LAW 4052/2012

CHAPTER D

Provisions re EOPYY

Article 10

EOPYY and NHS hospitals revenue following the implementation of DRGs

1. In paragraph 1 of article 17 of Law 3918/2011 (A' 31) the phrase "is supervised by the Ministries of Employment and Social Security and Health and Social Solidarity" is replaced by the phrase "is supervised by the Ministry of Health and Social Solidarity".
2. From 1/1/2013 the NHS hospitals receive from EOPYY all the revenues for claims of the Social Insurance Funds under EOPYY including the relevant subsidies provided by the Ministry of Finance for this purpose. The procedure and every relevant issue for the implementation of this provision is determined by a decision of the Ministers of Health and Social Solidarity, Employment and Social Insurance and Finance.

Article 11

a. The monthly pharmaceutical expenditure of Social Insurance Funds cannot not exceed one twelfth of the amount of pharmaceutical expenditure included in the annual state budget. Any amounts in excess of this limit shall be returned to social insurance funds by the marketing authorisation holders. The amount in excess is calculated bimonthly and it is returned by the MAHs within one month following its verification in a bank account indicated by the Secretariat General of Social Security. By decision of the Minister of Health and Social Solidarity which must be issued within fifteen days following the publication of the present law, will be determined every detail regarding the implementation of the present article and especially the precise method of calculation of the amounts that every MAH must return on the basis of: i) the percentage of participation of each medicine to the expenditure (without VAT), ii) the market share of each medicine in the therapeutic cluster of the reimbursement list, ii) the possibility of final off-setting of any eventually outstanding amounts on the basis of the total turnover of each company, iv) the consumption of each medicine compared it's market share in the respective period of time in the previous year, v) every detail concerning the method and the time of settlement of the amounts due as well as the procedure of eventual off-setting with following bills. In case of non timely return of the rebate of the present paragraph, it is collected according to the Code for the Collection of Public Revenues procedure.

b. For the calculation of the above parameters the sales of medicines collected by EOF are taken into consideration excluding parallel exports and hospital sales. The development ratio (added value of the product) of each MAH can also be taken into consideration either alternatively or cumulatively.

c. The provisions of paragraph a and b of the present article are implemented irrespectively of article 35 paragraph 1 of Law 3918/2011, as in force each time.

d. The present article shall be in force from 1.1.2012 up-to 31.12.2015.

Article 12

Offsetting of claims of Social Insurance Funds, hospitals and pharmaceutical companies

1. Claims of Social Insurance Funds against pharmaceutical companies or MAHs of medicinal products of paragraph 3a of article 12 of Law 3816/2010 (A' 6) as supplemented by paragraphs 1 and 3d of article 36 of Law 4025/2011 (A' 228) are mandatorily assigned to the hospitals against the payment of the hospital expenses of their beneficiaries. The hospitals offset mandatorily the amounts assigned according to the above provisions with hospital debts to pharmaceutical companies. The amounts assigned and offset according to the provisions of the first subparagraph of the present paragraph as well as the relevant procedure can be determined by Joint Ministerial Decisions of the Ministries of Finance, Employment & Social Insurance and Health & Social Solidarity.

2. The respective rebate to be paid on the basis of paragraph 1 of article 35 of Law 3918/2011 as in force each time, the amount resulting from article 11 of the present law as well as the entry fee for the reimbursement list of article 36 of Law 4025/2011 are deducted from the taxable income as productive expenditure of the person finally depositing the amount.

3. The Ministry of Health and Social Solidarity can conclude annual framework agreements with pharmaceutical companies for additional discounts on medicines for hospital use.

CHAPTER G

Regulation of matters relating to the National Organisation for Medicines

Article 16

Provisions on the pricing of medicinal products.

Transfer of responsibilities

1. Case d of paragraph 2 of article 15 of P.D. 95/2000 (A' 76) is replaced as follows:

"d. Department (Ybd) of pricing of medicinal products"

1. The issuance of price bulletins determining the prices of medicines for human use, following recommendation by EOF and the opinion of the Pricing Committee.

2. The examination of any appeals filed by MAHs following the publication of the Price Bulletin.

3. The issuance of Ministerial Decisions and recommendation for actions to be taken to protect public health and consumers.

4. The referral of various subjects to the Pricing Committee and the recommendation on referred matters as well as record keeping of the minutes of the Secretariat of the Pricing Committee.

