

## THE „RISK” CONCEPT IN THE HEALTHCARE SECTOR AND ITS IMPLICATIONS FOR THE CONTRACTING OF MEDICAL SERVICES

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*“In the achievement of health and the use of health care,  
risk is ubiquitous” (Prof. Mark V. Pauly)*

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### ABSTRACT

*The study starts from the identifying of specific “risk” concepts in the healthcare field and how it is directly or indirectly influencing the contracting of medical services. It also explains the relationship between the general health risks and the normative acts in force, as well as the implications of these risks in the field of contracting medical services and also in the field of some national preventive and curative health programs. The study of these “risk” concepts is continued with the analysis of the most recent legislative changes, the reasons behind these changes, their meaning and their implications at the beginning of the contracting process and also during the development of the contracts. One of the conclusions of this measure is that, apart from the influences on the legislation, the risks selected from the public health or medical field may lead to other types of risks (legislative, financial, technological etc.) during the contracting of medical services.*

**KEYWORDS:** *EU, contracting medical services, health legislation, health policies, health risk, Romanian NHS, risk factor,*

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### 1. INTRODUCTION

From the beginning until today, the “risk” concept has penetrated all areas of life and their scientific correspondence relating to: society, security, economy, finances etc. In sectors such as health policies, sanitary legislation, health insurance, medicine, the scope of the “risk” concept is ample being met in hundreds of forms, therefore there is no definition covering all segments of health, even if some of them are closely related (eg. environment – security – health). Most *risk* definitions include the same elements: factor, exposure, disease, probability, and the literature discuss various aspects of health risk.

The word “risk” is used in: “compromises between the risks and benefits of medical interventions”, “risk pooling” through insurance and “risk analysis” in clinical decisions, often as if there was a consensus on meaning the term “risk”, but in reality, this short word is used in a variety of ways (Pauly, 2007: 653). A careful risk analysis, in the multitude of meanings, belonged to the economic field and its related disciplines such as decision analysis and actuarial science (Pauly, 2007: 653).

Both risk management treaties and empirical health risk studies have highlighted the importance of distinguishing between *risk* and *uncertainty*. Knight considers the risk as *a measurable form of uncertainty in contrast to the immeasurable uncertainty* (cited by Asano & Shibata, 2011: 79; Ciocoiu, 2014: 20). The risk (R) is insurable, but in decisional contexts it depends on the

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uncertainty of the given situation (U) and on the risk degree that the decision maker is familiar with. Interpretation formulated, as follows:  $R_{perceived} = U + R_{existing}$  (Popescu, 2004: 70).

In regards to the non-clinical business process of the clinics, there were determined risks related to 7 major categories (medical care, financial, legal, transfers of facilities or business etc.), but these non-clinical classical risk factors could be subdivided into 48 others (Okoroh et al., 2002: 43).

The Executive Director of the *Romanian Pharmaceutical Manufacturers' Association* referred to the Romanian NHS, describing the risk from the compulsory insurance perspective and considered that if 5 million Romanians contribute to the health care of 20 million Romanians, the system is "disproportionate, deformed, unsustainable and unfair". Therefore, there are "enormous financial risks for the mandatory health insurance system for the next 5 years" (Damian, 2018). One of the reasons is represented by the insufficient financing of the Romanian NHS in GDP (4.2%/2015, the EU average – 7.1%), Romania being the last country to be financed, but the first country based on the level of deaths, although Romanian patients are entitled to medical services at an European level (R. Gănescu, President of the *Coalition of Chronic Patients' Organizations in Romania*, transmitted at the 6th meeting of the *Association of Patients' Community* – the program "Modern management dedicated to patient associations"). Other authors have studied the risk based on the allocation of health subsidies and have shown that high-risk workers may be eligible for a job thanks to subsidies (Ketsche, 2004: 91) or that in developed countries, retired people with health risks make the safest investments in health insurances, financial risks, associated with retirement age, decreasing by 20%, so health risk reduces exposure to financial risk (Edwards, 2008).

