

DAF/COMP/WP2/WD(2018)39

Unclassified

English - Or. English

5 November 2018

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS COMPETITION COMMITTEE

Working Party No. 2 on Competition and Regulation

Designing publicly funded healthcare markets - Note by Bulgaria

26 November 2018

This document reproduces a written contribution from Bulgaria submitted for Item 4 of the 66th OECD Working Party 2 meeting on 26 November 2018.

More documents related to this discussion can be found at

http://www.oecd.org/daf/competition/designing-publicly-funded-healthcare-markets.htm

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JT03438792

Bulgaria

1. Introduction

Healthcare services as well as use and trade of medicines are extremely regulated sectors as they directly affect the life and the health of people. The regulatory framework of healthcare services in Bulgaria is quite extensive and includes laws, bylaws and other normative and administrative acts, adopted by the Council of Ministers, Ministry of Health, National Healthcare Insurance Fund.

2. Health insurance system in Bulgaria

- 2 Health insurance in Bulgaria is based mainly on the mandatory health insurance provided by the National Health Insurance Fund (NHIF). The NHIF is a state body, financed by the state budget, mandated to collect the mandatory health insurance payments and to reimburse the healthcare services to providers within the scope defined by laws, bylaws and other regulatory acts. The mandatory health insurance payments are collected from the following sources –payments from employers and employees, payments from the state for the civil servants, police and military personnel, children, retired people and unemployed, registered in unemployment offices. The state, through budgetary transfers from the Ministry of Healthcare, covers also the emergency medical services for all Bulgarian citizens, as well as the medical treatment of some serious illnesses, predefined in an ordinance. The percentage for the mandatory healthcare payments is set by a law and they does not depend on the health status of the insured. The NHIF is based on the solidarity principle.
- 3. The NHIF reimburses the medical services by healthcare facilities within the scope of the illnesses and medical procedures, set by the law. The fund also covers fully or partially the price of the medicines and medical products, the scope and price of their reimbursement is again set by laws and bylaws. In order to receive reimbursement from the fund, the medical facilities should conclude annual contract with NHIF. The contracts with the medical providers specify the exact medical services for which are eligible for reimbursement. For example, a multidisciplinary hospital may have contract with the NHIF only for some of its units, the other units providing medical services are not reimbursed by the fund. There are regulatory restrictions for some medical providers, both for primary and hospital medical facilities, to have contracts with the fund, which restrictions are discussed further in this report. In case the medical providers are eligible to conclude contract with the NHIF, it is up to them to decide if they opt to conclude it. The legal requirements for medical facilities wishing to conclude contracts with the fund are not based on the type of the ownership of the medical facilities, but are mostly based on substantive criteria setting minimum standards as regards the quality of the service provided.
- The reimbursement level for the services provided by the medical facilities is set annually in the National Framework Contract. The exact list of the services, the scope of the mandatory medical activities and the reimbursement level, within the annual budget of the fund as set in the NHIF Budget Law, are negotiated between the National Health Insurance Fund, the Bulgarian Medical Union and the Bulgarian Dental Association as representatives of the medical practitioners and the dentists. In case there is no agreement

between the parties, the Supervisory board of the NHIF has the right to adopt the National Framework Contract itself. The reimbursement is set as lump sum for clinical pathways for the hospitals, or for specific activities (examination, etc.) for the primary healthcare facilities. General practitioners receive dual reimbursement – a lump sum for each patient in their list and a payment for each examination/procedure.

