Gov. Gazette 114A/10.5.2014 Article 54

1. At the end of par. 5(a) of article 21 of Law 4052/2012 the following clauses B and C are added as follows:

"B. By virtue of the decision of the Minister of Health, closed budgets, financial or other targets and limits (ceilings), limitations and other conditions may be imposed on the prescription of medicinal products as well as other necessary means for controlling prescriptions issued by the physician. By virtue of a same decision, the budget, targets, limitations, conditions and measures may vary with regard to the specialty of the physician, the number of patients he/she attends, as well as the characteristics and diseases thereof, the territory and the demographic data thereof, the month of the year (seasonality), any changes of the prices of medicinal products, the inclusion of new medicinal products (originals and generics) in the positive (prescription) list and finally, the course of the pharmaceutical expenditure in relation to the targets occasionally set. In addition, prescription may be associated with the patient's disease, as this is defined based on the International Classification of Disease. Specific targets, limits and prescription budgets may be incorporated in performance contracts that are concluded between EOPYY, the physicians prescribing to insured persons of the organisation and motives can be set (bonuses) and penalties with regard to the achievement of the targets and the observance of the limits and budgets. By virtue of the decision of the Minister of Health, the devices and procedures for the exception from the above provisions, of specific categories of physicians, medicinal products, healthcare units, groups of patients or individual cases of physicians are additionally set out together with the manner of incorporating the above provisions in the electronic prescription system, the control methodology, the field of application (private of public) as well as any measure necessary for the effective application thereof.

C. By virtue of the decision of the Minister of Health, similar measures, limitations and control requirements may be set on prescription and performance of laboratory, diagnostic and other services by the physician and the healthcare provider. The above include measures such as closed budgets, financial or other targets and limits (ceilings), limitations and conditions, rebates, claw back, diagnostic and therapeutic protocols, clinical and financial control, preliminary approval, second opinion, evaluation of infrastructure and quality, reimbursement based on targets and performance, positive list, reference prices, discounts, price agreements, volume and risk allocation agreements and other similar items. With a same decision, the measures may vary with regard to the specialty of the physician, the capacity and characteristics of the healthcare provider, the number of patients he/she attends, as well as the characteristics and diseases thereof, the territory and the demographic data thereof, the month of the year (seasonality), the changes of the prices of consumables and technology and finally, the course of the pharmaceutical expenditure in relation to the targets occasionally set. In addition, prescription and conduct of tests and the performance of services may be related to the disease of the patient, as this is defined based on the International Classification of Disease. Specific targets, limits and prescription budgets may be incorporated in performance contracts that are concluded between EOPYY, the physicians prescribing to insured persons of the organisation and motives can be set (bonuses) and penalties with regard to the achievement of the targets and the observance of the limits and budgets. By virtue of the decision of the Minister of Health, the devices and procedures for the exception from the above provisions, of specific categories of physicians, medicinal products, healthcare units, groups of patients or individual cases of physicians are additionally set out together with the manner of incorporating the above provisions in the electronic prescription system, the control methodology, the field of application (private of public) as well as any measure necessary for the effective application thereof.

2. At the end of par. (a) of article 11 of law 4052/2012, as amended and currently in force, a clause is added as follows:

"In addition, by decision of the Minister of Health the methodology for the calculation of the claw back, as well as the rebate of the pharmaceutical companies is particularised, in cases the pharmaceutical expenditure of EOPYY has transgressed the targets set in the occasional annual budget. For the calculation of the overrun ot the allocation of the amount to be refunded, the net expenditure of EOPYY may be applied, as this results after the subtraction of the VAT, the patients' participation, the discounts of pharmaceutical companies and pharmacies, the rebate for the inclusion in the positive list and the volume rebate of pharmaceutical companies, the expenditure for the medicinal products set out in the list 1A of Law 3816/2010, the wholesaler's profit margin which is returned by the pharmaceutical companies when they sale directly to the pharmacies, and other amounts which are defined in the relevant decision. With a same decision targets for the pharmaceutical expenditure per year may be set, at a level of medicinal product, active substance (ATC5) or therapeutic category (ATC4). In addition, the procedure for the off-setting of the amount in excess of the pharmaceutical expenditure of EOPYY may be determined, in general against the amount by which the pharmaceutical expenditure of public hospitals falls short, in relation to their budget. In addition, monthly targets for the pharmaceutical expenditure may be defined, with regard to the course of the measures of the pharmaceutical policy, in relation to the annual targets and any measure necessary may be determined for the more effective implementation thereof".