According to the study "The Impact of Migration on Health Employees" (Dumitrescu, 2018), another cause of the unsustainability of the Romanian NHS are the migrants from the country going to the West, who no longer contribute to the Romanian health insurance fund, but to the funds of the host countries. The distortions and discontinuities of the income in healthcare made the salary increase to have a positive but small impact as against the estimated one. Due to professional risk factors (working conditions, medical staff shortage, living conditions in the country etc.), a very large percentage of doctors (83.7%) continue to consider migrating to the West, fact based on the study "The impact on the quality of professional life on the labor migration trend of the health personnel", conducted by the *Center for Social Research and Development "Solidaritatea"*, in September 2018 (Neagu, 2018). It is formulated an older, but advised opinion (Vlădescu, 2004: 16) again by contesting the Romanian NHS model, who has to propose policies based on the complexity of the *factors* influencing health, the multitude of *interventions* and the balance to be found in the allocation of *budgetary* resources. The current standard is focused on the relationship between health care and illness and, at best, by some interventions on the risk factors for major affections. Last but not least, the major risks of the NHS have also been associated with politics, corruption, demography and funding (Szuhaneck & Szuhaneck, 2014: 98) and it can be said that regardless of the health care risk associations, which has certain peculiarities, the risk influences health regulations and their changes, a phenomenon also encountered in other areas.

## 2. OBJECTIVES AND METHODOLOGY OF RESEARCH

**The main objectives** of this study are:

- i. identifying the "risk" concepts in various health segments;
- ii. establishing a connection between the concept of "risk", the normative acts in force in the health sector and, as the case, the risks in the scope of contracted medical services.

**The methodology of research** consisted in:

- i. analyzing databases (Web of Science, JSTOR, ProQuest, etc.) that include scientific materials on health risk and also using statistical databases belonging to WHO, ECHI, NCTDSC etc.;
- ii. identification in the literature, blending into the European context, selecting and evidencing those risks that can be brought into line with the national legislation;

iii. highlighting the relationship and the influences between the concepts of "risk", the new legislative changes and the contracting of medical services according to the theoretical field and based on our own expertise.

### 3. RISK CONCEPTS IN THE PUBLIC HEALTHCARE FIELD: RISK FACTORS, RISK POPULATION, EPIDEMIOLOGICAL RISK

The objective of human epidemiology – "the fundamental basis of public healthcare field" – concerns the distribution of health and disease, the risk or protection factors and the examining of associations between these elements, in order to establish prevention and combat strategies (Zanoschi, 2003: 64). *The risk factor* is associated with an increased frequency of the disease, and the *at-risk population* is represented by the groups prone to illness. *The risk of disease* for the exposed population is determined by the ratio:  $R_1 = a/(a+b)$ , and for the unexposed ones by:  $R_0 = c/(c+d)$ , where **a** represents the diseased persons; **b** – exposed to disease but not contacting it; **a+b** – the total of exposed persons; **c** – unexposed but contacting the disease; **c+d** – the total of unexposed persons (Vlădescu, 2004: 28).

One of the most widespread risk factors for disease is smoking, the WHO statistics for 2011 (<http://www.euro.who.int>, after S. Irimie), showed a prevalence of smoking in Romania for about 4.3 million of individuals and estimated premature deaths related to this factor for 2.1 million current smokers, a figure that can increase in the absence of serious policies that can stop the phenomenon. In mid-September 2018, the *Romanian Society of Oncological Pathology of Head and Neck* (RSPHN) reports that smoking is related to 85% of cases of head or neck cancers. Other risk factors for cancer but also for other diseases that did not undergo major changes between 1990–2010 and whose distribution does not differ greatly in our country compared to Central Europe (Eclemea, 2015) are: alcohol, unhealthy diet, blood hyperpressure, lack of physical exercises and chronic infections. With regards to the latter, it should be mentioned that the *European Liver Patients' Association* (ELPA) conducted a "Hep-CORE 2018" survey in 23 European countries (<http://www.elpa.eu>) that showed that the most difficult populations at risk for hepatitis C are people using injectable drugs, people who can be ignored for treatment unless they are included in risk reduction programs. Hepatitis C is a transferrable disease for which there is no vaccine but it is curable (99.32% of the patients treated with innovative medicines were healed in 2017). On this note, it should also be mentioned that through the new cost-volume contracts carried out by *National Health Insurance House* (NHIH), the target is 10,000 patients in F2 – F4 stages of fibrosis and 2,000 patients with hepatic cirrhosis decompensated with hepatic C virus.

