AUTORIDADE DA CONCORRÊNCIA

FAIR PLAY.

Competition in Hemodialysis Care Provision in Portugal

Final Version

Executive Summary

In March 2020, over 12,000 people in Portugal were undergoing hemodialysis, which is the predominant method of dialysis therapy for treating chronic kidney disease. Hemodialysis is mostly provided by private operators – about 93% of patients. The prevalence of chronic kidney disease in Portugal is high compared to other countries and the number of patients undergoing treatment has increased, on average, *circa* 3.5% per year, between 1998 and 2019.

The Portuguese Competition Authority (Autoridade da Concorrência - AdC) undertook an analysis of the conditions for entry and expansion of new centers and the level of concentration in the sector, given the prevalence of hemodialysis and the concerns raised by the National Association of Dialysis Centers. The concerns brought to the AdC related to barriers to opening new centers and the high level of concentration in the market. The AdC collected the views of several stakeholders on this regard.

The high level of concentration and the existence of unnecessary barriers to entry can have a negative impact on the well-being of chronic kidney patients and on the State, as a procurer of dialysis services. Indeed, the price paid by the State to the private centers is regulated and the treatment is subject to quality control. Still, there are specific dimensions of competition in the provision of in-center hemodialysis care, namely the location of the centers and the quality of the services provided. The vulnerabilities resulting from high concentration and limited competition can affect these competition dimensions and in turn, negatively affect patients.

The AdC found high concentration levels in the hemodialysis sector. Several geographical areas (NUTS III) are serviced by a single private operator (excluding the option of the public sector). In March 2020, the four largest operators held around 81% of the hemodialysis centers in mainland Portugal and were responsible for the treatment of about 88% of patients. Concentration is high in all geographical areas in the country.

Between 1990 and 2020, the share of centers of the remaining operators (excluding NephroCare, Diaverum, DaVita and B. Braun) reduced by *circa* 60 pp. (from around 78% of the centers in early 1990 to about 19% in 2020). We identify a high stability of market shares of these private operators, following their entry and establishment in the market.

Only 24% of the centers of the largest private operators were obtained by opening new centers. *Ex novo* entry increases the proximity of chronic kidney disease patients to centers.

We also identified barriers to entry as a result of the procedures in place to open new centers. This, in turn, can compromise the coverage of the network of hemodialysis centers, with a negative impact on patients' well-being by affecting their choice and proximity to centers. There is legal uncertainty in the regime of private contracting of NHS services (i.e. convention regime). Significant legal uncertainty may result from the delays when contracting a convention, and from the the multiplicity of entities and the multiplication of procedures in the convention regime and in the licensing procedure. Indeed, the existing procedures to open a new centers can take several years. This is reinforced by the required investments prior to the authorities' decision to license and to grant the convention, that can reach 2.5 million euros. These barriers create disincentives to invest by new operators, especially smaller ones.

Promoting patient choice and reducing barriers to entry will have a positive impact on the well-being of chronic kidney patients. Our aim is to promote effective and well-informed patient choice, as opposed to a model of allocation of patients to centers. This can intensify competition for quality and innovation in the market. The removal of unnecessary barriers to

the opening of new centers can result in greater proximity between patients and centers, to the benefit of patients' quality of life.

The AdC proposes a number of recommendations to the Government primarily to promote the well-being of chronic kidney patients. The recommendations are put forward in the context of the existing legal framework for dialysis care provision in Portugal, including the Health Framework Law[1]**.** In this context, the recommendations of the AdC aim at promoting the conditions for competition in the market.

In the public consultation, some stakeholders argued for measures to promote quality differentiation, namely by promoting alternative forms of treatment to outpatient hemodialysis. While the AdC does not exclude that such measures may be complementary to the AdC's recommendations, they are based on choices regarding medical treatments and, as such, they are outside the scope of the competition assessment undertaken by the AdC.

AdC Recommendations for the hemodialysis sector

Removal of unnecessary barriers to opening new centers of hemodialysis

Recommendation 1: Ensure a timely publication of the new standard clause concerning hemodialysis, in accordance with the 2013 convention regime (Decree-Law no. 139/2013), in order to reduce the legal uncertainty concerning the convention regime.

Recommendation 2: Within the scope of the procedures for private operators adhering to a standard clause, (a) assess the possibility of granting a convention by tacit approval or, if not possible, assess alternative mechanisms to increase legal certainty for private operators; and (b) introduce a deadline to respond to convention requests.

Recommendation 3: Remove unnecessary obstacles that prevent entry of operators and/or the opening of centers because of the existing capacity, the concentration in the market, or the profitability and/or use of existing resources, namely:

a) Within the scope of the Health Regulatory Authority (ERS)'s prior opinion, take into account the possible positive effects of the expansion of supply resulting from the opening of new centers, as to properly balance the effects of increased concentration resulting from the opening of new centers.
b) In the new standard clause, do not include a clause similar to paragraph 5 of Clause 5 of Order 7001/2002.

Recommendation 4: Create a unique portal and/or form that, from the point of view of the operators, link both the licensing and the convention procedures required in the NHS sector, in charge of the ERS, the Central Administration of the Health System (ACSS) and the Regional Health Administrations (ARS).

Recommendation 5: Ensure that the quality requirements in the best practice guidelines for hemodialysis, under discussion, are technologically neutral.

Promotion of effective and informed patient choice regarding the hemodialysis center

Recommendation 6: In the non-emergency patient transport regulations:

a) Introduce a duty for the ARS to inform the patients when several centers meet the NHS transportation management criteria.
b) Develop a cost-benefit analysis on the possibility of introducing a reimbursement option for patients who ensure their own transport, limited to a certain reference value.

Recommendation 7: Create a system to compare centers on quality and outcome indicators of hemodialysis treatments, based on the monitoring results of the National Dialysis Monitoring Commission (CNAD).

[1] In particular, clause no. 25 establishes that the private sector may only provide healthcare services to beneficiaries of the National Health System (NHS), when the NHS lacks the capacity to provide such care in a timely manner.