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Supervision of medical activities

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Abstract It is investigated what kind of supervision could be exercised over medical activities in order to ensure the highest attainable quality of healthcare and access to medical services. To this end rights and especially duties of healthcare providers, definitions of sickness and effective healthcare provision, as well as various supervisory mechanisms and procedures for enforcing the rights, are analysed. It is argued that legal definitions of sickness and effective healthcare provision, stricter supervisory mechanisms and a single, legally regulated professional complaint procedure are required *de lege ferenda*.

KEYWORDS: • healthcare provision • sickness • mandatory health insurance • supervision • complaint proceedings • judicial review

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1 Introduction

It goes without saying that health is among the highest values of every society. It enables the existence and further development of every individual and society as such. Therefore, the right to health is subject of national and international legal regulation.[1]

In addition, the European Union (EU) recognises importance of health (Strban, 2013: 392). Especially when social risks of sickness or injury occur, it is essential to ensure accessible, high-quality and sustainable healthcare.[2] Equitable access[3] to healthcare has to be guaranteed in all its forms. Not only geographical access, which presumes proximity of medical facilities, but also financial, timely, procedural and informational access[4] has to be ensured for effective medical treatment of everyone under equal conditions.

This normative framework does not mean that we have the right to be healthy. Neither individuals nor States could guaranty a specific level of health. It is determined by individual's heredity and environment, and corrected by health interventions to a certain degree (Tomaševski, 1995: 125).

Therefore, healthcare providers are one of the cornerstones of (retaining and regaining) good health and their position has to be legally regulated as well. They have certain rights and duties in relation to their professional society, the State, mandatory health insurance and the patients.

Although, there are numerous interesting topics concerning healthcare providers, not all could be addressed in the present paper. Among them are discussions on (*bona fide*) errors and accidents in healthcare provision,[5] and on no-fault medical insurance, or rather important topic on protection of especially sensitive personal data, like medical data.[6] Also topics of criminal medical law and criminal responsibility of physicians will not be in the focus of this paper, since there is abundance of literature on this topic.[7] It could similarly be argued for civil medical law, including tort law and damages awarded by the courts of law, when damage is caused to the patient by a liable physician.[8]

Rather the research question of the present paper is what kind of supervision could be exercised over medical activities in order to ensure the highest attainable quality of healthcare and access to medical services. There is a constantly ongoing discussion in Slovenia on how to modify, modernise or reform the mandatory health insurance and healthcare provision. As a rule, hot topics are the 'basket' of benefits from mandatory health insurance (whereby recent proposals are in the direction of removing some of them and cutting cash benefits), finding more financing sources for healthcare, and delineating between public and private responsibility for health. There is hardly any debate on the supervisory mechanisms and procedures for enforcing healthcare rights by the patients.

The structure of the paper follows the topics of rights and especially duties of healthcare providers, definitions of sickness and effective provision of health care, various supervisory mechanisms and procedures for enforcing the rights, before presenting some concluding thoughts. The focus shall lie on physicians, recognising at the same time that other professions are equally important for providing suitable healthcare.

2 Rights and duties of healthcare providers

2.1 Rights of healthcare providers

The basic right of healthcare providers is the right to be paid for healthcare provided. Method of remunerating health care providers may influence also the relation between them and the patients.

Physicians may be employed and salaried. In this case they are not directly concerned with the method of payment by the public health insurance or NHS (or other source of financing) of their employers. Their autonomy of treating all beneficiaries equally with the same or similar health status could be more protected. Conversely private healthcare providers may be paid a capitation fee (fee per registered patient). The risk of the number of registered patients is in the domain of the health insurance. However, all other risks are transferred to physicians, especially the risk of morbidity. Additionally, physicians have no incentive to use more expensive methods of treatment, or to make many diagnostic (e.g. laboratory) tests, as this would reduce their disposable assets.

Physicians might be paid (solely or additional to capitation fee) a fee for service rendered. In this case, they might be tempted to provide more services, since they do not carry the burden of morbidity. Despite a clear awareness of the cost inflation potential of fee-for service, the power of private physicians has often made it difficult to adopt only capitation payment, which is as a rule less remunerative (Bennet, 1991: 31).