Another input to epidemiological risks comes from nosocomial infections, with statistics showing that in Romania, 10% of patients can get infections during hospitalization compared to the 7% average found in high income countries. These are added to other socio-economic, environmental, cultural etc. factors, and it has been shown that deaths can be avoided and the mortality level lowered, if proper prophylactic and curative measures would be correctly applied (Zanoschi, 2003: 39). Almost a decade ago, the results of a poll conducted in 5 municipalities (Ristea et al., 2009: 286, *Table 3*), on people with living with risk factors (alcoholism, tobacco, disability) who were approached positively in healthcare facilities, showed a difference of 6 times bigger between the lowest and the highest percentage (14.1% – 86%), which indicates the lack of locally unitary policies, even by virtue of decentralization. Although the Ministry of Health (MH) has consistently advertised for free flu vaccination and anti-measles for people, the lack of firm regulations continues the dispute between MH and anti-vaccination NGOs, resulting in hundreds of thousands of doses of unused vaccine in certain seasons.

Between 2016 and 2018, Romania faced three major diseases (flu, measles, meningitis/encephalitis) with a high frequency over a large number of individuals, but even though the mass media presented it as epidemics, the MH did not agree. Files issued by the *National Council for*

*Transmissible Diseases Surveillance and Control (NCTDSC) of the National Institute of Public Health in Romania (NIPHR) presented several indicators summarized in Table 1.*

**Table 1. Viruses with epidemiological risk in Romania (2016–2018)**

Virus	Analysed timeframe	Cases	Deaths (from cases)	Notes
Flu virused	2017–16.05.2018	44,332	129	Clinical flu, acute respiratory infections and pneumonia. Until 20.05.2018, 1,016,707 people were vaccinated against flu
Measles virus	2016 –21.09.2018	15,352	59	In 7 counties the incidence was over 99.1% of cases per 100,000 inhabitants
West Nile	02.05.2018–19.09.2018	216	25	Virus carried by mosquitos that causes meningitis/encephalitis, febrile syndrome

Source: adapted from <https://cnsbt.ro/index.php/informari-saptamanale/>

According to WHO guidance, people most at risk of flu are elderly and children, chronic patients, pregnant women and medical staff, some of whom are also exposed to West Nile, and the most exposed to the measles virus are children. Through the COM file (2018) 244, the European Commission communicated the EU Council suggestions on enhancing cooperation to combat vaccine-preventable diseases. Furthermore, according to the *European Core Health Indicators (ECHI)*, the European Commission established a series of documents on health risk assessment: the possibility of training risk assessors through courses since 2008, the setting up of scientific committees in the field of health, environment and of new developing risks, through Decision C (2015) 5383/07.08.2015 and the procedural rules for the functioning of these committees in the following year, documents with implications in the compliance of some provisions in our country.

From the Romanian official websites point of view, consulting the (MH, NHIH, NCTDSC) or foreign (WHO), it can be stated that a large number of those who have confirmed a diagnosis of illness and are registered in the patients associations consider these instruments in case of any epidemiological risks, another category being that of healthcare workers, who through their activity are obliged to be informed, while people at risk of illness (elderly, children, obese and others) are satisfied with what is communicated through the media (TV, radio, written press).

From the perspective of protecting the health of the population and risk groups, preventing epidemics, combating risk factors, preventing, monitoring and controlling infections, reducing prevalence and mortality and screening, a legal correspondent, can be found in *G.D. no. 155/2017 on the approval of national health programs for 2017 and 2018*. These are preventive national health programs (NHPs), funded and contracted by the Ministry of Health (MH), the main responsible for public health policies, on communicable and non-communicable diseases, vaccination, HIV/AIDS, tuberculosis, microbial resistance etc. For example, in the section V.2. it is mention the *Subprogramme for the prevention and combating the tobacco consumption*, having the objective “improving the health of the population by promoting a healthy lifestyle and fighting the main risk factors”. In the doctrine, it was noted that the legal norms in the sanitary field are extremely strict, for at least three reasons: the reason of the activity, the “high risk perceived and the emotional side induced by the transactions in the healthcare services sector” (Răducanu, 2008: 162). Considering Romania’s presidency, in 2019 at the EU Council, MH has announced that representatives of the *WHO Regional Office of Europe* will provide technical assistance for creating a new legal framework in the healthcare field in our country.