- Besides the reimbursement by the NHIF, there is mandatory co-payment by the patients for each visit to medical practitioner from the out-of-hospital facilities and for each day stay at hospital, but not more than 10 days annually. The amount of this so called "consumer tax" is set by the Council of Ministers and is currently ~3 Euro. Some categories of citizens – children, pregnant women, disabled persons, do not pay consumer tax. For some of these categories the state reimburses the medical practitioners the amount of the consumer tax.
- Additional payments by the patients are more widely spread for hospital services. There is an exclusive list what types of payments the hospitals are allowed to ask from the patients. They include choice of treating medical team (doctor/s and/or nurses), separate or better room, food menu by order, etc. The co-payment for choice of medical team is tied to the reimbursement sum for the procedure itself. No additional payments could be asked for procedures/manipulations/medicines/examinations/care, which are part of the clinical pathways paid by the NHIF. At the same time some medicinal products/devices, which are needed for the treatment, but are not paid by the NHIF, should be paid by the patients. This is usually the case with medicinal products for orthopedic, neurosurgery, ophthalmology, etc. patients.
- Besides the mandatory health insurance by the NHIF, there is a possibility to have 7. private corporate or individual health insurance with an insurance company. Still, the private health insurance is not very well developed in Bulgaria. Private health insurers offer both out-of-hospital, dental and hospital medical services. They conclude contracts with the medical providers and the insured chose between them. The scope of the services provided by the private insurers differs in scope. Generally speaking, the added value they offer, is the direct contact with specialized out-of-hospital medical providers, without the need to go to GP first, fast and facilitated visit to these doctors, treatment by medical providers not working with the NHIF, payment of medicines not reimbursed by the NHIF, etc. For hospital treatment, the private insurers usually top-up the coverage by the NHIF, paying for the services that are otherwise born by the patients, like choice of medical team, better room, but also second opinion by another doctor, etc. Rehabilitation, in-house services for patients like visits by a nurse, small medical manipulations, etc. could also be paid by private insurers as part of some of the insurance packages. Such services are not reimbursed by the NHIF.

3. Legal framework governing healthcare in Bulgaria

Healthcare in Bulgaria follows the model of functional separation of the medical services provided to patients into two levels: out-of-hospital healthcare services (primary healthcare and specialized primary healthcare) and hospital services (hospitals and other healthcare facilities). This functional separation of the healthcare services was made as part of the reform of the healthcare system back in 1999, as part the political and economic changes following the fall of the communist regime.

3.1. National Healthcare Map

- 9. The National Healthcare Map is designed to be the main tool for the state management of the healthcare system in Bulgaria. Its aim is to reflect the needs of Bulgarian citizens for out-of-patient and hospital services by regions, based on data for the population, age, existing medical facilities by type, etc. The National Healthcare Map summarizes the data contained in the Regional Healthcare Maps. It is made by a national commission consisting of: the Head of the National Health Insurance Fund (NHIF), the director of the National Center for public health and analyses, the Managing director of the Executive agency "Medical Audit", the Chairperson of the National Association of Municipalities in Bulgaria, two representatives of the Bulgarian Medical Association, one representative of the Bulgarian Dental Association, one representative of the Bulgarian Nurses Association, one delegate from nationally representative patient organizations, and three representatives of the Ministry of Healthcare. The national map is approved by the Council of Ministers and is mandatory for the purposes of planning by type of the medical and healthcare activities of the healthcare facilities, with the exception of those established by dentists. The map is fully updated in 3-year period, with a possibility for partial update in this latter period if needed subject to certain conditions.
- In the regions, where there are more hospital beds than needed per types, as entered in the National Healthcare Map, the regional offices of the National Health Insurance Fund may conclude contracts with hospitals or their associations based on criteria set by an ordinance of the Council of Ministers.

3.2. Organizational setting

- The functional separation of the healthcare services is further reflected into the legal 11. and organizational separation of the healthcare facilities. The healthcare facilities, under the provisions of the Law on Healthcare Facilities (LHF), include: primary healthcare facilities (general practitioners), specialized out-of-hospital healthcare facilities, hospital facilities, other healthcare facilities (emergency medical center, center for transfusion hematology, mental health centers, dermatology and STDs center, complex oncology center, hospice, center for complex healthcare for children with disabilities and chronic diseases, dialysis center, tissue bank). The healthcare facilities could be established by the state, by the municipalities, by legal or natural persons. The emergency medical centers, centers for transfusion hematology, residential mental health centers, medical-social facilities for children could be established only by the state. The healthcare facilities should be registered under the Commercial Act or under the Law on Cooperatives. Non-profit organizations are not registered under the above-mentioned laws, so if they wish to perform medical services, they should register formally as owners a separate company acting as undertaking.
- 12. The legal requirement that each separate medical facility as legal person performs activity only for either out-of-hospital or hospital services (with some exceptions) imposes in practice a formal prohibition on vertical integration. Thus, GPs with two specializations cannot work for or establish specialized medical practice; the hospitals' diagnostic units cannot perform out-of-hospital medical services. As regards the hospitals, many of them escape from the formal prohibition on vertical integration registering their diagnostic units as separate legal person, usually as diagnostic-consultative centers.

