

Ss. Cyril and Methodius University in Skopje



INSTITUTE FOR  
SOCIOLOGICAL  
POLITICAL AND  
JURIDICAL  
RESEARCH

INSTITUTE FOR SOCIOLOGICAL,  
POLITICAL AND JURIDICAL RESEARCH



# CHALLENGES OF CONTEMPORARY SOCIETY II

Proceedings from the International conference

17 November 2017, Skopje, Macedonia



INSTITUTE FOR  
SOCIOLOGICAL  
POLITICAL AND  
JURIDICAL  
RESEARCH

“Ss. Cyril and Methodius” University in Skopje  
Institute for sociological, political and juridical research

# CHALLENGES OF CONTEMPORARY SOCIETY II

**Proceedings from the International conference**

**17 November 2017,  
Skopje, Macedonia**

"Ss. Cyril and Methodius" University in Skopje  
Institute for sociological, political and juridical research  
International conference:  
CHALLENGES OF CONTEMPORARY SOCIETY II  
17 November 2017,  
Skopje, Macedonia

---

## **International program committee:**

**Prof. Mirjana Borota Popovska**- Director, Institute for sociological, political and juridical research, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

**Prof. Reinhard Heinisch**, Head of Department of Political science, Faculty of Political science and Sociology, University of Salzburg, Austria

**Prof. Tamara Dzamonja Ignjatovic**, Faculty of Political science, University of Belgrade, Serbia

**Prof. Panajotis Cakirpaloglu**, Department of Psychology, Philosophical Faculty of Palacky University in Olomouc, Czech Republic

**Assoc. Prof. Camelia Florela Voinea**, Political science faculty, University of Bucharest, Romania

**Assist. Prof. Katerina Spasovska**, Department of Communication, Western Carolina University, USA

**Assist. Prof. Annick Magnier**, Department of Political and Social Science, University of Florence, Italy

**Prof. Ljiljana Kaliterna Lipovčan**, Ivo Pilar Institute of Social Sciences, Croatia

**Prof. Fimka Tozija**, Institute of Public Health, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

**Prof. Ulrich Laaser**, Faculty of Health Sciences University of Bielefeld, Germany

**Assist Prof. Giorgia Bulli**, Department of Political and Social Science, University of Florence, Italy

**Assist Prof. Jacek Bylica Jagiellonian**, University in Kraków, Poland.

**Assoc Prof. Eleonora Serafimovska**, Institute for sociological, political and juridical research, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

**Assoc Prof. Marija Topuzovska Latkovikj**, Institute for sociological, political and juridical research, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

**Prof. Ganka Cvetanova**, Institute for sociological, political and juridical research, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

---

**Prof. Branislav Radeljic**, Associate Professor of International Relations, School of Social Sciences University of East London, United Kingdom

**Prof. Dragan Todorovic**, Faculty of Philosophy, Nis, Serbia

**Prof. Ruzica Cacanovska**, Institute for sociological, political and juridical research, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

Coordinator of the International program committee and Organizational committee:

**Assoc. prof. Marijana Markovikj**, Institute for sociological, political and juridical research, "Ss. Cyril and Methodius" University in Skopje, R. Macedonia

**Ranko Sovilj, PhD, Research Assistant**

[soviljpeca@gmail.com](mailto:soviljpeca@gmail.com)

**Sanja Stojković-Zlatanović, PhD, Research Assistant**

Institute of Social Science, Belgrade, Serbia

[sanjazlatanovic1@gmail.com](mailto:sanjazlatanovic1@gmail.com)

## **THE LEGAL REFORM OF HEALTH CARE SYSTEM IN THE REPUBLIC OF SERBIA<sup>1</sup>**

### **Abstract**

Serbian law joined the active reforms in the health care sector. The procedure for the adoption of several laws in the area of health care is undergoing, aiming at improving health care services. The main reason for the adoption of new legislation is need for harmonization in the area of health care and health insurance system taking into account modern developments in the region countries and in the EU. Increasing the scope of mandatory health insurance is projected due to the growing needs of population for health care. It covered the new categories of the population, providing greater scope of health care to vulnerable social groups. Furthermore, the obligation of the individual to respond to a call for targeted preventive examination or screening under appropriate national programs is introduced. As a part of health care reform, Serbian government adopted Biomedical assisted fertilization Law creating preconditions for the promotion of donations in order to increase the number of successful treatments.