5. Ensuring the appointment of the members of the Pricing Committee."

2. At the end of case b of paragraph 2 of article 3 of Law 1316/1983 (A' 3) a subparagraph is added as follows:

"The competence of submitting a proposal for the determination of prices of medicines for human use is assigned to EOF".

3. In paragraph 1 of article 9 of P.D. 142/1989 case e is added as follows: "d) Pricing of medicines".

4. At the end of paragraph 2 of article 9 of P.D. 142/1989 case e) and sub-cases ea) to ef) are added as follows:

"e) In EOF shall be entrusted the competence of the determination of the prices of medicinal products for human use. Specifically:

ea) The responsibility for searching the prices of medicines in the European countries, data collection and the determination of prices, in accordance with the decisions of the Ministry of Health and Social Solidarity.

eb) The review of cost reports submitted by pharmaceutical companies.

ec) The responsibility for the collection and processing of data included in the Price Verification Sheets, which are mandatorily submitted by all marketing authorisation holders (hereinafter referred to as MAHs) for the determination of the prices of their products.

ed) The responsibility for the collection of data on the pricing systems for medicines adopted in other countries, as well as preparation and submission of proposals to the Minister of Health and Social Solidarity so as to adopt the most appropriate pricing system.

ee) The responsibility for the collection and processing of data on the cost and the prices of medicines, raw materials, packaging material and accompanying devices, as well as monitoring of the evolution of a number of economic variables regarding medicinal products.

ef) The responsibility for data processing, final determination of prices in accordance with the decisions of the Minister of Health and Social Solidarity regarding the pricing of medicines, in force each time, and the submission of a proposed Price Bulletin to the Department of Prices of Medicines of the Ministry of Health.

5. EOF's Department for the pricing of medicines shall be staffed forthwith, (by personnel transfers in accordance with Articles 71 of Law 3528/2007 and 35 paragraph 5 of Law 4024/2011 (Government Gazette A 226) and 68 par. 1 of law 4002/2011) with: one (1) IT expert, university graduate; two (2) IT employees, Technical Institute (TEI) graduates; one (1) economist (AEI/Econ.); two (2) administration officers (AEI/admin.); (2) pharmacists (AEI/pharm.); and two (2) cost accountants. The vacant existing permanent positions of EOF can be staffed with personnel transfers in the same way.

6. By decision of the Minister of Health and Social Solidarity shall be determined. Every necessary detail for the implementation of the present article and the date of its entry into force.

Article 17

1. In paragraph 1 of Article 3 of Law 1316/1983 (GG A 3), a new indent (f) shall be added as follows:

"f) the issuance of wholesalers' licenses".

2. The terms and conditions for the issuance by EOF of wholesalers' licenses, the entry into force of the relevant provisions and any other detail necessary shall be specified by a decision of the Minister of Health and Social Solidarity, following a recommendation by EOF, in accordance with Article 14 paragraph 4 of Law 1316/1983.

3. Paragraph 1 of Article 27 of Law 1316/1983 (O.J. A'3) shall be replaced as follows:

"1. a. The manufacturing plants and laboratories manufacturing the products referred to in indents b, c, d, e, f, g, h and i of Article 2 (2) of this Law shall employ on a full time basis a Production Manager and a Quality Assurance Manager, who can be qualified chemists, pharmacists, physicians, biologists or veterinarians, holding a degree from a domestic University or Technical University or an equivalent foreign institution.

b. The manufacturing plants and laboratories manufacturing the products referred to in indents a, l and o of Article 2 paragraph 2 of this Law shall employ on a full time basis a Production Manager, who can be a qualified chemist or pharmacist or physician doctor or biologist or veterinarian, holding a degree from a domestic University or Technical University or an equivalent foreign institution.

c. The manufacturing plants and laboratories manufacturing the products referred to in indents i, k, m, n and p in Article 2 paragraph 2 of this Law shall employ a Responsible Officer (as full- or part-time employee or as an independent contractor) under the condition that proper and adequate performance of his/her tasks is ensured. Such officer can be a graduate of a domestic University or Technical College or hold an equivalent degree from an accredited foreign institution in a specialty relevant to the products manufactured, so as to implement the specifications of the products according to the legislation governing the respective product category".

Article 18

Paragraph 6 of Article 39 of Law 3918/2011 (O.J. A'31) shall be amended as follows:

"6. The Committee's task shall be to deliver opinions on matters related to the prices of medicinal products within EOF's competence and referred to in indents b through i of paragraph 2 of Article 2 of Law 1316/1983 (O.J. A' 3).