- In order to perform their activities, the out-of-hospital healthcare facilities and the hospices should be registered by the Regional Health Inspections, which are administrative units under the authority of the Ministry of Healthcare.
- The hospitals and the others healthcare facilities (mental health centers, dermatology and STDs centers, complex oncology centers, medical-social centers, dialysis centers) are subject to licensing regime. Permission to perform the latter activities is given by the minister of healthcare and the healthcare facilities are entered into a registry, maintained by the Ministry of Healthcare. Before the new hospitals and the other abovementioned facilities are issued a license to perform medical activity, they apply to the Ministry of Healthcare for evaluation of the needs of the citizens for medical aid in the particular region based on the data in the National Healthcare Map. The applicants should provide information on their investment ideas, the type, structure and envisaged number of hospital beds and medical activities per types and competence levels of the relevant structure; they should supply as well an opinion by the regional office of the Bulgarian Medical Union or Bulgarian Dental Association. The documentation pack is reviewed by the commission, which issues positive or negative opinion. Positive opinion is issued if there is shortage for the particular type of hospital beds, medical activities per type and level of competence on the territory of the respective region/city as defined by the National Healthcare Map. In case the already existing beds exceed the necessary number in this region, the commission issues negative opinion. In case of negative opinion, the new healthcare facility is not included in the National Healthcare Map and it cannot conclude contract with the National Health Insurance Fund until the regular update of the map is done. The same procedure as described above applies not only for new hospital facilities, but also for new medical activities of existing hospitals, for example, in case of new hospital unit. Again, a negative opinion of the commission excludes the new medical unit from the National Healthcare Map and from contract with the NHIF until the next regular update of the map.

3.3. Patient rights and choice

- By law, the patients in Bulgaria are free to choose a medical facility on the whole territory of the country to have treatment. Patients must choose a general practitioner and this choice is valid for one year. Each year they could change their GP. The general practitioners are the ones that direct the patients to specialized out-of-hospital doctors or to hospital admission, the patient themselves cannot go directly to specialized out-of-hospital doctor if they wish to have their visit being reimbursed by the NHIF. The GPs however do not have the formal right to direct the patients to particular medical facility; they just issue written paper stating preliminary diagnosis and the need for specific examination, procedure, etc. and the patients could choose freely from those facilities, which have contracts with the NHIF. Travel to the chosen medical facility is not reimbursed by the NHIF.
- 16 For the most popular hospitals there are waiting lists of patients. The waiting time should not exceed two months.

3.4. Healthcare providers under the competition law

The CPC applies the notion of undertaking and association of undertaking as defined in the case law of the European commission and the CJEU. Therefore, the medical providers in Bulgaria, regardless of the fact on which level of the healthcare system they operate – primary or hospital care, fall within the scope of the notion of "undertaking". The professional organizations of the medical practitioners – physicians and dentists, are also caught by the provisions of the competition law as the notion of "association of undertakings" is applicable to them. The CPC has enforcement record of sanctioning in 2012 the Bulgarian Medical Union as association of undertakings for fixing the price of the examination not reimbursed by the NHIF. This CPC decision was appealed and the court confirmed the Commission's conclusions and the sanction.

18. On the other hand the National Health Insurance Fund has been defined in a number of CPC opinions and decisions as state body and not as undertaking. In its evaluation the Commission followed the CJEU case law for the bodies managing solidarity health insurance or pension schemes.