---

<sup>1</sup> This paper is the result of work on projects No. 179023 and No. III 41004 financed by the Ministry of Education and Science of the Republic of Serbia.

It is likely to enhance the quality of health care taking into account modern standards of medical science and practice, complying with the EU legislation as well. There is also an initiative for adoption of new Pharmacy Law aiming to regulate pharmaceutical industry based on demographic, geographic and technical criteria.

**Keywords:** health care, compulsory health insurance, voluntary health insurance, transplantation of cells, tissues and organs, biomedical assisted fertilization

## Introduction

The period behind us was marked by active legislative reform in the field of health care. There are several health-related laws in the parliamentary procedure, which should be adopted by the end of the year, while some of them have already been adopted, such as the Law on Biomedical Assisted Fertilization<sup>2</sup> and the Transfusion Medicine Act.<sup>3</sup> The main goal of the reforms envisaged is the improvement of health care, and health services. Another important reason for the adoption of new laws is the need for harmonization of the Health Care System and Health Insurance with modern achievements both in the region countries and in the EU.

The Draft Laws are based on the principles of solidarity, reciprocity, and social justice, so that the scope of the mandatory health insurance coverage could be extended to as many citizens as possible. There is also a possibility of contracting a larger scope of rights by introducing a voluntary health insurance package in the context of the specialization of additional services. Extension of the scope of rights in mandatory health insurance is taking place due to the constantly increasing population needs for health services. Comparative analysis shows the trend that more and more funds for health care have been allocated in recent years.<sup>4</sup> One of the reasons is a demographic factor, i.e. the

---

<sup>2</sup> Law on Biomedical Assisted Fertilization, *Službeni glasnik RS*, No. 40/2017

<sup>3</sup> Law on Transfusion Medicine, *Službeni glasnik RS*, No. 40/2017

<sup>4</sup> Institut za uporedno pravo (2014) *Sistemi zdravstvene zaštite i zdravstvenog osiguranja, Uporednopravna analiza u evropskim zemljama*. Sindikat lekara i farmaceuta Srbije – Gradska organizacija Beograda, Beograd.

population aging trend. This is why a domestic legislation endeavors to introduce the mandatory targeted preventive screening program within the framework of social responsibility for an individual's health. The plan is also justified regarding the aspect of protecting the general interest in the field of public health, reducing the costs of health care in terms of the prevention of serious diseases, and the preservation and improvement of the health of individuals.

## **Health Care Protection Issues – Proposed Novelty**

At the end of 2016, the Ministry of Health of the Republic of Serbia proposed the Draft Law on Health Care.<sup>5</sup> Bearing in mind the current Law on Health Care it can be observed that the draft has systematically improved both the systematization of the provisions, and the terminological compliance of the institute. The impression is that the Draft has a better logical structure and harmonization of the regulatory issue and it is terminologically well-balanced. Addressing the general social interest and concern for the health of the population, the Draft provides the extension of health care to foreign nationalities and stateless people with permanent and temporary residence in the Republic of Serbia, as well as internally displaced people from the former Yugoslavia. Also, displaced unemployed persons with a low monthly income with a place of residence in the territory of Serbia are protected by the Draft Law.<sup>6</sup>

For the first time in the Health System of the Republic of Serbia, the Draft Law has foreseen the introduction of mandatory targeted preventive screening or screening for an individual.<sup>7</sup> The introduction of a mandatory citizen response to targeted screening is considered justified from the aspect of protecting the general interest in the field of public health, reducing the costs of health protection in the context of the prevention of serious diseases and condition, preserving and

---

<sup>5</sup> Ministry of Health of the Republic of Serbia. *Draft Law on Health Care*. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt\\_zakona\\_o\\_zdravstvenoj\\_zastiti\\_1.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt_zakona_o_zdravstvenoj_zastiti_1.pdf) (accessed 10 September 2017).

<sup>6</sup> Draft Law on Health Care, Art. 3, 11.

<sup>7</sup> Draft Law on Health Care, Art. 15.

improving health, and reducing mortality from cancer, cardiovascular diseases, diabetes and other chronic diseases. Screening programs should be implemented relying on the principle of usefulness for the Health Care System and harmonized with the principle of privacy and confidentiality of personality data of the participants in screening programs. Given that the Draft provides mandatory screening, a more thorough regulation of the procedure for its implementation is needed, as it is the case with in comparative law, requiring mandatory full information on the purpose and importance of the screening.