In addition, the Committee will have the following tasks:

a. to verify the prices of medicines before the issuance of the Price Bulletin;

b. to verify the outcome of appeals before the issuance of a corrective Price Bulletin;

c. to submit proposals to the relevant service of the Ministry of Health and to EOF on pricing systems for medicines".

Article 19

1. The first subparagraph of indent d) of paragraph 5 of Article 17 of Legislative Decree 96/1973 (A' 172), as amended and in force after the words "The price of each medicinal product" the words "for which the active substance is covered by a valid first National or European patent" shall be inserted.

In indent d of paragraph 5 of article 17 of L.D. 96/1973 (A' 172) as amended and in force, the text "The price of each medicinal product is mandatorily determined

by the department of prices of medicines of the Directorate of medicines and pharmacies of the Ministry of Health & Social Solidarity up to twice a year" shall be replaced by the following text:

"EOF proposes to the department of prices of medicines of the Directorate of medicines and pharmacies of the Ministry of Health & Social Solidarity the price of each medicinal product which is published in Price Bulletins by the Department of Prices of Medicines, Directorate of Medicines and Pharmacies up to four times per year".

Article 20

The provision of article 38 of Law 3918/2011 (A' 31), article 26 of Law 2072/1992 (A' 125) and paragraph 5 of article 13 of the L.D. 96/1973 (A' 172) are repealed.

CHAPTER H

Provisions on medicines

Article 21

1. Indent c of paragraph 5 of Article 17 of Legislative Decree 96/1973 (A' 172), as amended and in force, shall be replaced as follows:

"c) Prices of original medicinal products, following certification by all expedient means of the expiry of the first national or European patent of the active substance of the respective products shall be reduced by at least fifty per cent (50%).The price of the first medicinal product having the same active substance and pharmaceutical form entering the market following the expiry of the first National or European (patent) of the active substance shall be reduced by at least sixty per cent (60%) of the retail price the respective original medicine, had just before the expiry of the first national or European patent of the active substance. The procedure for determining the prices of medicinal products under the preceding provisions shall be applied automatically by the Department of Prices of Medicines of the National Organization for Medicines. The MAHs have the right to ask the determination of a lower price than the price determined by the provisions in force."

2. When additional medicinal products of the same active substance and pharmaceutical form enter into the market after the first generic product, the prices are reduced by an additional 10% for new medicines which are not protected by a patent. Following a decision of the Minister of Health & Social Solidarity, which is published within fifteen days from the publication of the present law, all the necessary details are determined re a number of medicinal products per active substance, form and strength, the determination of criteria for the priority of the applications submitted as well as every other detail necessary for the implementation of this paragraph.

3. With decisions of the Minister of Health having the power of market decrees, which must be published within fifteen days following the publication of the present law, the profit margins of the wholesalers of medicinal products are determined, which may be escalated or a combination of escalated margins and fixed amounts. In any case the gross profit margin resulting from the sales of medicinal products, which are partly or fully reimbursed by social security funds shall not exceed 4.9% and it is calculated on the ex-factory or import price.

4. Electronic register of all prescriptions from pharmacies to Social Insurance Funds is mandatory, irrespective of whether an electronic or a manual prescription method has been used by the physician. For each manual prescription recorded electronically by pharmacies, the prescribing physician shall be charged with an administrative fee to compensate the pharmacy for the service of electronic recording. Hand written prescriptions are in no case reimbursed by the social insurance funds and the pharmacies cannot claim payment of these prescriptions.

By a decision of the Minister of Health and Social Solidarity shall be defined the amount of fee, the collection method and any other detail for the implementation of this provision.

5. a) In all NHS hospitals it is obligatory starting April 1st 2012 to include in the prescription the chemical substance of the medicine (active substance). The computerized systems of the hospitals are obliged to provide the relevant information to the physicians.

b) From April 1st 2012 all physicians shall prescribe to patients insured in social insurance funds indicating on the prescription exclusively the chemical substance (active substance) of the medicines for the ten (10) first highest in consumption active substances, for which there are patented medicines and generics, excluding medicines for serious diseases. By decision of the Minister of Health & Social Solidarity, to be published within 10 days from the publication of the present law the specific active substances shall be determined. From June 1st 2012 prescribing by active substance is rendered mandatory and universal.

c) The National Organisation for Medicines (EOF) shall establish a list with the chemical names of the active substances and the corresponding trade names of medicines and will post it on its website by March 31, 2012".