4. CPC advocacy cases and sector inquiry in healthcare markets

4.1. Advocacy opinion on the hospital services

- With Decision No. 1193/2013 the CPC adopted advocacy opinion on the legal framework governing the provision of hospital services.
- 20. The CPC analyzed the provisions on the National Healthcare Map and considered that the administrative determination of the maximum number of healthcare facilities on territorial basis could restrict effective competition, being equal to quantitative territorial restriction. The Commission added that such provisions contradict the right of the patients to choose a medical facility on the whole territory of the country and the right of all medical providers to perform their activities if they fulfill the medical requirements for this. The CPC underlined that efficient public spending and control by the NHIF for hospital activities should not be achieved by restricting the number of the hospitals, but by setting clear qualitative criteria for receiving public funding by the NHIF. The CPC considered that instead of NHIF funding all hospitals that fulfill the minimum quality requirements, a change to selective system of funding based on quality could be done. This will create incentives for the more efficient hospitals to offer better quality and will promote competition. As regards the existence and the viability of the hospitals outside big cities, the CPC pointed out that the state could provide for additional incentives for such hospitals to be assessed, however, as to their compliance with EU state aid rules.
- The Commission also discussed the existing problem with the reimbursement level of the clinical pathways. All medical providers associations as well as patients associations pointed out in their submissions during the proceedings that the reimbursement level is administratively determined and is not based on evaluation of the real costs. Some clinical pathways are said to be underpaid (like treatments for habitual pulmonary illnesses, etc.), while other are overpaid (cardiac invasive procedure are usually given as an example). According to the CPC, equal reimbursement for services of different quality, as well as some clinical pathways being underpaid, while others are overpaid, lead to inefficiency of the healthcare system. The CPC proposed either to create objective methodology for quantifying the clinical pathways or to make a transition to diagnosis-related groups' reimbursement. The use of diagnosis-related groups' reimbursement could remedy the existing problem both for hospitals and for patients that a patient with one main diagnosis (e.g. treated for pneumonia) for which she/he was admitted, could not be treated for his additional conditions (e.g. cardiac or kidney conditions), because the clinical pathway covers only the pulmonary condition, accordingly the NHIF reimburses only this pathway.

As regards the legal provision that emergency medical services centers could be established only by the state, the Commission expressed the view that the state could reserve for itself only the coordination activities (operating emergency telephone center, distributing and directing the ambulances), but the substantive part of the medical service. namely the transportation with ambulance and medical treatment during the transportation and in hospitals, should be open to all medical facilities that comply with the medical standards for emergency medicine.

4.2. Advocacy opinion on out-of-hospital specialized healthcare services

- 23. In its' Decision No. 122/2014 the CPC analyzed the legal framework governing the out-of-hospital specialized medical services.
- The Commission explained the benefits and the negatives of vertical integration and expressed the opinion that the existing prohibition of vertical integration in healthcare should be put to wide public debate.
- As part of the problems with the prohibition of vertical integration, the CPC reviewed provisions not allowing some hospitals to receive public funding from NHIF for out-of-hospital specialized healthcare. The problem concerned the hospitals, owned by the state and governed by the Council of Ministers, Ministry of Defense, Ministry of Interior and Ministry of Telecommunications and Transportation. Historically, the above mentioned ministries manage medical facilities with special tasks, e.g. to provide medical treatment for certain groups – members of the parliaments, ministers, diplomats, military personnel, police, detained persons and prisoner, aircraft pilots, etc. For these specific tasks the medical facilities receive funding from the budget. Apart from this, they could conclude contracts with NHIF for providing hospital services to all insured Bulgarian citizens. Because of their special legal form, it is much more difficult for them to register separate legal entity for provision of out-of-hospital specialized healthcare services in order to be reimbursed for them by the NHIF. The CPC considered that the legal framework should not create artificial and difficult barriers for entry to specific market to healthcare facilities that fulfill the quality requirements for providing such services.
- Another provision, assessed by the Commission assessed as restrictive, stated that doctors, working in hospitals on main labour contract, could not to register their own outof-hospital specialized medical facility or work in such facility, including to be reimbursed by the NHIF. The law provides that such practice is admissible only in cities, where there is no other registered medical facility of this type, or there is a shortage of medical practitioners with a particular specialty. The assessment for lack of the necessary facilities/practitioners is made by the Regional Healthcare Inspection. The medical practitioners concerned still have the possibility to establish their own or work for another medical facility for out-of-hospital specialized healthcare, but they or the facility they work for should not have the right to receive public funding from the NHIF.
- The CPC considered the above mentioned provision to distort the competition by restricting the market entry with negative effect both for the quality of the services provided and for the choice of medical provider by the patients. As one of the motives for the introduction of this provision was to provide protection to those medical practitioners who work only in out-of-hospital specialized medical healthcare, the CPC underlined that, if done by undertakings, such arrangement would qualify as market partitioning.