Reform of the Health Care System foresees reintroduction to the Health System clinic and the Health Center. In the provisions governing the activity of the health center the provision of emergency medical assistance is omitted, and this activity is transferred to the regional Emergency Medicine Units, which, in addition to the existing 4 institutes, will be established for the territory of one or more local self-government units. This solution completely changes the system that has functioned well in practice and calls for the formation of new units, which will undoubtedly cause new additional costs. It would be more useful to improve the existing system than to introduce a new one without an adequate reason based on good experience. Also, it is planned to establish new types of the institute: Institute for Palliative Care, Institute for Laboratory Diagnosis and Institute for Radiological Diagnostics.<sup>8</sup>

On the other hand, the reason for the adoption of the new Law on the Application of Human Cells and Tissues is the need for the field of human tissue applications to be based on the highest standards of medical science and practice, given that the field of medicine is intensively developed and offers great opportunities for treatment.<sup>9</sup>

The current Law has created confusion in practice because it has not clearly defined an institution that could be a tissue bank. This was the reason why the bank has never been established. With the clear

---

<sup>8</sup> Draft Law on Health Care, Art. 28, 74, 80-89

<sup>9</sup> Ministry of Health of the Republic of Serbia. *Draft Law on the Application of Human Cells and Tissues*. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/NACRT\\_ZAKONA\\_o\\_primeni\\_celija\\_i\\_tkiva.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/NACRT_ZAKONA_o_primeni_celija_i_tkiva.pdf) (accessed 25 September 2017).

defining of conditions regarding the performance of activities, space, equipment and personnel issues, health institutions will be able to obtain a license for performing these activities. In order to set out the modern medical standards in the field of transplantation of human cells and tissues, it is necessary to define the Register of donors of hematopoietic stem cells, which allows finding unrelated donors and providing cells for transplantation. The Draft simplified the procedure in terms of licensing the Health Care institutions for performing human organ transplantation activities and established a single Information System. The Draft Law proposes the presumed consent of the deceased provider, i.e. the opt-out solution.<sup>10</sup>

The development of science and a wider use of human body substances have led to their commercialization without the consent of the authorities. The case of John Moore is well known, whose spleen cells, as unique, used to produce proteins important for the immune system, and later, to a large extent, are commercially exploited. The market value of this drug (which would not have developed without these unique cells) was about \$ 3 billion. John Moore who has not been informed and has not given the consent claimed to be a stakeholder in the proceeds of the sale of a drug, which was recognized by the California Supreme Court ruling. Data on the taking and sale of parts of the corpse to pharmaceutical companies without the consent of the authorized persons are published in the media, primarily abroad (Sjeničić, 2003).

The intention of the legislator is to systematically regulate the area of transplantation of human organs for the purpose of a treatment. Also, the legislator's intent is to establish and ensure the conditions for achieving quality and safety standards in transplantation of human organs, as well as to set up working conditions and organization of the health system aimed at ensuring the optimal viability of transplant organs and a high level of protection of human health. The Draft Law on transplantation of human organs for the purpose of treatment emphasizes the perseverance of the priority interests in order to protect life and health of individuals and ensures exercising the basic human rights and dignity of both the donor and the recipient.<sup>11</sup>

---

<sup>10</sup> Draft Law on the Application of Human Cells and Tissues, Art. 28.

<sup>11</sup> Ministry of Health of the Republic of Serbia. Draft Law on transplantation of human

As one of the main reasons for adopting a new law is increasing the number of successful organ transplants, and reducing the waiting list for organ transplants. It presupposes establishing effective procedures for donation in accordance with professional standards and ethical principles. In the preamble of some international documents, it is noted that the number of organ transplants from deceased persons indicates the level of development of society. Despite all achievements of this medical procedure, transplantation is still accompanied by numerous controversial issues and dilemmas, which show that it has not been yet fully defined by legal and ethical norms (Mujović-Zornić, 2013:1).

The need for organs is on the rise all over the world and the waiting lists are long. It is estimated that in the EU about 61,000 people are waiting for organ donations, and approximately 12 people die every day while waiting for a transplant. Therefore, scientific attempts has examined the possibilities of the so-called xenotransplantation, i.e. the process of transplanting organs or tissues between members of different species (for instance, between animals and humans).