6. By decision of the Minister of Health and Social Solidarity a lower rate of patient co-payment may be specified as defined in paragraph 1 of Article 38 of Law 4025/2011 (O.J. A' 228) when the medicine dispensed is the lowest-priced product of the same active substance, strength and pharmaceutical form as the one prescribed by the physician with the consent of the insured. In order to implement the previous provision, the pharmacist can dispense the lowest priced medicinal product of the same active substance, strength and pharmaceutical form rather than the one prescribed by the physician. In case the insured person wishes to receive a more expensive medicine of the same active substance, the Social Insurance Fund reimburses the price of the cheapest medicine and the insured pays the difference.

7. Indent b of paragraph 1 of Article 12 of Law 3816/2010 (A' 6), as amended and in force, shall be replaced as follows:

"b. For the establishment, revision and supplementation of the reimbursement list a system of classification of medicinal products according to the Anatomic Therapeutic Chemical classification (ATC) of the World Health Organization (WHO) is applied, and a reference price system per therapeutic category of medicinal products is introduced. As reference Price is defined the lowest price of cost of daily treatment (CDT) among the medicinal products of each therapeutic category. In parallel, the safety and efficacy of the products are examined and the indications, strengths and packages reimbursed by social security shall be selected for each medicinal product. By joint decision of the Minister of Health and Social Solidarity and the Minister of Employment and Social Insurance (published in the Official Journal and posted on the website of the National Organisation for Medicines) are specified the methods to be used for the therapeutic classification of medicines and the calculation of the reference price per therapeutic category and the other criteria and how the list shall be revised

and supplemented, as well as the reimbursed indications, strengths and packages per medicinal product and every other relevant issue. Social Insurance Funds reimburse medicines protected by a valid patent of the active substance and with a marketing authorisation issued in Greece after 1.1.2012, under the condition that they are reimbursed by the social insurance in 2/3 of the EU member states or in at least 12 EU member states, whose Social Insurance Funds reimburse the medicines following assessment by valid health technology assessment bodies, under the condition that the EC Directive 89/105 re transparency is fully implemented. By decision of the Minister of Health & Social Solidarity medicines which are characterized as necessary against a life threatening danger or orphan medicines may be excluded, only if they are covered by international clinical protocols. Until the establishment of the reimbursement list according to the criteria of the present paragraph, the positive reimbursement list as published in the Ministerial Decision no DYG3/oik.104893 (B' 2141/2011) and eventually amended by the first implementation of article 37 of Law 4025/2011 (A' 228) and supplemented by the procedure described in the Ministerial Decision no DYG3a/G.P.95872 (B' 2155), is in force."

Article 22

Paragraph 1 of Article 35 of Law 3918/2011 (A' 31) shall be replaced as follows:

"1. a) For every medicinal product prescribed by a physician and the cost of which is covered by social security funds (SSF), the EOPYY and the Seamen's Home, a "reimbursement price" (hereinafter "TKA") shall be introduced, which is the ex-factory or import price as defined each time by the ministerial decision in force on the pricing of medicines, reduced by 9%. The Social Security Funds reimburse prescribed medicines up to the amount of the retail price reduced by the co-payment of the insured and the resulting difference between the producer or import price and the reimbursment price. The expenditure of 9% is born exclusively the MAHs of medicinal products and it is considered as a rebate of the MAHs of medicinal products to the Social Insurance Funds and EOPYY.

b) The amount to be paid by each company or marketing authorisation holder for medicinal products shall be calculated on the basis of the total sales per medicinal product, after deducting sales to hospitals and parallel exports according to the data of the National Organisation for Medicines (EOF). The calculation shall take into account the ratio of public to private pharmaceutical expenditure, i.e. 80%-20%.

c) In addition to the provisions of the preceding subparagraphs (a) and (b), MAHs shall be required to pay every quarter starting from 1/1/2012 a further escalated rebate, at rates varying according to the total volume of sales of each medicinal product in the previous quarter, as shown in the table below:

Quarter total sales volume per medicinal product	Additional rebate further to the rebate under subparagraph (a) of the present paragraph
€400.0000- €800.000	2%
€800.001 - €1.500.000	4%
€1.500.001 - €2.500.000	6%
Over €2.500.001	8%

To calculate the final amount, the conditions referred to in case (b) of this paragraph shall be taken into account. The additional rebate shall be calculated according to the sales of the previous quarter based on sales data of EOF and shall be paid, respectively, for the first quarter by 30 April, for the second quarter by 31 July, for the third quarter by 31 October of the same year and for the fourth quarter by 31 January of every following year.