The payment of (especially) hospital treatment in the form of diagnose related groups (DRGs), rather than hospital days, seems to be established. Hospital receives a lump sum payment per initially diagnosed health disorder. Physician's autonomy and therapeutic freedom are somewhat limited, since it should be exercised within the framework of a lump-sum payment. However, such lump-sum payment may be modified according to certain weights (ponders), for instance when next to the main diagnosis also other diseases could be detected. In this case the tendency might be to perform a very thorough medical check and list all possible diagnosis in order to increase the lump-sum amount.

Sometimes budgetary limit per fiscal year might be applied for hospitals. However, this may lead to unequal treatment of beneficiaries, simply because they

require healthcare in distinct periods of time (e.g. at the end rather than beginning of the year).

Provision of medicinal goods, like pharmaceuticals or spectacles is usually paid as goods. However, it is not the pharmacy, which is solely responsible for providing pharmaceuticals. Equally important are negotiations and partnerships with manufactures of pharmaceuticals. Maybe even more important is to control if physician's therapeutic choice for a certain pharmaceutical was made *lege artis*. Physicians have to act in the best interest for the patient, but also in the best interest of solidarity community of contributors (to mandatory health insurance) or taxpayers (of NHS).

In many countries, patients have to share costs for healthcare, be it in a form of co-payments or other cost-sharing mechanisms[9] (Strban, 2014: 10). When patients have to pay healthcare providers directly, their desire to exercise consumer control over providers may increase. When there is no third party (e.g. mandatory health insurance) involved in the transaction, direct payment makes the provider more accountable to the patient (Mossialos E., Dixon A, 2002: 22).

Historically, the relation between the patient and the physician was the first one to emerge. Economically speaking it was an exchange relation in which patient demanded and physician supplied medical services. The latter obliged him to provide medical treatment and the patient rewarded it. Honorarium was at first not considered as a sinalagmatic obligation. During the times of Roman Empire and later in common law it was considered separately. Physician's services were provided '*honeste'* (because of honour) and without payment. In accordance with the art of medical profession, the wellbeing of patients was in the forefront of any treatment and not the acquisition of money. In fact, Roman physician was rewarded with non-mandatory payment, so called 'honorarium' (Gurgel, 2000: 5).

With the development of mandatory health insurance (also NHS and private health insurance products), which covers all inhabitants of a specific country, more complex relations have emerged, which had to be legally regulated. Next to the initial relation between the patient and the physician, relations between patients and social insurance carriers, and these carriers and healthcare providers developed. Insured patients do not claim medical services and medicinal goods at mandatory health insurance carrier (in Slovenia *Zavod za zdravstveno zavarovanje Slovenije*, hereafter the ZZZS), who is under obligation to provide them (especially in agreement with healthcare providers), but directly at healthcare providers, which are included in the treatment of insured patients.
These healthcare providers have to respect certain (general and more specific) duties.

2.2 Duties of healthcare providers

Among the general duties are duties obliging all healthcare providers, i.e. when providing services for private patients and when providing services for socially insured patients. The distinction between 'patients' and 'insured persons' is emphasised also in the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare [2011] OJ L88/45 (Strban, 2013: 399).[10]

2.2.1 General duties

General duty of physicians is to perform medical services, including medical prevention, medical diagnostics, acute medical treatment and medical rehabilitation. All physicians are responsible carriers of medical activities and they have to act *lege artis*, i.e. according to the current stand of medical science and professionally verified treatment methods.[11]

This opens two questions. One is personal, i.e. who ca perform medical services, and the other is material, which services should be performed. As to the personal dimension, medical services entail the so called physician's reservation (ger. *Arztvorbehalt*, slo. *zdravniški pridržek*, Strban, 2005: 198). Medical treatment is reserved only to persons who are licenced physicians. They have to advance in their professional knowledge and periodically renew their medical licence. Other persons might be excluded, even though they might have experience in healing people, e.g. healers in Slovenia.[12] At the same time, medical treatment includes not only personal (diagnostic and treatment) services of a physician, but also other, non-medical personnel. Delegation to such personnel may be allowed, if ordered and controlled by a physician, who remains responsible for medical treatment.

