

Ministry of Health regulates Productive Development Partnerships (PDPs) and the Local Development and Innovation Program (PDIL)

On June 21, 2024, the Ministry of Health published Ordinances No. 4,472/2024 and No. 4,473/2024, which amend Consolidation Ordinance GM/MS No. 5/2017 to regulate, respectively, the [Productive Development Partnerships Program \(PDP\)](#) and the [Local Development and Innovation Program \(PDIL\)](#).

With the publication of these ordinances, the programs now benefit from robust regulations, which [deserve special attention from the health sector](#):

- **Ordinance No. 4,472/2024 (PDP)** introduces important updates to the previous PDP model, such as (i) the inclusion of the historical internalization of products subject to PDP into the portfolio of the Public Institution (IP) or Scientific, Technological, and Innovation Institution (ICT) as a criterion for classifying PDP project proposals, and (ii) the possibility of adjusting the proposed price for the PDP product in response to price variations in national and international markets.
- **Ordinance No. 4,473/2024 (PDIL)** details the operation of this new dynamic, defining relevant aspects such as (i) the instruments through which the PDIL can be implemented, and (ii) the criteria to be adopted for evaluating the content of PDIL project proposals.

The Ordinances came into force on the date of their publication.

[SEE BELOW](#)

PDP - Productive Development Partnerships Program

Ordinance No. 4.472/2024 revokes Annex XCV of Consolidation Ordinance GM/MS No. 5/2017, which provided for the PDP framework, aiming to address potential challenges and inefficiencies in the previous model.

With this purpose, the ordinance:



Requires the IP and/or ICT to select the private partner through a selection process that complies with the principles of Public Administration, set out in the Federal Constitution and in the Brazilian Public Procurement law (e.g., legality, equality, transparency, morality, efficiency);



Establishes maximum terms of 3 and 10 years for the duration, respectively, of Phases II (planning between partners and conducting training sessions) and III (effective technology transfer), respectively.



Establishes more detailed procedures for changing the partners, the technology being transferred and the timetable in Phases II and III, as well as a more incisive regime for monitoring and evaluating the execution of PDPs (from Phase II to Phase IV); and



Provides for a specific regime of sanctions for total or partial non-performance of the Term of Commitment established for the partnership, with the possibility of applying sanctions such as warnings, fines (which can vary from 0.5% to 30% of the contract value) and temporary suspension from participating in new PDPs.

Eligible Products for PDPs

According to the Ordinance, products eligible for PDPs are those indicated in the Health Productive and Technological Challenges Matrix, which meet the following requirements:

- i. Sanitary registration in the country or the prospect of submitting the registration within 36 months from the project proposal submission date, for solutions subject to Health Surveillance;
- ii. No patent restrictions impacting the proposed arrangement (or expiration of such restrictions within 36 months);
- iii. Centralized acquisition or potential for centralization, or acquisition through programs, measures, initiatives, and specific actions aimed at rationalizing access to strategic products and services for the Public Health System (SUS), within the framework of the Health Economic Industrial Complex (CEIS); and
- iv. High dependence on imports or expected discontinuation of the product in the country.

PDIL - Local Development and Innovation Program

Unlike the PDP Program (which focuses on strengthening national capacity through the transfer of known health technologies held by private companies), the PDIL aims to reduce the productive and technological vulnerability of the Public Health System (SUS) by promoting the local development of innovative solutions.

The PDIL aims to:

- i. Promote national production within the framework of Health Economic Industrial Complex (CEIS) in connection with the Health Productive and Technological Challenges Matrix;
- ii. Foster technological productive development and local innovation;
- iii. Promote training actions for public ICT producers, startups, and private companies, aiming to develop technologies for incorporation into the SUS; and
- iv. Contribute to digital and ecological transformation and the sustainability of the CEIS.

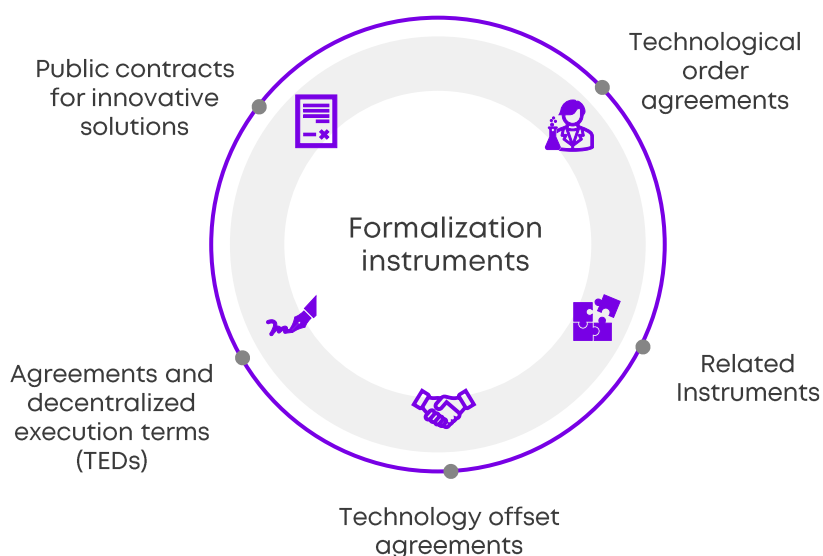
To participate in the PDIL, the eligible solutions will be those listed in the Health Productive and Technological Challenges Matrix (currently outlined in Ordinance GM/MS No. 2,261/2023).

Project Selection

The Ministry of Health will select projects with support from the Secretariat of Science, Technology, Innovation, and Health Complex ("SECTICS"), following the opening of a submission period for proposals.

The PDIL project proposal must be submitted by an ICT, public institution, or nonprofit private entity, which may establish strategic alliances with other public entities, private companies, and startups for the development of the proposed technology or product.

Support for PDIL projects can be formalized through any of the instruments aimed at promoting innovation:



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