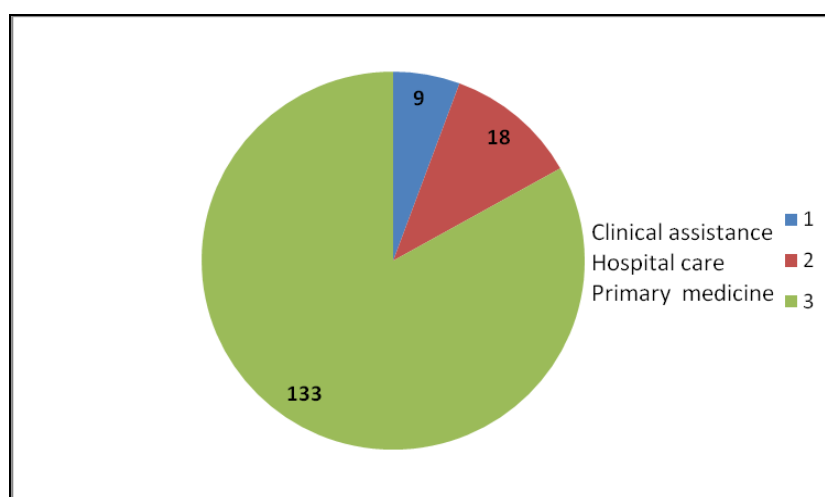
#### 4. MONITORED RISKS IN THE NEW LEGISLATIVE AMENDMENTS TOWARDS SOME ASSISTANCES

From the legislative perspective in the healthcare field, 2018 started with the issuance of *MH/NHIIH Order no. 397/836/2018 concerning the approval of the Methodological Norms of application in 2018 of G.D. no. 140/2018 regarding the approval of the service packages and the Framework Contract regulating the provision conditions of medical care, medicines and medical devices within the health insurance system for the years 2018–2019*. The implementation of this normative act has been identified by two essential aspects: **a.** new supplies provisions on medical services, medicines and health care facilities, in order to facilitate patient access and **b.** the making of a digital contracting, called electronic or online, for the purpose of waiving the submission of contract documents on a paper basis.

This last aspect has been appreciated by both suppliers and officials, although the burden of the former has been relieved by the lack of moving documents manually upon contracting, but the latter it was harder because they now had to check on computer monitors thousands of digital documents. Some HIHs developed online digital submissions for contracting purposes. These platforms (e.g., [https://www.casmb.ro/uploads\\_contractare.php](https://www.casmb.ro/uploads_contractare.php)) include: work steps (input of identification data, uploading files etc.), recommendations for optimal use of the platform, transmission of automated receipt confirmations, contact for technical issues, statistics on assistance on the number of suppliers who submitted the documents, the percentage of new suppliers etc.

##### 4.1 Primary medicine

Compared to other assistances, an interrogation of Annexes no. 1-6 of Order MH/NHIIH no. 397/836/2018 on primary medicine reveals that the frequency of the word “risk” (including in compound form, eg “riskogram”) is much higher than in the annexes on clinical (7-9) or hospital care (22-26) – *infra* **Figure 1**, but in the annexes of the other assistances (paraclinic, recovery, dentistry etc.) the word is absent. This shows the importance of primary medicine, as well as the fact that the family doctor is most often the first to discover the risks of the patient’s illness (diabetes, cardiovascular etc.), having the power established by law in case of intervention on patients’ already diagnosed. It is of interest to include in the annexes of the health legislation some economic terms (cursive): “*integrated management of cardiovascular risk factors*”.