As to the material dimension, the questions might be which medical services should be performed and whether they could be exercised in accordance with the development of medical doctrine in a specific country. For instance according to the Slovenian Patients' Rights Act (*Zakon o pacientovih pravicah*, hereafter the ZPacP)[13] one of the rights is the right to adequate, quality and safe healthcare. It has to be in line with the contemporary medical doctrine, professional standards and norms, and development of the Slovenian health system. Medical services encompass all known (verified) treatments, who satisfy the above conditions and provisions of code of medical deontology.[14]

However, (under)development of the national health system might not suffice. The Court of Justice of the EU (CJEU) has harmonised the standard of medical services, by emphasising that satisfying the objective, non-discriminatory criteria involves treatment according to the state of international medical science and medical standards generally accepted at international level, not in the professional circles of each member state (Case C-157/99 *Geraets-Smits and Peerbooms*

[2001] ECR I-5473, EU:C:2001:404). If equal or equally effective medical services could not be guaranteed without undue delay in a home country, a person might have the right to healthcare in another (EU) country. This applies even if a specific method of treatment is not available (maybe not even performed, or would not be performed in a concrete case) in home country (Case C-173/09 *Elchinov* [2010] ECR I-8889, EU:C:2010:581). With such decisions, the CJEU has harmonised the standard of medical services within the EU.

Other general duties of healthcare providers could be found in the ZPacP, required to ensure patients' rights. Among them are the rights to equal access to healthcare and to respect the patient's time. The latter concerns waiting lists and consequences, if the patient misses an appointment (but no sanctions are foreseen, if the physician is not available at the agreed time). The right to be informed and to cooperate includes the duties of healthcare providers to seek informed consent by the patient. Information has to cover possible treatments, persons engaged, and costs of such treatments. Only exceptionally, the patient does not have to be informed. Healthcare providers have to enable the patient to be acquainted to medical documentation concerning him or her, to protect privacy and personal data.

Next to this, according to their nature more procedural rights, certain substantive duties could also be found in the ZPacP. Among them are the rights to preventive treatment and palliative care, which are more precisely regulated for socially insured patients in a tripartite general agreement between ZZZS, healthcare providers and the State.

2.2.2 Specific duties

Physicians might require a specific authorisation or accreditation for providing medical services to socially insured persons. For obtaining it, some subjective and objective criteria might have to be met. They might range from inclusion in a specific register, certain training period, age limit, setting *numerus clausus* of available places, i.e. a public network of contracted physicians (and other healthcare provides) who may provide healthcare to socially insured persons. In this way they take some specific duties, but gain the right to (secure monthly) payment. In Slovenian legislation such conditions are not prescribed, and all licenced physicians (and their employers) may compete for social health insurance funds.

Among specific duties is the duty to accept a socially insured patient. It is true, that every (socially insured or private) patient has the right to choose freely a physician and medical institution. However, this right is truly important only for socially insured patients. The other side of this right is the duty of a chosen physician to accept a patient. He or she may refuse such patient only under exceptional and legally regulated circumstances. According to Slovenian Rules of

mandatory health insurance[15] refusal is allowed, if the number of registered patients is above a certain number (set by mandatory health insurance carrier), a physician would be chosen against the rules, or due to long distances all the services for which a physician is responsible could not be provided.[16]

The right to choose freely a physician is in Slovenian law regulated in the Health Care and Health Insurance Act (*Zakon o zdravstvenem varstvu in zdravstvenem zavarovanju*, hereafter the ZZVZZ),[17] to which the ZPacP is also referring. It encompasses the right to choose freely a personal physician, a specialist and medical institution (contracted by the ZZZS), which is at the same time the duty to accept a socially insured patient by these healthcare providers. However, the right of inured persons is not unlimited. It has geographical and timely limits, as well as limits for certain groups of insured persons (e.g. prisoners) and profession of the physician (no 'doctor hopping', i.e. without consulting the chosen personal physician first, the so called 'gate keeping' function, or 'doctor shopping' of physician of distinctive specialities is as a rule allowed, Strban, 2005: 260)

There are far less limits when a private (self-paying) patient enforces the right to free choice of healthcare provider. Some even argue that there are no limits at all.[18] Such patient may choose a physician at any level and any medical institution. ZPacP sets limits to refusing a private patient. He or she might be refused only, if treatment would be less successful or impossible. In this context the conscientious objection and mistrust between a patient and a physician are being mentioned.[19] A physician must substantiate the rejection in writing, and this duty applies to all (socially insured and private) patients.