In order to promote donation, the state creates the possibility of opt-in for a donor card. Progress in organizational terms has not been accompanied by an increased number of transplants since Serbia took the last place in Europe by the number of transplants. The main reason is the lack of voluntary donors. On the other hand, there have been cases in which individuals offered the sale of their own bodies, most often through advertisements in the press. The occurrence of trafficking in human organs was noticed in 1980s in the countries of Southeast Asia and since the year 2000 trafficking in organs has started to spread globally. Over time it has also evolved as one way of health tourism between developed and poor countries (Mujović-Zornić, 2013; Nedić, 2016). Organ transplantation is also a form of organized crime.

The draft law provides the presumed consent of the deceased donor.<sup>12</sup>

---

organs for the purpose of treatment. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacr\\_Zakona\\_o\\_presadjivanju\\_organu\\_u\\_svrhu\\_lecenja.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacr_Zakona_o_presadjivanju_organu_u_svrhu_lecenja.pdf) (accessed 25 September 2017).

<sup>12</sup> The organs of the deceased can be taken for transplantation, if the adult donor with legal capacity, before death is not verbally or in writing for life, or if the parent,

If we consider the existing models of legally accepted organs from the diseased donors, the two different systems can be identified in the comparative law:

1) An opt-in system or explicit consent: parts of the deceased body cannot be taken unless explicit consent is given in the manner prescribed by the law (Denmark, Germany, The Netherlands, Switzerland, Australia and the United States). This significantly reduces the circle of potential organ donors. Therefore, the legislators of these countries extended the possibility of consent to the relatives of the deceased. The family has the right to the subsidiary decision if the deceased hadn't declared it.

2) An opt-out system or a system of the presumed consent: the deceased is allowed to take organs if he hadn't objected to life. In this regard, the consent is assumed. Taking is allowed even when there is a doubt about the will of the deceased. This means that taking organs from dead people is not prohibited in principle. This increases the number of potential donors, because they also include those who haven't even made a statement at all. Laws on the transplantation of most EU countries accept this model (Italy, France, Spain, Belgium, Poland, Austria, Sweden, Norway, Croatia, and Slovenia) (Mujović-Zornić, 2013:5).

Biomedical assisted fertilization is an area of medicine that has been intensively developed over years, offering great opportunities for the treatment of various forms of infertility and sterility (Mujović, 2017:440). So far, the field of biomedical assisted fertilization has been regulated by the Law on the treatment of infertility by procedures of biomedicine-assisted fertilization.<sup>13</sup> The current law regulating the field of infertility treatment by the methods of biomedical assisted fertilization has not recognized the importance of defining and regulating the activities of biomedical assisted fertilization and the conditions under which this activity can be performed. These conditions include testing, obtaining, processing, freezing, defrosting, conservation, storage and

---

spouse, extra-marital partner or adult child died at the time of death did not expressly object. Draft law on transplantation of human organs for the purpose of treatment, Art. 23.

<sup>13</sup> Law on the Treatment of Infertility by Procedures of Biomedicine-Assisted Fertilization, *Službeni glasnik RS*, No. 72/2009.

distribution reproductive cells, zygotes and embryos, as well as the import or export of reproductive cells. It caused long-standing practice that biomedical fertilization procedures are being carried out in health institutions without defining the conditions at the national level under which they will be performed (Mujović, 2017:442).

The Law brings novelty in the area of private practice, where private health care institutions could provide health services if it meets the requirements prescribed by the law<sup>14</sup>. The increase of incidence of infertility in our country in recent years has indicated the necessity of involving as many couples as possible in the procedures of biomedical assisted fertilization. This means the reorganization of health care institutions, where private health care institutions could participate under the same conditions as public institutions.<sup>15</sup>

The Law has expanded the definition of biomedical assisted fertilization to the case regarding the preserving of fertility, while the previous law was concerned only with the cases of infertility. This solution increases the chance for the successful procedure of biomedical assisted fertilization for those persons who, for medical reasons, are not able to be in the process at the time of its implementation.