**Figure 1. Frequency of the word “risk” for assistances**

Source: MH/NHIIH No. 397/836/2018 Order

Prior to the entry into force, on 1<sup>st</sup> April 2018, the methodological norms for the implementation of the framework contract (Order no. 397/2018), the NHIIH Press Office issued a communication

regarding the main novelties stipulated in the normative act. It announced that the primary care physician would be allowed to carry out new consultations and services on certain risks, such as: recommendation for screening tests for hepatitis B and C virus infection for all insured persons; continuous measurement of BP for 24 hours (Holter performance and interpretation) for patients with high cardiovascular risk. The early diagnosis of mammary tumors and risk pregnancy surveillance can be performed in a special clinic ambulatory. In order to avoid a technological risk (high probability and major impact – given the large number of patients), the source of which was the impossibility of transposing legislative information, the legislator deferred until 1<sup>st</sup> January 2019 prescribing medicines and recommending medical analyzes to patients regardless of the HIH at which they are insured.

It must be mentioned that in case of identifying risks related to reproductive health, women who want to remain pregnant but fail, MH have been running since 2011 a: *Subprogram for in vitro fertilization and embryo transfer*. At the same time, a draft regulation of ambulatory cabinets within the sections (proper management of hazardous waste, compliance with sanitary and hygienic norms to avoid the health risks of the tenants, which may have a major impact) is also envisaged. This project will be reflected, from the contracting perspective in a logistic risk (low probability and low impact), characterized by all binding documents sent to the suppliers and checked by the officials, for closing the contracts: new valid sanitary authorizations, proof of cabinet valuation, malpractice insurance policies on the cabinet etc. Failure to comply with the new provisions may lead, under the terms of the contract, to suspension or termination of contracts already concluded.

#### 4.2 Medical care at home

In the medical care at home are, the novelty provided by the Order 397/2018 [Annex 31A, Art. 3, par. (1)] consisted in installing, starting this year, the contract values for this type of suppliers, the being allocated based on a score attributed to suppliers, by the staff employed and its schedule. The methodology is similar to the scoring award for outpatient health care providers in paraclinical or physical and rehabilitation care. In accordance with the provisions of Annex 31A, Art. 3, par. (2); a) – c) it is specified the manner of determining the value of the contract for each supplier, which can be expressed in the following formulas<sup>1</sup>:

a) determining the total number of points by adding up the number of points obtained by each individual supplier:  $TP_{S1-Sn} = P_{S1} + P_{S2} + P_{S3} + \dots + P_{Sn}$

b) calculating the value of a point by dividing the budget allocated to health care at home to the total points of all suppliers:  $V_P = B_{HCH} / TP_{S1-Sn}$

c) the maximum possible amount to be contracted for each supplier by multiplying the value of a point by the number of points obtained by each supplier:  $CV_{S1} = V_P \times P_{S1}$

The verification key resides in the formula:  $B_{HCH} = CV_{S1} + CV_{S2} + CV_{S3} + \dots + CV_{Sn}$

Par. (3) states that the contracted amount should be broken down by quarter and month.

Attributing contract values based on score was one of the few possible ways to avoid financial risk. For example, in 2017, we have found cases where the budget allocated to these providers was exhausted in the first 3-4 days, when hundreds of home care requests were registered. In the beginning of the months, this phenomenon led to over-financing, and for the rest of the months, there were no longer any such claims on the part of patients, a sub-financing situation being visible. Excessive funding/underfunding, two extreme financial risks, were highly probable and major impacts, temporarily affecting most applicants. This year, due to the fact that new limits were mentioned in the contracts, it can be seen that the registration of the tens of applications in a week and, consequently, a balanced monthly distribution of the budgetary resources allocated to this area of assistance, the financial risk having a probability low and a minor impact.

<sup>1</sup> Where:  $P_S$  – total points obtained by each individual supplier;  $TP_{S1-Sn}$  – total number of points of all suppliers;  $B_{HCH}$  – budget allocated to health care at home;  $V_P$  – value of a point;  $CV_S$  – contract value for each individual supplier.

## **5. NEWS ABOUT THE RISKS FOUND IN THE NATIONAL HEALTH CURATIVE PROGRAMS**

We must state from the beginning, unlike MH programs that are disease prevention, NHPs run by NHIH are addressed to patients with a high risk of chronic diseases. A high number of chronic patients has a major impact over the economical system for the following reasons: costs (this patients require a treatment that becomes more and more expensive), a gap is created in the workforce, high rate of absenteeism (sick leave), and low productivity as a result of mortality and morbidity and others. Other information sources argue that the final loss cost in production associated to mortality and morbidity caused by cardiovascular diseases reached €54 billions in EU, while the treatment cost, went up to €45 billions (Guță, 2018).