Contracted healthcare providers do not only have the duty to accept socially insured patients, but also to provide medical treatment. It has to be provided within the scope and according to standards agreed with the ZZZS. This duty has to be fulfilled *lege artis*, since a physician is in a somewhat tense position, providing required medical services to a patient, but at the same time protecting the solidarity community of all socially insured patients. Hence, not all wishes of a patient could be accommodated (if they are not at the same time medically indicated).

2.2.3 Defining sickness

Healthcare providers have to guarantee medical benefits in cases of sickness or injury (or for preventing them). Therefore, it is necessary to define what sickness and injury are. Such definition might be again more important for socially insured patients, since private patients could successfully request medical services, even if they are not medically indicated (e.g. beauty surgeries).

Although, the substance of sickness (and injury) remains in the domain of medicine, definitions have to be legal ones. Disease in medical terms could be

every subjectively sensed and/or objectively determined health disorder (irregularity).[20] Moreover, medicine can be fully operational also without general notions. For its effective functioning more specific definitions might suffice, i.e. establishing a certain disease or injury which could be diagnosed and treated. More general definition becomes important only, when medical behaviour (prevention, diagnostics or therapy) is set in an extra-medical context (in our case in the context of social law).

Additionally, socio-political goals could not be considered as proper basis for such definitions. For instance, sickness could not be defined as everything contrary to the definition of health. In the preamble of the WHO Constitution health is defined very broadly, as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.'

Also legal definition has to be in the field of social law, and not criminal (e.g. various degrees of injury) or civil law (e.g. when adjudicating damages for immaterial damage). According to such definition, disease could be endogenously and injury exogenously caused bodily or mental disorder in the functioning of a human body (i.e. functional definition), which requires medical attention and/or causes incapacity for work. Excluded may be intentional infliction of a disease or injury, or when they are caused by criminal offence, or at certain extremely dangerous activities (Strban, 2015: 177).

The definition of sickness might be important in order to establish the law that has to be applied (the one in force when social risk occurred) and to provide equal access to healthcare to patients with equal or similar health condition.

2.2.4 Most effective and efficient provision

Clinical pathways and rules on most effective and efficient provision of healthcare may enable more clarity in provision of medical services and easier supervisory mechanisms. In Slovenian ZPacP, some elements of efficient provision of healthcare are determined within the right to suitable, quality and safe healthcare, especially when it is provided from public funds, i.e. mandatory health insurance.

Socially insured patient is entitled to healthcare, if it is *lege artis* necessary, beneficial for the patient and benefits are higher than risks and burdens.[21] Also the Rules of mandatory health insurance set the principle that entitlements to healthcare exist only, if a physician establishes that they are well founded.[22]

According to the principle of effective and most efficient healthcare provision (emphasised in many countries), medical services have to be on one side sufficient, rational (for achievement of one of the goals of medical treatment, which are recognise a disease or injury, healing it, preventing its deterioration, or

easing pain and discomfort) and efficient. On the other hand, they may not go beyond necessary treatment (Strban, 2005: 194).

Such principle may have double importance. In relation to socially insured patient it determines the scope of medical benefits, and in relation to healthcare providers, it determines the limits of their behaviour. Services, which would not be necessary or effective (e.g. certain non-efficient pharmaceutical) or efficient (e.g. when less expensive, but equally effective treatment is available), could neither be claimed by the patient, nor performed by the physician, and also not paid by the mandatory health insurance carrier (the ZZZS).

A private patient, could, *argumentum a contrario*, be entitled to unnecessary and ineffective medical services, of course, if there is a willingness to pay them.

3 Possible supervisory mechanisms

Supervision of the health care providers may be performed by the State or local communities' bodies, special agencies, public health care system carriers (for instance verifying the fulfilment of contractual obligations), or by professional bodies, e.g. healthcare provider itself or by a special physicians' association. Patient usually has a possibility to announce the provider breaking legal norms to a supervisory body, but he or she as a rule does not take part in such supervisory proceedings.

3.1 Professional supervision

Several kinds of professional supervisory mechanisms are possible. Professional supervision could be internal or external. According to Slovenian legislation, internal supervision is performed by physicians themselves (so called self-supervision, which does not sound very convincing). Moreover, no (self-)sanctions are foreseen, if someone would establish that he or she has done something wrong. It is expected that the behaviour is corrected *ex nunc* (for the future). The same applies, if the control is exercised by a physician responsible for *lege artis* provision of healthcare at each healthcare provider. Although the Medical Practitioners Act (*Zakon o zdravniški službi*, hereafter the ZZdrS) does not regulate such self-supervision, ZZDej as *lex generalis* might be applied also to physicians.