4.3. Advocacy opinion on the participation of BMU and BDA in the negotiation of NHIF reimbursement level of medical services

- 28 The CPC analyzed in its Decision No. 1005/2014 the legal provision that the NHIF volumes and reimbursement levels are negotiated annually between NHIF and the Bulgarian Medical Union and the Bulgarian Dental Association. The Commission's concern was based on the fact that the representative organizations of the medical practitioners and the dentists fall within the scope of the notion "association of undertakings", as membership in these organizations is mandatory and the medical practitioners and dentists are professionals who could perform economic activities as freelancers
- 29. In its' opinion the CPC took into account the fact that the NHIF has the characteristics of state body, it manages solidarity health insurance scheme, therefore it cannot be defined as "undertaking" under the competition law provisions and the case law of the Court of the European Union. The Commission also considered the legal nature of the National Framework Contract which has the features of administrative act and not of a contract, regardless of its name.
- The CPC concluded that having in mind the health insurance model in Bulgaria with the state body NHIF managing the insurances, the approach for determining the reimbursement levels of medical services is based on taking into account the views of all stakeholders. Having regard to this the CPC proposed that the patients organizations should be admitted to this process. Finally, the Commission expressed the opinion that, for reasons of legal stability and legal certainty, the subject matter of the National Framework Contract is better to be regulated by a legal act of higher level.

4.4. Advocacy opinion on the regulatory framework of the General Practitioners

- With Decision No.1419/2014 the CPC adopted an advocacy opinion on the legal framework regulating the activity of the general practitioners (GPs) in Bulgaria.
- The Commission reviewed the legal provision, prohibiting the GPs to perform primary ambulatory medical care in specialized ambulatory practices. The CPC expressed the opinion that the competent authorities should assess the necessity of the formal ban for vertical integration of ambulatory practices for primary and for specialized medical care taking into account the advantages and disadvantages of such integration. The CPC found that there are no barriers for the GPs to establish medical centres for specialized ambulatory medical care.
- 33. The CPC also assessed the requirements for medical trials to be performed only in hospitals or ambulatory practices for specialized medical care, as well as to be managed by a doctor with medical speciality in the relevant field. The Commission considered that the GPs should be able to take part in certain medical trials if they have the necessary education and experience.
- The CPC opinion on the possibility for the GPs to perform medical trials was taken into account and the respective provision was amended accordingly.

4.5. Sector inquiry of the insurance markets

35. In 2016 the CPC adopted a decision No. 682/2016 for sector inquiry of the insurance markets for the period 2010-2014. According to the information received for the sector inquiry, the healthcare markets of voluntary insurance have relatively low share, so even though the commission gathered some data on them, these markets were not the main focus of the sector inquiry.