### **5.1 Hearing loss risks and the launching of new devices within the National Hearing Loss Treatment Program**

Hearing loss risk (reduced hearing) led to the opportunity of purchasing some sound processors for the patients carrying a cochlear implant from the suppliers agreed by NHIH (for example the Clinical Hospitals from Cluj-Napoca, Targu Mures, Craiova and others, mentioned by the *NHIH Order no. 245/2017 for the approval of the Technical Norms for the implementation of national curative health programs for 2017 and 2018*) for the development of the National Hearing Loss Program.

These new devices had been financed through the NHPs financial scheme, according to *NHIH Order no. 932/2018 concerning the modification and completion of the Technical Norms for the implementation of a the national health programs for the years 2017 and 2018, approved by the Order of the President of the National Health Insurance House no. 245/2017*, available in chapter IX, NHP Activities of Hearing Loss Treatment, par. (2), a)–b). This legal modification is included in the budgeting section, available on the official web page ([www.cnas.ro](http://www.cnas.ro)) financed through the *Unique National Health Insurance Fund*, as commitment credit indicator, chapter 6805/subchapter 03/paragraph 03 and enclosed by the supplier's contracts.

Between the time when doctors are requesting these devices, following the legal procedure (Off. M's public announcement, listing, budgeting and others) and the time of acquisition done by the suppliers, a few months, period of time that can be considered itself a risk for the patients who can't afford buying these devices using personal funds.

In this particular situation the legislator anticipated the possibility of exchange if the sound processors are overused, broken, without the option of being fixed, doesn't work within the optimum parameters, all these considered itself a risk for hearing. It is considered the following: ongoing medical procedure and achieving the desired outcome from the intervention, its adapting possibility, same as for the repaired prosthesis or of their components, for the patients carrying a prosthesis, part of the Orthopedic NHP, or the replacement of the automatic implantable cardiac defibrillator for patients with cardiovascular diseases and a high risk of unexpected death. The funding of these defibrillators is available through Cardiovascular Diseases NHP, enclosed by NHIH Order no. 245/2017, chapter IX, program's activities, 5) point, while the replacement procedure for a defibrillator is mentioned by Order no. 397/2018, 23BII Annex, 158 point, still enclosed on the legislation.

An example missing from the legislation is the replacement of generators, component of the neurostimulator implanted to epileptic patients and financed through the *Epilepsy Resistant to Drug Treatment Subprogram*, implanting the vagus nerve activity (NHIH Order no. 245/2017). During the post-operation phase the doctor is keeping the patients under observation, considering the following risks: infection, dysphasia, hoarseness and others.

One of the most important achievements of the Romanian medicine is that, out of the 81 patients who benefit from an implant procedure between 2012 – Jan. 2015 at the *Emergency Hospital*

"*Bagdasar Arseni*" from Bucharest, only one – 1.24% – suffered dysphagia, and 11 – 13.54% – had immediate effects (Gorgan et al., 2015: 158). The generator is extremely vital because the battery status can be checked; any impedance and disruption of the entire system, considering a life cycle of 5 years per generator, and any missed replacement can lead to an epileptic status risk for the patient. For this reason, the contract with HIH is covering just the neurostimulators, without considering the generator's costs, a situation highlighted even by the doctors. Seeing the excellent results of this subprogram, *per analogia legis*, financing the costs of these generators is compulsory as part of the subprogram, same as for the sound processors and defibrillators.

## 5.2 Vital risk for diabetic children and introducing new medical materials within the National Diabetes Program

In mid September this year, the Finance Minister asked NHIH to prepare all the secondary normative documentation within maximum two weeks in order to receive finance for the National Diabetes Program until winter time. The Minister's words *ad litteram* were: "A child is being injected eight times per day and three out of four children die. Their parents are watching them while the children are sleeping and they don't know if will ever wake up" (Ciocotisan, 2018). Same Minister drew public attention towards another two interdependent risks: *the vital risk* for children who do not know how to monitor and control the glucose level and to calculate themselves the number of food calories and also the *legislation risk* from the authorities who delay the secondary legislation.