Other option is external professional supervision with counselling. For physicians it is exercised by the Medical Chamber of Slovenia, either as regular supervision, according to the yearly plan, or as irregular supervision on the initiative of minister for health, payer of medical services (either private patient, or social health insurance carrier), or other person. Within both supervisory possibilities a concrete case may be under scrutiny (from a professional point of view and not as adjudicating on patient's rights).

According to ZZdrS (Article 60) regular supervision is financed by the State budget and irregular by the initiator. Question is, whether this is also the case, when irregularities have been discovered. No such provisions could be found in the ZZdrS (dealing with the legal position of physicians),[23] but it is regulated in more general ZZDej (Article 82). In the case of irregularities the costs of supervision have to be borne by the health institution or private healthcare provider, at which such irregularities were discovered.

In the latter case, also various measures could be applied. They range from recommendation of binding guidelines, to notice, duty of additional training, and the most severe one, i.e. (temporary or permanent) withdrawal of medical licence.

3.2 Administrative and financial supervision

Another external supervision of healthcare provider is administrative control over the legality of conducting businesses of medical institutions and individual private physicians. It is exercised by the ministry of health, again either as regular or irregular supervision. The later can be initiated by a patient, patient's relative or guardian, healthcare institution, employer, responsible chambers, court of law, or minister's own initiative. If irregularities are discovered, they have to be remedied. Moreover, also a temporary measure can be imposed, and the costs have to be covered by the institution or person, where irregularities were discovered.[24]

Healthcare providers, who are contracted by the ZZZS and included in the provision of health services to socially insured patients, are also under supervision of the social health insurance carrier (ZZZS). It controls effective and efficient provision of contracted healthcare providers. To this end planned and unplanned controls are exercised, which may encompass financial-medical and administrative controls. First are controls over correct calculation of medical services and medicinal products. Second are controls over overall financial statements, procedures for providing healthcare and other contractual duties, like business hours, availability of personal physicians to be chosen by insured persons, administering waiting lists an waiting periods, and ordering of patients (ZZZS, 2015: 40).

If individual provider breaks the rules, the social health insurance carrier may terminate the contract (with 30 day notice period)[25] and claim possible damages.[26]

Question might be what the options are, if physicians collectively decline healthcare provision to socially insured patients. Duty of the ZZZS towards socially insured persons is to secure healthcare provision (by contracting healthcare providers). It this can no longer be guaranteed, also due to a collective action of providers, socially insured patients could visit any, also non-contractual physician (in home country or abroad) and claim full reimbursement of costs also

for not-urgent medical treatment. Moreover, the ZZZS could terminate the agreement and conclude one with available medical institutions at home and in other countries, in order to fulfil his basic duty towards socially insured patients, i.e. guarantee medical benefits (Strban, 2005: 262).

4 Complaint procedures and judicial review

Patients may sometimes initiate supervisory mechanisms, but they are neither party in such proceeding, nor are they suited to decide on patients (substantive or procedural) rights in a concrete case. Therefore, effective complaint procedures have to be legally regulated as well.

4.1 Complaint procedures

It is essential to provide speedy, professional complaint proceedings, before the possibility of initiating court action. Sole availability of court (malpractice) action is not available and might lead to defensive medicine and more expenditure for solidarity community (e.g. due to extra tests and investigations, Bennett, 1991: 42). Only with legally well-regulated complaint procedure equal access to health care may be provided.

The possibility to freely substitute a chosen personal physician (after a certain period of time, where he or she is acting as a 'gate-keeper'), or receive a referral to specialist treatment (which is no right of a patient, especially if issuing such referral is not medically indicated), cannot be considered as sufficient.

4.1.1 Deciding in administrative procedure

According to Slovenian legislation legal position of socially insured patients is well protected, when an administrative decision is taken by the appointed (ZZZS) physician. However, it is rather limited and available only in cases of spa treatment, some (more expensive) medicinal goods and (possibly) on cross-border healthcare. In this cases complaint is possible to the Health Commission, again deciding with an administrative decision in a rather short period of time.[27]

Appointed physician and Health Commission have no competence for deciding on suitability of concrete preventive, diagnostic, therapeutic or rehabilitative measures ordered by a competent physician (chosen personal one or a referred medical specialist). However, there are quite numerous professional procedural paths that a patient may (but is not obliged to) take with respect to healthcare provision.

