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Law 5102/2024: Public Measures – Regulations for Strengthening the National Healthcare System

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Background

Recently enacted Law 5102/2024 [Government Gazette 55/A/13-4-2024] (hereinafter referred to as the “Law”) provides for measures and changes in the public health sector and the National Healthcare System, known as “ESY”. A brief summary of the most significant provisions is set out below.

New Regulations for Physicians and Nursing Staff of the National Healthcare System

- (a) ESY physicians may offer their services privately under certain conditions and as an exception.

In particular, it is specified that, ESY physicians may:

- maintain a private practice and/or
- provide medical services to any type of private company that provides or covers health services,

subject to the granting of a license, in accordance with the procedure laid down in Article 7 of the Law.

Failure to comply with the above licensing procedure will constitute disciplinary misconduct and will result in the immediate revocation of all associated licenses and the termination of the relevant contracts.

In addition to the above, the new regulations also provide as follows:

- (b) Members of the Teaching Research Staff who are physicians and assigned to university clinics, units or laboratories located in ESY hospitals or in university hospitals, may also offer their services privately, subject to the licensing procedure.
- (c) Physicians and other scientific and nursing staff of the ESY, may, in exceptional cases, be allowed to participate in type A and B scientific events, both in Greece and abroad.
- (d) Physicians, other scientific and nursing staff of the ESY, as well as university doctors working in ESY hospitals or universities, may also participate in working groups, such as "Advisory Boards" for medicinal products and treatments, with a strictly scientific content, held in Greece or abroad, with physical presence or remotely by electronic means, provided that they have been authorized to do so by the body supervising them.

It is expected that a Ministerial Decision will be published to regulate all matters related to the initial implementation of the Law.

Evaluation of the Prescription Rates of (a) Diagnostic Tests and Medical Procedures and (b) Medical Devices and Special Nutrition Products

The Prescription Monitoring Committee of the National Organization for the Provision of Health Services (“EOPYY” as per its Greek abbreviation) shall monitor, audit, and evaluate the prescription of (a) diagnostic tests and medical procedures and (b) medical devices and specialized nutrition products to assess compliance with the prescribed diagnostic protocols and good medical practice.

Infringement and Sanctions

If, based on the available data, the Prescription Monitoring Committee considers that the prescribing behavior of the physicians is not justifiable, the physicians will be requested to provide a written justification. The explanations shall be provided within a period of ten (10) days of the notification/receipt of the relevant document.

Failure to provide an adequate justification for the breach may result in the imposition of administrative sanctions.

Each physician may appeal within thirty (30) days from the notification/receipt of the sanction decision. During this thirty (30) day period, and in the event of an appeal, the enforcement of the decision imposing sanctions shall not be suspended until a new decision is issued.

Expiration of Protection Period and Negotiation of Price

For medicinal products whose protection period expires and for which there are priced generic or biosimilar products, the Negotiating Committee may unilaterally terminate the relevant agreements for these medicinal products and

invite the MAHs or the pharmaceutical companies of the products and their generic or biosimilar products to negotiate.

Contribution Fee for the Renewal of the Circulation in the Market of Finished Medicinal Cannabis Products

Any application that modifies, amends, or renews the specific marketing authorization for the circulation in the market of finished medicinal cannabis products is now subject to a contribution fee payable directly to the National Organization for Medicines (“EOF”).

Next Steps

We are looking forward to seeing how Ministerial Decisions will detail the newly applicable framework and implement the changes and the new mechanisms provided for in the Law.

For expert legal advice and assistance, consider contacting the dedicated Life Sciences & Healthcare team at KG LAW FIRM.

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