d) The method of calculation of the amounts by EOF, as described in subparagraphs b) and c) of this article does not apply in cases where the social security fund has joined the electronic prescribing system (hereinafter "the EPS") until the full implementation thereof or has another system in place for the electronic scanning of manual prescriptions. In these cases, the rebate amount to be paid by each company or marketing authorisation holder shall be calculated either through the EPS or through such other system separately for each social security fund or for EOPYY and shall be allocated to the social security funds and EOPYY accordingly.

e) i) In the event of failure to pay in due time of the rebate under subparagraph (a) above or of the additional rebate under subparagraph (c) of this paragraph, these amounts shall be collected on the basis of the procedure specified in the Code for the Collection of Public Revenues.

ii) The medicinal products for which the rebate has not been paid shall automatically be removed from the reimbursement list referred to in paragraph 1 of Article 12 of Law 3816/2010.

iii) Pharmaceutical companies shall be entitled to certification of the payment of the rebate for fiscal use.

f) By joint decision of the Minister of Finance, the Minister of Employment and Social Security and the Minister of Health and Social Solidarity shall be specifed the procedure, deadlines and method of payment of the rebate under subparagraph (a) and of the additional rebate under subparagraph (c) of this paragraph by the MAHs to social security funds or to EOPYY and the Seamen's Home, the allocation of the collected amount to beneficiary entities and the sanctions for non-compliance with this provision, and shall address any other matter relevant to the implementation of this article.

g) This paragraph shall take retroactive effect as of 1 January 2012.

Article 23

1. Case c of paragraph 2 of article 12 of Law 3816/2010 (A' 6) is replaced as follows:

"c. By ministerial Decision of the Minister of Health and Social Solidarity, published in the Government's Gazette, are approved, following EOF's recommendation, two lists including medicinal products for serious diseases of paragraph 2 of the present article as follows: i) for exclusive distribution by hospitals and private clinics and ii) for distribution by private pharmacies as well. By identical decision the above mentioned lists are revised and supplemented at least once per year. For the determination of the cost the wholesale price of the medicinal products and their packaging in combination with the cost of daily treatment are taken into account. The price of the medicinal products in the list which are i) distributed by hospitals and private clinics is determined at the hospital price + 5% + VAT, while the price of the medicinal products of list ii) distributed by private pharmacies is determined by a decision of the Minister of

Health & Social Solidarity, which has the force of market decree. This decision shall determine a fixed amount as pharmacist's profit or a combination of profit margin and a fixed amount as pharmacist's profit."

2. At the end of article 40 of Law 3918/2011 (A' 31) a subparagraph is added as follows:

"By identical decisions shall be determined, instead of the pharmacist's profit margin, a fixed amount per medicinal product as pharmacist's profit or a combination of profit margin and a fixed amount as pharmacist's profit, in specific categories of high cost medicines, which are determined by a decision of the Minister of Health & Social Solidarity, which is issued within fifteen days from the publication of the present law, following EOF's recommendation. During the first implementation of this law and for the medicines reimbursed by the Social Security and whose wholesale price exceeds €200, the profit margins are determined as follows:

Medicines of paragraph 2 of article 12 of Law 3816/2010

PRICES OF MEDICINES	PERCENTAGES AND FINAL PRICE
With special wholesale price* up to €500	Hospital price +2%+8%+€30
With special wholesale price €501-1000	Hospital price +2%+7%+€30
With special wholesale price above €1001	Hospital price +2%+6%+€30

*Special wholesale price = hospital price +2%

For the remaining medicines apart from par. 2 of article 12 of Law 3816/2010 and with wholesale price above €200, as the table:

PRICES OF MEDICINES	PERCENTAGES AND FINAL PRICE
With wholesale price from €200-500	Wholesale price 8%+€30
With wholesale price €501-1000	Wholesale price 7%+€30
With wholesale price above €1001	Wholesale price 6%+€30

In next re-pricing which cannot take place later than June 15,2012, the profit of pharmacist for the medicines whose wholesale price exceeds €200, will correspond to €30 on the wholesale price and on the special wholesale price".

3. In article 9 of Law 2889/2001 (A' 37) paragraph 10 is added as follows:

"10. The cost of medicines for serious diseases of the list of case c of paragraph 2 of article 12 of law 3816/2010 (A' 6) and of those medicines which are excluded from DRGs by public hospitals and private clinics to social insurance funds is determined on the hospital price +5%+VAT".