4.1.2 Internal complaint procedures and the right to a second opinion

The General Agreement between the ZZZS, the State and healthcare providers obliges the latter to organise internal complaint procedures, with their internal legal acts.[28] Such internal procedures, i.e. within the same healthcare provider, might not be fully unbiased and they are not possible with private, single self-employed physicians.

Since the ZPacP is in force, several procedural rights are enshrined in this legislative act, in case of patient-physician disagreement. Among them is the right to a second opinion. Sometimes, patient's procedural rights might differ considerably for private and socially insured patients. For instance, private patient enjoys an unlimited right to a second opinion, of course, if he or she is ready to finance it.

Conversely, for socially insured patient there are many limitations. He or she is allowed to exercise this right only on the secondary (hospital and specialist) and tertiary (clinics) level. *Argumentum a contrario* this means, that there is no possibility on the primary level, i.e. to test the decisions of the chosen personal physician. Moreover, he or she may only do so once for the same medical condition, and only for the future medical procedures (hence, it cannot be considered as an appeal in legal terms). Before exercising this right a socially insured patient has to discuss the reasons, purpose and necessity of the second opinion with the attending physician (Article 40 ZPacP), whose opinion he or she already knows. It is not completely clear, why the legislator fully respects the autonomy of physicians, while at the same time doubts the autonomy of patients.

Not only that, the second opinion is given by the same healthcare provider, i.e. a colleague of a treating physician, which might raise a question of bias. Only if this would not be possible another healthcare provider within the public network may give the second opinion. Therefore, it could be argued that such right to second opinion might actually deter patients from exercising it. Then, the law is more to the benefit of physicians than patients, whose position should actually be protected by the ZPacP.

It might be better, if the right to a second opinion would be shaped as an appeal procedure, available also against the (past) decisions of a personal physician. Such solution was proposed in a draft ZPacP, but was never adopted. In this case, second opinion could be given by the specialised physician, with more profound knowledge in a specific field (hence, procedurally on the second instance). It seems that similar solution is adopted in Norway (Ivanc, in Balažic, 2009: 200).

4.1.3 The right to process a breach of patient's rights

This right may be exercised in several phases. At first the ZPacP defines a non-agreement between a patient and healthcare provider as 'misunderstanding'. It should be settled immediately with additional explanations and other measures (Article 56 ZPacP). Only if this is not possible must a healthcare provider, in accordance with the principle of information and support of a patient, in an understandable manner inform a patient of a right to initiate a process of breach of patient's rights (Ivanc, in Balažic, 2009: 265).

Such claim for a first hearing of a breach may be lodged at the responsible person of the same healthcare provider where the alleged breach occurred. It is an informal, professional procedure. Competent person may conduct a conversation with a patient and may even conclude a settlement. It may be on apologising to the patient, acquiring of a second opinion (although this is a right of a patient) and damages for up to certain amount. Again, it seems, that this procedure might be more to the benefit of healthcare provider, who may rather quickly, with mild measures and not high financial impact solve the patient-physician disagreement.

If a patient does not agree with an offered settlement of a dispute, a second hearing of a breach of patient's rights might be initiated. It is decided by a special, independent, professional and unbiased body, i.e. the Commission of the Republic of Slovenia for the protection of patient's rights. Its president is appointed by the government and members by the minister of health. Procedure is formalised and general administrative procedure should be applied (Strban, 2009: 261).

According to the report of the president of this Commission (Šikovec Ušaj, 2015), the number of claims is rising. However, the Commission is confronted with serious administrative obstacles (administrative support should be provided by the ministry of health), and even the exact number of handled cases in 2014 is not exactly known. They also observe lack of interest of the Medical Chamber, even when they are directly contacted.

4.1.4 Assistance when exercising patient's rights

Patient could be assisted or even represented by patients' advocates (13 of which were active in 2013, Government of the RS, 2015: 4). Such an advocate may lodge a formal complaint or informally intervene with healthcare provider, in order to come to a speedy solution. Assistance is free for patients and provided to private and socially insured patients.