In a recent interview, T. Ciuhodaru, who is a doctor but also a deputy, explained the benefits of these new regulations, approved through *G.D. no 737/2018 for the amendment of Section B of the Annex to G.D. no. 155/2017 on the approval of national health programs for the years 2017 and 2018*, for the 830.000 diabetics, from which 3.000 are children who are insulin-dependet and 239.460 under insulin treatment: it is the first time when the Romanian authorities are launching a diabetes program dedicated to youngsters, offering free of charge medication and a chance to a normal life; new medical materials are funded (sensors for permanent monitoring of glucose level and insulin pumps designed with a monitoring system of glucose); more than 4.500 sting procedure that a T1 diabetic child should do are eliminated. Amongst new other clauses, more legal rights are given to diabetic children who are insulin-dependent: they will benefit from a carrier up until the age of 18, an allowance of 200 RON and others (Mitu, 2018).

The G.D. no. 737/2018 comes as a modification of G.D. no. 155/2017, IV point, b) – c) as can be found below, including the latest changes (cursive):

b) providing medical treatment for diabetic patients, including the specific *medical devices* (insulin pumps, *insulin pumps systems with continuous monitoring sensors for glucose level* and consumable materials for it);

c) auto-monitoring for diabetic patients under insulin treatment (*auto-monitoring glucose tests and permanent glucose monitoring systems*).

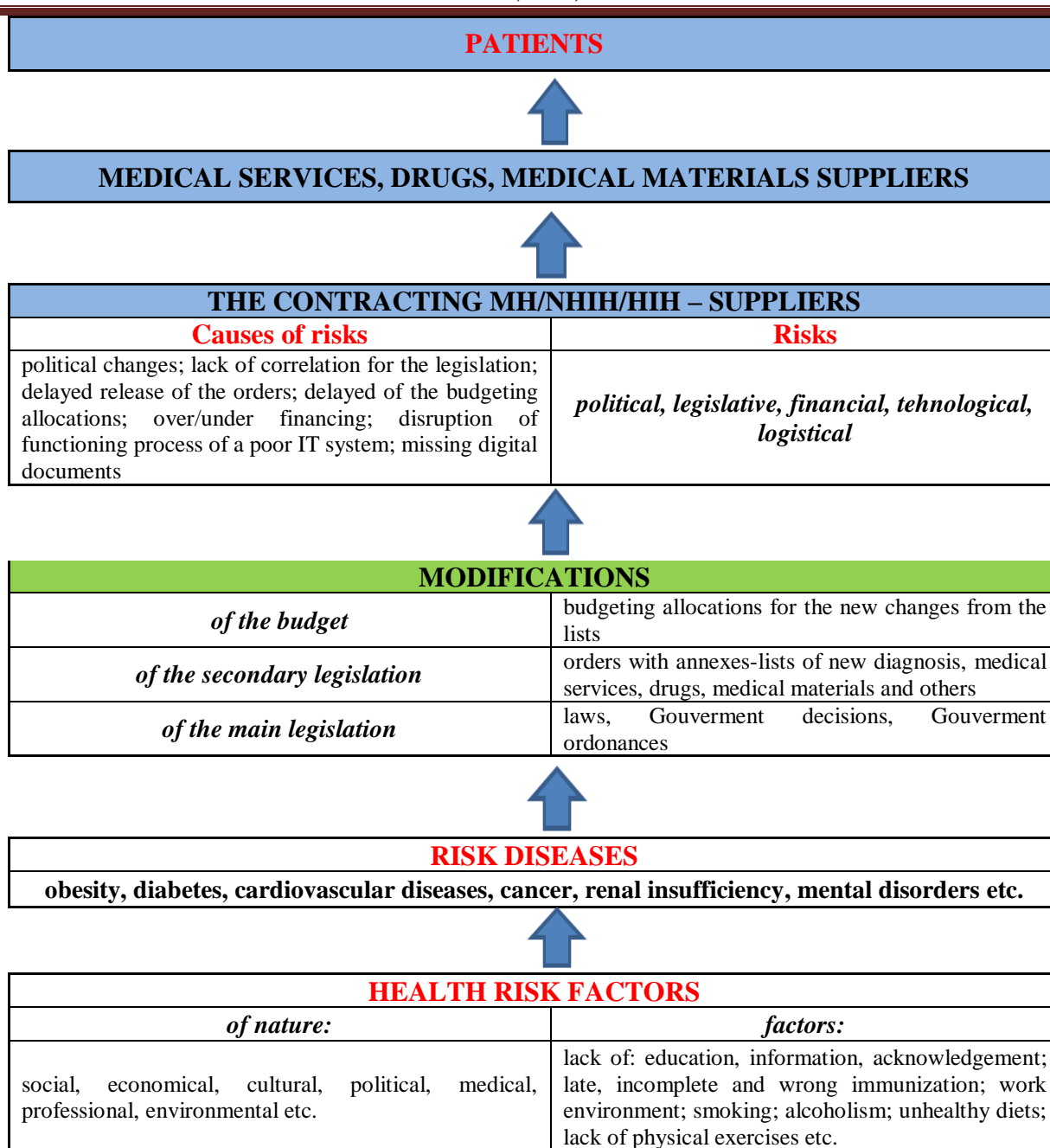
The legislative risk comes from the lack of correlation between the secondary and main legislation. For this reason, the simple modification of G.D. no. 155/2017 that is just mentioning the programs without modifying NHIH Order no. 245/2017 regarding some important legal aspects of how it should be applied (activities, eligibility criteria for patients and decision making factors, physical and efficiency indicators, type of payments, the sanitary units that can run the program and others) delays the knowledgde of how to apply G.D. no. 155/2017. This delay has been avoided through one of the most efficient institutional teamwork, taking just 14 days between the day when G.D. no. 737/13.09.2018 was released and the *NHIH Order no. 1328/2018 amending and supplementing the Technical Norms the attainment of national health programs for the years 2017 and 2018, approved by the Order of the President of the National Health Insurance House no. 245/2017*, who regulates all these practical aspects mentioned above.