It is stipulated that the right to biomedical assisted fertilization has an adult, a capable woman and a man who needs the help of biomedical assisted fertilization in the treatment of infertility, leading a joint life in accordance with the law governing family relations i.e. spouses or extra-marital partners.<sup>16</sup> Also, the right entitles a woman with legal capacity living alone and is capable of performing parental duty taking into account her psychosocial condition and interest of a child to undergo the procedure of biomedical assisted fertilization.<sup>17</sup> Furthermore, the

---

<sup>14</sup> Law on Biomedical Assisted Fertilization, Službeni glasnik RS, No. 40/2017, Art. 14.

<sup>15</sup> We believe that this solution is justified, since it allows access to most couples. In recent years, couples have often gone to other countries to access biomedical assisted fertilization. It is impossible to tell how many people travel in order to access fertility services. In 2010, Shenfield et al. estimated that there were about 24–30,000 cycles of cross border fertility treatment within Europe each year, involving 11–14,000 patients (Jackson, Millbank, Karpin, Stuhmcke, 2016).

<sup>16</sup> It is also regulated in other countries in the region. To see (Alinčić, 2006; Žnidaršić-Skubic, 2008).

<sup>17</sup> The law does not envisage the age limit to which the procedure of biomedical as-

Law stipulates that the right to biomedical assisted fertilization has also a legally capable woman or a man who has postponed the use of their reproductive cells because of the possibility of reducing or losing reproductive function that meets the requirements prescribed by this law. The existence of medical indications would be determined by the competent specialist.<sup>18</sup>

The donated reproductive cells could be used in the biomedical assisted fertilization in two cases: 1) when it is not possible to use reproductive cells of one of the spouses or extra-marital partners and 2) when the conception could not occur for medical reasons or when other medical assisted procedures were unsuccessful. Also, this could be applied when it is necessary to prevent a severe hereditary disease of a child. The above procedures show that the use of donated reproductive cells is allowed only for one spouse, or extra-marital partner (Georgijević, 2009). In the biomedical assisted fertilization, donated embryos of spouses/extra-marital partners in the homologous method of fertilization can be used, only when spouses or extra-marital partners who do not want to use their embryos for their own fertilization provide their explicit written consent.<sup>19</sup>

By enacting a new law, conditions will be created for the promotion of donation and awareness raising on the importance of donation, as well as the organization of the health service for the implementation of the process of biomedical assisted fertilization, which will increase the number of successful treatment and improve the quality of the provided health care according to the regulation of the EU in this field.

---

sisted fertilization can be undertaken, but has taken a more flexible approach using standards that spouses or extra-marital partners are in such a psychosocial condition that they can be expected to be able to perform parental duties. This leaves enough space for assessing in each case the suitability for biomedical assisted fertilization without strictly binding years of life. In comparative law, the trend of determining the upper age limit for women, for example, is evident: 45 years old in France, 47 in Belgium, 50 in Greece (Cvejić-Jančić, 2010:7) Although the law does not specify the boundary, this is done by the Rulebook, which raises the age limit for women entering the process of biomedical assisted fertilization from 40 to 42 years. Rulebook on the content and scope of the right to health care from compulsory health insurance and participation for 2017. *Službeni glasnik RS*, No. 8/2017, Art. 10

<sup>18</sup> Law on Biomedical Assisted Fertilization, Art. 25.

<sup>19</sup> Law on Biomedical Assisted Fertilization, Art. 30.

## Health Insurance Issues – Proposed Novelty

The introduction of the Draft Law on Health Care was followed by the Draft Law on Health Insurance.<sup>20</sup> The need for adoption of the new Law is explained by importance of harmonization the health insurance system with modern achievements in the region and in the EU, although the current Health Insurance Law regulated the same matter, with minor differences.

The draft has extended the circle of insured persons on several grounds: it introduced two basic insurance schemes for farmers; it presented insurance scheme based on the performance of the notary's affairs; it also presented two insurance schemes for both persons receiving a pension or invalidity allowance exclusively from the foreign insurance holder and those with a permanent or temporary residence in Serbia.<sup>21</sup>

The Draft Law on Health Insurance creates a possibility of denying mandatory health insurance to insured persons in particular situations. Thus, healthcare services are not offered to the insured person who unjustifiably refuses to respond on call for a particular screening survey.<sup>22</sup> Although it is repressive and discriminatory, this provision aims at stimulating certain categories of population in terms of taking preventive examinations for the early detection of the disease. It caused much controversy among the scientific and professional public. To sum up, the mandatory screening of certain diseases has been introduced by the draft, whereby failure to respond to the call is sanctioned by the denial of health care funding. It favors the principle of economic utility rather than the principle of the individual's autonomy. The proposed solution is unconstitutional, since the Constitution of the Republic of Serbia guarantees that everyone has the right to the protection of his physical and mental health.<sup>23</sup> Furthermore, the introduction of