However, this does not diminish the right of socially insured patients to claim professional and legal assistance from the mandatory health insurance carrier (ZZZS). It may ensure the provision of healthcare from mandatory health insurance with guidelines, advice and interventions at healthcare providers,

especially if they restrict access to healthcare, prolong waiting period, ask for direct payments, or treat patients unfairly. ZZZS is obliged to verify all the claims, but has some margin of discretion on which it will be acted upon (Strban, 2009: 263).

Moreover, one of the substitutes of the Ombudsperson also acts as an ombudsperson for patients' rights. Again, it is an informal procedure for patients which may lodge complaints.

4.2 Judicial review

Already according to the Slovenian Constitution, the right to judicial protection is one of the fundamental human rights (Article 23). Everyone has the right to have a decision taken by an independent and impartial court of law without undue delay on every right, duty, and any charges brought against him or her. This implies a possibility of judicial review also when exercising the rights to medical benefits from mandatory health insurance or when acting as a private patient.

Moreover, judicial review may be requested, even if no complaint procedure for establishing a breach of patient's rights before the (same) healthcare provider has been instigated. Hence, if a socially insured patient does not want to discuss a matter with a physician, a claim before the social court may be lodged (or a civil court for private patients). Such information should be publicly available to patients in the premises of healthcare providers as well.

The question might be what constitutes a decision of a physician, against which a claim could be lodged. As argued above, only exceptionally will an administrative decision be issued by the ZZZS. Nevertheless, a decision on diagnose and treatment inserted in the medical documentation should be considered as a formal decision (or at least its operative part). Even more so, if a prescription for a pharmaceutical was issued, since administrative decisions might come in various forms.

Social dispute resolution proceedings are decided by specialised social judges. The procedure must be conducted in a speedy manner and should be more claimant friendly that than civil law procedure.

5 Concluding thoughts

It is established that healthcare providers have certain rights, the right to remuneration being the most prominent one, regardless whether they are paid from private or public funds. In both cases certain supervisory mechanism should be in place, in order to ensure that all transactions are justified and in accordance with the law. When patients themselves have to pay healthcare providers directly, their desire to exercise direct consumer control over providers might increase.

As with every right, also the right of remuneration brings certain duties of the healthcare providers. They may range from more general duties for all physicians to more specific duties of contracted healthcare providers guaranteeing medical benefits to socially insured persons. Among the latter are the duty to accept a socially insured patient, and provide healthcare according to the agreed rules and standards of the mandatory health insurance.

In order to ensure that all socially insured patients have equal access to healthcare, the social risk of sickness (and injury) has to be defined. Mandatory health insurance does not cover everything that could be treated by the healthcare providers, but only those diagnoses which could not be borne by the patients themselves and might even endanger the existence and free development of the society at large. Without the social law definition of sickness it might be unclear when the duties of healthcare providers commence. Moreover, also the scope of medical benefits has to be clearly defined, e.g. by the rule of effective and efficient provision of healthcare. Without such definitions, supervisory mechanisms might also be ineffective.

There are several supervisory mechanisms available, from professional, administrative and financial supervision. They might ensure higher quality of healthcare provision, but could also impose stricter sanctions in case of irregularities. However, they are not intended to improve the legal position of a patient in a concrete case. To this end complaint proceedings are regulated.

It is argued that numerous professional complaints proceedings, with possible assistance of patients' advocates and ombudsperson, might not be the most effective solution and might raise the question of partiality and bias. The second instance, national Commission for protection of patients' rights, headed by a lawyer, is confronted with many obstacles. Not clear delineation between various complaints procedures might cause confusion, which does not contribute to the foreseeability of behaviour, a cornerstone of legal certainty and the rule of law.

Hence, formal complaint proceedings should be stipulated for private and even more for socially insured patients. For latter, a decision of a board of physicians, composed of representatives of attending physician, mandatory health insurance carrier, and an impartial physician, could be a reasonable solution (similar to the French system, Bubnov Škoberne, 2003: 5). Also the option of a special public institute for medical expertise might be further investigated.

So far, there was hardly any debate on the supervisory mechanisms and procedures for enforcing healthcare rights. Future reforms in Slovenia will have to focus on regulating more precisely the provision of healthcare and enforcement of (socially insured) patients' rights in special, legally formalised proceedings, before the judicial review is requested. Moreover, also for the judicial social disputes

resolution, it should be clear that against all medical decisions a judicial review is admissible.