## 6. CONCLUSIONS

Within the health system, risk can be found under different forms, considering many aspects (medical, economical, legal) and it is linked to a various number of subareas: health insurance, medical care, finance, or associated to political and demographic factors and others. A first correlation can be observed at the public health level between: risk factors, exposure of the citizens with sickness risk, epidemiological risk and NHPs of prevention conducted by MH, who is the main responsible for public health policies. Without any doubt the primary care doctor is often the first who identifies the illness risks for a patient, the frequency of "risk" word being ten times higher in primary medicine legislation than the average for other assistances. The logistical risk can be associated with transmitting the documentation contracting medical services, documents that must always be updated according to the latest legal modification in order to be considered valid. By including new legal requirements (mentioning the value of contract) the authorities managed to avoid further financial risks for some assistance sectors (medical care at home). There is a need for further regulation, using the analogy of the law, for bringing all together – financially wise the funding for some parts of medical devices which are worn in time and are covered financially in some situations, but are excluded by the law in other occasions.

This is just one of the causes that lead to legislative risk, same as the lack of correlation for the secondary legislation, ambiguity in interpretation, delays regarding the acknowledgement of new updates such as inclusion/exclusion from the list of some diagnosis, drugs, medical materials and others. Still, the speed for releasing the new law amendments must appraised as it reduces the sickness or even saves the patient's LIFE. It can be stated without any doubt that there is a strong link between health risks, legislation, budgeting and some risks associated to contracting process with suppliers. This link mentioned by the legislation for some sectors, and quite rare, completely starting with risk factors and ending with the benefits that patients can get from it (services, drugs, devices and others), can be seen in **Figure 2** on this occasion.

In the "Digital Era" the lack or disruption of sickness registers can be seen as a risk for patients and for authorities, who can not answer a simple question such as "How many patients are and what type of needs do they have?". Furthermore, patients don't take advantage of the information available on the public websites and for this reason the lack of information, education and risk knowledge can be considered causes for other public health risks regarding costs, services, travels, epidemics and others. At an institutional level it must be appreciated the access to a digital platform for contracting medical services that facilitates the access and avoids technological risks and also the delaying from the authorities's side of some projects with a national scale impact until the time when digital infrastructure will be adapted to all these new changes.



**Figure 2. Implications: risk factors – risk diseases – legislation – contracting – suppliers – patients**

Source: authors

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