population's health condition and provide indiscriminating access to health services of all population categories (rural population included),

considering the increased tendency of healthcare professionals' migration to other Member States, as shown by the release, as of 2007, of over 20,000 documents required for recognition in the EU of nurse and midwife Romanian diplomas and another 4,000 such documents before the end of 2014,

considering the increased rate of this staff migration to private healthcare facilities providing more attractive working and wage conditions,

given the risk in this context of decrease of the retirement age concerning dramatic decrease of the number of nurses and midwives employed in public healthcare units already having to cope with a major shortage of specialised staff,

taking into account regulations in force on [contest procedure on the filling of vacancies](#) resulted from retirement to be performed in minimum 45 days,

considering the major imbalance resulting in this context from the provision regarding retirement of medical assistants/nurses and midwives at ages stipulated by Law 263/2010 regarding the integrated public pension system, as amended and the risk of blockage of public healthcare units and, consequently, prevention of the equal access to health services for all categories of population, particularly those in poor/rural areas,

having in mind the major impact of such issues upon public health, which involves overall public interest and represents extraordinary and emergency situations whose regulation cannot be postponed,

the Government of Romania hereby adopts this Emergency Ordinance.

ARTICLE I

Law 95/2006 on healthcare reform, published in the Official Gazette of Romania, Part I, No. 372 of 28 April 2006, as amended, is hereby amended as follows:

1. Under Article 29 (2), a new paragraph, (3), is introduced, which reads as follows:

"(3) The manner of use and setup of the patient electronic health dossier is established through implementation rules related to the patient electronic health dossier, approved through Government Decision."

2. Under Article 54, a new paragraph, (8), is introduced after paragraph (7), which reads as follows:

"(8) The manner of inclusion, extension of indications, non-inclusion or exclusion of medicinal products on/from the list mentioned under paragraph (7) is shown under Article 232¹."

3. A new Article, 232¹, is introduced after Article 232, which reads as follows:

"ARTICLE 232¹

(1) The criteria for assessment of medical technologies, the dossier to be submitted by applicants, methodological devices used in the assessment process concerning inclusion, extension of indications, non-inclusion or exclusion of medicinal products in/from the List of International Non-proprietary Names of medicinal products for insured persons, with or without personal contribution, based on medical prescription, in the social health insurance system, as well as the International Non-proprietary Names of medicinal products granted within national health programs are approved through Order of the Minister of Health, as proposed by the National Agency for Medicines and Medical Devices.

(2) The assessment technology for inclusion, extension of indications, exclusion of indications, non-inclusion or exclusion of medicinal products in/from the List of International Non-proprietary Names of medicinal products for insured persons, with or without personal contribution, based on medical prescription, in the social health insurance system, as well as International Non-proprietary Names corresponding to medicinal products granted within national health programs, as well as the means for appeal are approved through Order of the Minister of Health, as proposed by the National Agency for Medicines and Medical Devices."

4. Under Article 331, paragraphs (2) - (5) are repealed.

ARTICLE II

In 2014, reassessment of medicinal products in the List of International Non-proprietary Names containing medicinal products for insured persons, with or without personal contribution, based on medical prescription and within the social health insurance system, as well as the International Non-proprietary Names of

medicinal products granted in the context of national health programs, under the conditions stipulated in Article I point 3, are performed until 30 October 2014.

ARTICLE III

Emergency Government Ordinance no. 144/2008 on profession of the positions of general physician, midwife and medical assistant/nurse, as well as the organisation and operation of the Romanian Order of Nurses, Midwives and Medical Assistants published in the Official Gazette of Romania, Part I, no. 785 of 24 November 2008, approved as amended through Law 53/2014, is amended as follows:

1. Under Article 22, paragraph (2) is amended as follows:

"(4) General medical assistants/nurses, midwives and medical assistants irrespective of gender retire at 65 years old."

2. Under Article 22, two new paragraphs, (5¹) and (5²), are introduced after paragraph (5), which read as follows:

"(5¹) Upon request, general medical assistants/nurses, midwives may retire, under the conditions stipulated by Law 263/2010 regarding the integrated public pension system, as amended.

(5²) By waiver from provisions of Article 56 (1) c) of Law 53/2003 – Labour code, republished, as amended, the working contract of nurses, midwives and medical assistants legally ceases on cumulative fulfilment of the conditions regarding the 65 years age limit and the minimum subscription period to the public pensions system on the date of communication of the decision for retirement for age limit, disability pension, anticipated old-age pension, anticipated pension, pension for age limit with decreased standard retirement age, as per provisions of paragraph (5¹)."

PRIME-MINISTER
VICTOR-VIOREL PONTA

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