Notes

[1] C.f. the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the European Social Charter (initial and revised), the African (Banjul) Charter on Human and Peoples' Rights, the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador). Equal treatment with respect to the right to health for children, women, all races, migrant workers and their families, and disabled persons is specially regulated.

[2] Communication from the Commission, Working together, working better: A new framework for the open coordination of social protection and inclusion policies in the European Union. COM(2005) 706 final, Brussels, 22. 12. 2005, reinforced in 2008 by the Communication from the Commission, A renewed commitment to social Europe: Reinforcing the Open Method of Coordination for Social Protection and Social Inclusion COM(2008) 418 final, Brussels, 2. 7. 2008

[3] Equitable access to health care of appropriate quality is emphasised e.g. in the Article 3 of the Convention on Human Rights and Biomedicine (1997).

[4] When patients would have to pay for all medical benefits, they would not be available in due time, patients would not be aware of their rights and procedures for their enforcement, full and equal access to healthcare could not be guaranteed (Strban, 2005: 86).

[5] For instance a seminar on human errors in healthcare and their prevention at Domus medica in March 2016 (http://www.domusmedica.si/dogodki/-love-ke-napake-v-zdravstvu-in-njihovo-prepre-evanje/6465--31096, accessed 25 January 2016.

[6] E.g. (*Strban et al., 2011)*

[7] E.g. *Korošec D.* (2004)

[8] E. g. *Strban, L.* (2008).

[9] Out-of-pocket payments may be divided into direct payments, informal payments and formal cost-sharing. Strban, 2014: 10.

[10] C.f. Article 3 lit. (b) and lit. (h) Directive 2011/24/EU.

[11] E.g. Articles 3 and 4 of the Slovenian Medical Practitioners Act (*Zakon o zdravniški službi*, ZZdrS), Official Gazette RS, No. 98/99 – 58/08).

[12] Complementary and Alternative Medicine Act (*Zakon o zdravilstvu*, ZZdrav Official Gazette RS, No.94/07, 87/11). Homeopathy, chiropractic and osteopathy could only be exercised by persons with completed university medical education.

[13] ZPacP, Official Gazette RS, No 15/08.

[14] C.f. Articles 4 and 11 ZPacP, and Article 45 of the Performing of healthcare act (*Zakon o zdravstveni dejavnosti*, ZZDej, Official Gazette RS, No. 9/92-14/13). ZZDej specifies the duties of larger professional collegiums and of the Health Council (Articles 74 and 75).

[15] Rules of mandatory health insurance, Official Gazette RS, No. 79/94 – 85/14.

[16] Article 166 of the Rules of mandatory health insurance.

[17] ZZVZZ, Official Gazette RS, No. 9/92 – 91/13.

[18] E.g. *J. Balažic*, in J. Balažic et. al., p. 79.

[19] *J. Balažic*, in J. Balažic et. al., p. 78.

[20] ILO Conventions 24 and 25 on sickness insurance industry/agriculture define it as 'abnormal state of his bodily or mental health' (Articles 3), and ILO Convention 102 on minimum standards of social security as 'any morbid condition, whatever its cause'. According to Slovenian Medical Dictionary (2002: 103) disease is any departure from normal constitution or function of any part, organ or system of a body, which shows typical

symptoms and characters and which etiology, pathology and prognoses may be known or not known.

[21] Article 12 ZPacP.

[22] Article 24 of the Rules of mandatory health insurance.

[23] C.f. also Rules on professional supervision with counselling, issued by Medical Chamber of Slovenia with consent of the minister of health, Official Gazette RS, No. 35/00.

[24] Article 16 of the Rules on administrative supervision in healthcare, Official Gazette RS, No. 14/95 - 6/12.

[25] Article 54 of the General agreement for the contractual year 2015, concluded between ZZZS, healthcare providers and the State (represented by the ministry of health).

[26] In 2014 the payments of the ZZZS were reduced for 2.618.184 euro and 379.569 contractual penalties were paid. ZZZS, p. 41.

[27] Articles 81 and 82 ZZVZZ.

[28] C.f. Article 36 of the General agreement for the contractual year 2015.

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