- The Financial Supervision Commission, which is the national supervisory body over the insurance companies, has issued licenses to 13 companies for voluntary health insurance.
- 37. Two main insurance products are offered in Bulgaria for healthcare services.
- 38. "Permanent health insurance" is an individual or group insurance, aimed to cover cases of accidents and/or illness that led to receiving medical treatment. In cases of corporate insurance, made by the employer, all the employees and the staff of the company, regardless of their age and health status, are covered by the insurer. In cases of individual insurance, persons aged 16 to 62 are insured. In the latter case persons fill declaration about their health status. This insurance was offered by 5 insurance companies. Herfindal-Hirschman index showed highly concentrated market, with values of between 3 000 and 8 000. In the period 2010-2012 there were three market leaders, and in the period 2013-2014 there were only two market players with one of them having significant market share.
- Under "Illness" insurance policy the medical expenses related to illness are paid either as lump fixed sum and/or are reimbursed. The policy covers healthcare services/medical goods not reimbursed by or outside of the scope of the mandatory health insurance. The insurer pays/reimburses services/goods of the following packagesprophylactics, out-of-hospital medical services, dental services, hospital care, other services, as well as reimbursement of medicines and medical products.
- The demand for such insurance policies is from corporate or individual clients wishing to insure themselves against possible future expenses for medical treatment and to guarantee higher quality of healthcare services in Bulgaria and abroad. Illness insurance policy is offered on the Bulgarian market since 2012 and as Herfindal-Hirschman index shows value of 10 000, there was only one market player on this market at that time. In the period 2013-2014 the values of the index were between 2 642 and 3 040, showing low levels of competition on this market with three main insurance companies and one of them being obvious market leader. There was a trend for a general decrease of the incomes from premiums from this insurance policy for all insurers.
- 41. As part of the sector inquiry the CPC asked the respondents to elaborate on the main problems for their business. The interested insurance companies underlined several problems related to the voluntary additional healthcare insurances. One of them is the procurement by state/municipal bodies for additional voluntary healthcare insurance policies, being evaluated on the basis of the lowest price. This was said to lead to financial loss for the insurance companies, which tend to participate in such procurement procedures led by the incentive to attract clients in case of introduction of a second pillar in health insurance. The other problem, according to insurers, is the normative ambiguity of the scope of the mandatory healthcare coverage reimbursed by the NHIF, the lack of clear rules on the scope of the services that have to be paid by the patients.

5. Public debate over the healthcare services and policy

- 42. The quality and the funding of the public healthcare system in Bulgaria has been a topic for hot public debates for many years. The main problems for different groups of healthcare stakeholders articulated during these debates include:
 - Continuously increasing total amount of NHIF budget with no obvious increase of quality of medical services;
 - Increasing number of private hospitals being established and receiving NHIF funding, especially cardiac units;
 - Low level of patients satisfaction of medical services;
 - High level of patients top-up payments;
 - Media reports of medical service providers doing unnecessary but well reimbursed procedures.
- 43. Up until recently the most important remedies for the above mentioned problems were articulated to be legal restrictions for new and more hospitals receiving public funding and more stringent control by the NHIF.
- In the last two months however the Ministry of Healthcare presented to the public draft strategy with two major scenarios. The first includes partial demonopolization of the NHIF with the introduction of the second pillar private health insurance in addition to the basic coverage by the public insurance of NHIF. The second scenario envisages full demonopolization of the NHIF and competition on the merits between NHIF and private insurers.
- 45. The draft strategy was met with objections by all stakeholders – the insurers and their association, the medical practitioners, the professional organizations of the doctors, the patients' organizations, economists, etc. It was declared that it is just a basic proposal open to public debate and that the final strategy should be elaborated on consensual basis.
- 46. At this first stage of the debate, the CPC was not asked to participate in it or issue opinion.

6. Conclusion

47. Provision of healthcare services in Bulgarian as well as their reimbursement have shown to lead to problems for all healthcare system stakeholders – the patients, the medical providers, the National Health Insurance Fund and the state. The CPC as competition authority has evaluated in its opinions the regulatory framework for all of the levels of medical services – general practitioners, primary specialized healthcare and hospitals. The Commission has identified certain restriction in the relevant regulations and advised the competent authorities on the need to amend or repeal them. Most of the CPC recommendations, however, need to be implemented as part of substantial structural reform of the sector. A public debate for such a reform has just been initiated and is in its preliminary stage. At a later stage, when there is a clearer concept of the reformed insurance and healthcare systems, the CPC might intervene as appropriate.