---

<sup>20</sup> Ministry of Health of the Republic of Serbia. *Draft Law on Health Insurance*. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt\\_zakona\\_o\\_zdravstvenom\\_osiguranju.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt_zakona_o_zdravstvenom_osiguranju.pdf) (accessed 10 September 2017).

<sup>21</sup> Draft Law on Health Insurance, Art. 11.

<sup>22</sup> Draft Law on Health Insurance, Art. 110.

<sup>23</sup> Constitution of the Republic of Serbia, *Službeni glasnik RS*, No. 98/2006, Art. 68.

penal provisions against insured persons could be criticized regarding the targeted population respond scarcely to screening programs. Conversely, if the state introduces a sufficiently functional call system, the appropriate level of citizen education and screening promotion penal provisions will not be necessary. It is also more important to work on further promotion and motivation of targeted population than on the penal policy and repression.

Medical examinations is not included into Health Care funding regarding enrollment in secondary schools, faculties, and courses obtaining a Health Care certificate for employees. Moreover, Health Care does not include medical examinations and treatments for professional and amateur athletes older than 14 years. Thus, the Law is harmonized with the Law on Sports which stipulates that mandatory health insurance provides funds for determination of general and special medical ability of children between 6 to 14 years in sports activities. Out of those cases in which insured persons do not provide Health Care, the legislator excludes women who have performed a mastectomy of one or both breasts and they can perform aesthetic reconstruction after the performed mastectomy on the basis of mandatory health insurance.<sup>24</sup> It is concluded that proposed solution is justified, since it contributes to improving the physical condition of the woman after the performed mastectomy.

The Draft Law on Health Insurance brings novelty in the area of voluntary Health Insurance, which has been regulated by the Regulation on Voluntary Health Insurance (by-law document).<sup>25</sup> The legislator seeks to precisely regulate this type of Health Insurance by proposing several models of voluntary Health Insurance. Furthermore, it sets up the implementation procedure, as well as the mechanism of financing. In this regard, voluntary Health Insurance is a long-term insurance, where contract period could not be shorter than 12 months. We consider that it is justified to regulate voluntary health insurance at the same level, since the current Health Insurance Law<sup>26</sup>

---

<sup>24</sup> Draft Law on Health Insurance, Art. 110.

<sup>25</sup> Regulation on Voluntary Health Insurance, *Službeni glasnik RS*, No. 108/08, 49/09.

<sup>26</sup> Health Insurance Law, *Službeni glasnik RS*, No. 107/2005, 109/2005, 57/2011, 110/2012 – decision US, 119/2012, 99/2014, 123/2014, 126/2014 – decision US,

only regulated in principle. It was regulated more detail by by-law document - Regulation on Voluntary Health Insurance, which makes these two insurance systems not the same way regulation of the same rank regulated. The draft proposes that the insurer could not conduct voluntary Health Insurance for an identical type, content, scope, standard, method, and procedure, as it is the case with the mandatory Health Insurance System. Taking into account International and Comparative Law, a prohibition of discrimination of insured persons based on age, sex or health status in terms of entering into a relationship of insurance has been provided. The considerable sensitivity of genetic data in the context of insurance has been considered, whereby the Draft prohibited the insurer to request genetic data, i.e. the results of genetic testing for hereditary diseases as a condition for establishing the insurance relationship. We suggest a new provision by adding the following "on the basis of the results of genetic testing, the premiums or sums of insurance could not be determined and limited." This statement represents a standard in Comparative Law, for instance, in the US law.

## **Discussion**

The Draft Law on the Application of Human Cells and Tissues proposes the presumed consent of the deceased provider, i.e. the opt-out solution. This solution was not unanimously accepted in domestic and foreign public as well as in foreign legislation. For instance, German, Swiss and Polish regulations accept an opt-in solution (the necessity of the explicit consent of the provider/donor). The Serbian legislator accepted the opt-out solution in order to increase the availability of cells and tissues for transplantation. Moreover, the law itself does not provide enough guarantee that the cells and tissues in the opt-out system will not be abused. Finally, given that the opt-out solution has been criticized, our legislator need to consider the experience of other opt-in countries, instead of forcing the presumed consent to promote the donation throughout various health-systemic mechanisms.

