

## **Social Security Institution Alternative Reimbursement Regulation Has Been Published**

As a consequence of the lawsuits filed against the provisions of the Alternative Reimbursement Regulation dated 10 February 2016, due to the regulation being published without obtaining the Ministry of Health's opinion, the articles subject to the lawsuits were cancelled based on formal deficiency.

The Social Security Institution Alternative Reimbursement Regulation ("Regulation") has been published in the Official Gazette dated 12 May 2023 and numbered 32188 and entered into force as of the date of publication.

While the Regulation generally contains similar provisions with the regulation dated 2016, the following are the notable developments:

- The phrase in the definition of an alternative reimbursement model in the previous regulation that referred to "*encouraging the production of product groups procured from abroad, which cannot be produced or are not available in Turkey, the transition of imported products to domestic production, and ensuring their availability in the market*" has not been included and the definition explicitly refers as alternative reimbursement models as models which may consist of "*determining discount rates different from the public institution discount rates specified in the relevant article of the Health Implementation Communiqué, bringing budget and patient number limits, including health services within the scope of payment by providing purchase guarantee, etc.*".
- It has been stipulated that the Alternative Reimbursement Commission (the "Commission") shall convene ordinarily at least twice a year, in June and December, and extraordinarily upon the invitation of the Chairman of the Commission. Thus, the calendar of the Commission's meetings has been established for the first time and predictability has been ensured regarding the process.
- It is envisaged that the period for the agenda item to be decided by the Commission will be one year starting from the date of the first inclusion of the item on the agenda. Thus, it will be prevented that the issues included in the agenda will remain in procrastination.
- The provisions regarding confidentiality, which were cancelled by the Council of State decisions, have entered into force in the same manner. Therefore, the provisions on the confidentiality of the Commission's work and the confidentiality of the application upon request will be applied in the same manner as before the cancellation decisions.

It is observed that the process in the development of alternative reimbursement models has been established in a way to serve the needs of the companies, by determination of the dates of the Commission meetings, the time limitation imposed on the items on the Commission's agenda and the defining of the confidentiality principle of the Commission's work with the new Regulation.

Following the publication of the Regulation, with the announcement published by the Social Security Institution on 18 May 2023, it is announced that the marketing authorization holders should update the date and number of their previous applications until the close of business on 26 May 2023. In addition, applications for reimbursement, if any, for health services for

which the contract period has expired or for which a maximum of 6 months remain until the expiry date, must also be made in accordance with the Regulation.