The opt-out solution is not adequate since the existence of a presumed

consent may be a result of the lack of information. Therefore, the institutions of the Health Care System need to create the mechanisms of donation promotion, rather than impose an opt-out solution as a way of transferring responsibilities from system to providers/donors. The opt-out solution is difficult to apply in practice since there is no register of persons who have opted not to be providers/donors. The reason for doing so was reducing the costs of keeping the register. However, the non-donor register needs to be established. Otherwise, it will remain unknown who explicitly denied becoming a donor. The lack of such register suggests that there is no serious intention of the legislator to actually record non-donors. Also, taking into account EU regulation, mainly Directive 2004/23/EC setting out quality and safety standards for donated human tissues and cells, Serbian legislator need to comply with those standards in a harmonization process. It means compliance with the provision of the voluntary donation and with the principle of mandatory and informed consent. Furthermore, the Directive encourages system registration of any serious adverse effects or reactions.

As Draft Law on the Application of Human Cells and Tissues, The Draft Law on transplantation of human organs for the purpose of treatment also provides the presumed consent of the deceased donor. If we proceed from the assumption of the presumed consent, there is a legal gap, since the draft does not state where the person who rejected being a donor could make a statement, although this possibility is envisioned by the Draft Law. The question that arises is where these persons will give the statement: with the general practitioners, the Biomedicine Administration, or there will be established a special register of these persons. In this regard, it could be said that there is a lack of a serious intention of the legislator to keep a register of these persons.

The new provision regarding the presumed consent of the deceased donor should be considered in the light of the prevention of possible abuse, the existing tradition and its established cultural and social norms. Thus, the active promotion of voluntary donation is a far better solution taking into account the current stage of development of Serbian society and Law.

On the other hand, the Draft Law on Health Insurance provides the

legal basis for the subsequent introduction of health insurance packages, which implies basic guaranteed rights within the framework of the right to Health Care provided by a universal mandatory health insurance. This can be interpreted as the basis for the subsequent introduction of health services packages, where only the basic package of services would be financed from the funds of mandatory health insurance, with the possibility of extending the scope of rights. The proposed solution is in line with the adopted solutions in the EU Member States, where primary public health insurance remains, but with the possibility of contracting a larger scope of rights in the context of the specialization of needs and services. Introduction the concept of specialization of needs and services presuppose the regulation of the voluntary health insurance according the EU standards. The voluntary health insurance is regulated as a financial service in the most EU countries where in the Third non-life Insurance Directive stands that voluntary health insurance represent a partial or complete alternative to publicly financed coverage taking into account the principle of freedom to provide services (Sagan, Thomson, 2016:86-89). Until now, in Serbia as in the most EU countries voluntary health insurance was regulated in the same way as any other financial services and special provisions regarding voluntary health insurance are not included in the text of the law. However in order to improve affordable access to voluntary health insurance special regulation of this area that goes beyond general insurance provisions must be encouraged taking into account recent trends in the most EU countries (Germany, France, Belgium, Croatia, Slovenia).

## **Conclusion**

As a principled comment, the question of justification of the adoption of the new Law on Health Care can be raised, when the current Law regulates the matter in the same way, taking into account that there are no significant changes related to the institutes themselves or different regulation of important health care issues.

When it comes to the Draft Law on Health Insurance, it should be emphasized that it is based on the principles of solidarity and reciprocity, and the principle of social justice. The draft introduces the possibility of additional, supplementary and private insurance as

a form of voluntary health insurance, which is a trend that has existed for several years in European countries, while the accession of Serbia to the EU requires the harmonization of domestic legislation in this direction. In this context, the justification for the adoption of a new law could be sought, since the existing Health Insurance Act regulates matter in the same way.

Finally, we conclude that the proposed and adopted solutions represent a significant improvement of the domestic Health Care System. There remains an open question of the application of particular institutes, such as the proposed transplantation solutions and biomedical assisted fertilization, taking into account the division of scientific and professional public. In addition, the inconsistency of certain solutions, inadequate conditions and mechanisms for their implementation should be added, which can lead to potential abuses and even more pronounced disagreement of the general public.

## References

Alinčić M (2006) Medically Assisted Procreation and Family Law Conflicts of Interest. *Zbornik PFZ* 56 (4): 890.

Constitution of the Republic of Serbia, *Službeni glasnik RS*, No. 98/2006

Cvejić-Jančić O (2010) Current Challenges of Biomedical Assisted Fertilization. *Pravni život* 59 (10): 7.

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, *Official Journal of the European Union*, L102/48

Georgijević G (2009) Medically Assisted Conception – Possible Suggestions from French Law. *Pravni život* 58 (10): 1099-1105.

Health Insurance Law *Službeni glasnik RS*, No. 107/2005, 109/2005, 57/2011, 110/2012 – decision US, 119/2012, 99/2014, 123/2014, 126/2014 – decision US, 106/2015, 10/2016,

Institute for Comparative Law (2014) *Health Care Systems and Health Insurance. Usporednopravna analiza u evropskim zemljama. Sindikat lekara i farmaceuta Srbije – Gradska organizacija Beograda, Beograd.*

Jackson E Millbank J Karpin I Stuhmcke A (2016) Learning form cross-border reproduction. *Medical Law Review*, 2.

Law on Biomedical Assisted Fertilization Službeni glasnik RS, No. 40/2017.

Law on the Treatment of Infertility by Procedures of Biomedicine-Assisted Fertilization Službeni glasnik RS, No. 72/2009.

Law on Transfusion Medicine, Službeni glasnik RS, No. 40/2017.

Ministry of Health of the Republic of Serbia. Draft Law on Health Care. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt\\_zakona\\_o\\_zdravstvenoj\\_zastiti\\_1.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt_zakona_o_zdravstvenoj_zastiti_1.pdf) (Accessed 10 September 2017).

Ministry of Health of the Republic of Serbia. Draft Law on Health Insurance. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt\\_zakona\\_o\\_zdravstvenom\\_osiguranju.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt_zakona_o_zdravstvenom_osiguranju.pdf) (Accessed 10 September 2017).

Ministry of Health of the Republic of Serbia. Draft Law on the Application of Human Cells and Tissues. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/NACRT\\_ZAKONA\\_o\\_primeni\\_celija\\_i\\_tkiva.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/NACRT_ZAKONA_o_primeni_celija_i_tkiva.pdf) (Accessed 25 September 2017).

Ministry of Health of the Republic of Serbia. Draft Law on transplantation of human organs for the purpose of treatment. Available at: [http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt\\_Zakona\\_o\\_presadjivanju\\_organu\\_u\\_svrhu\\_licenja.pdf](http://www.zdravlje.gov.rs/downloads/2016/Decembar/Nacrt_Zakona_o_presadjivanju_organu_u_svrhu_licenja.pdf) (Accessed 25 September 2017).

Mujović H (2017) Vantelesna oplodnja sa stanovišta medicinskog prava – zakonodavne promene u Srbiji. *Aktuelnosti građanskog i trgovačkog zakonodavstva i pravne prakse*, Sveučilište u Mostaru, Pravni fakultet, Neum, 440-442.

Mujović-Zornić H (2013) Donation and Organ Transplantation. Available to: <http://www.ius.bg.ac.rs/prof/Materijali/dramar/h.mujovic.transplantacija.pdf> (Accessed 7 October 2017).

Nedić T (2016) Criminal – and Medico-legal Aspects of (in)Admissible Removal and Transplantation of Human Body Parts in the Republic of Croatia. *Pravni vjesnik* 32 (1): 59-60.

Regulation on Voluntary Health Insurance, Službeni glasnik RS, No. 108/08, 49/09.

Rulebook on the content and scope of the right to health care from compulsory health insurance and participation for 2017. Službeni glasnik RS, No. 8/2017.

Sagan A Thomson S (2016) Voluntary health Insurance in Europe, Role and Regulation, World Health Organization.

Sjeničić M (2003) Komercijalno korišćenje čovekovih telesnih supstanci – osvrt na nemačko pravo. Pravni život 52 (9): 317-330.

Žnidaršić Skubic V (2008) The Issue of Consent in Bio-Medically Assisted Reproduction Procedures (The Case of “Evans V. The United Kingdom”). Zbornik PFZ 58 (5): 1145-1146.