

Market Access & Reimbursement
in Brazil

Avania

December 2025

There are several considerations for device companies seeking to export to Brazil.

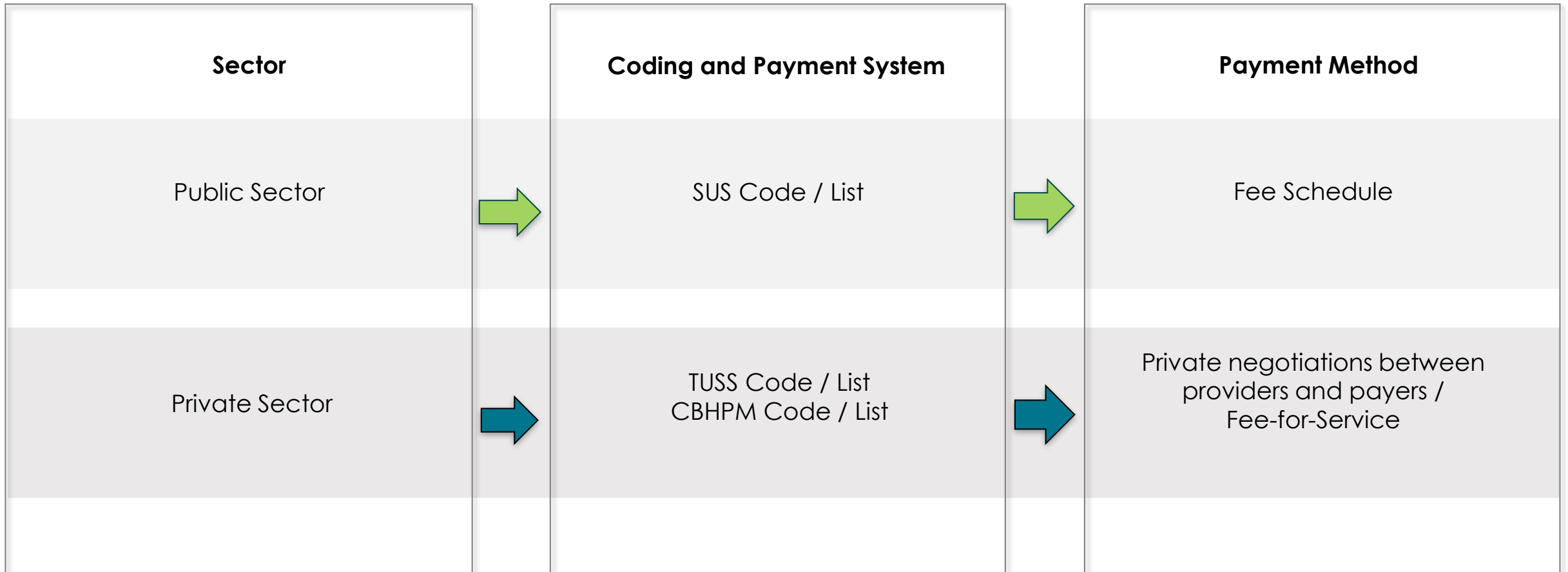
- A devaluation of the Brazilian Real has depressed prices locally.
- This can make it more challenging to show cost effectiveness.
- Separately, Brazil has had aggressive tariffs on certain imported medical products, as high as 80% for some products.
- Consequently many companies choose to assemble their products locally.

Swiss Franc vs Brazilian Real, Dec. 2020 to Dec. 2025



The Brazilian health system includes a universal public sector and a supplementary private sector, with coding and payment varying based on sector.

Overview of Hospital Inpatient and Outpatient Reimbursement in Brazil



Overview: The Brazilian Health System



Public Sector

- The Sistema Único de Saúde (SUS) is Brazil's public healthcare system providing universal coverage. It is federally coordinated and administered by municipal, state, and federal authorities.
- Procedure reimbursement depends on inclusion in the SUS list and its fee schedule, but payments vary by state, municipality, and hospital budgets.
- Medical devices and high-cost disposables are funded separately through hospital and government budgets, with pricing negotiated locally based on existing technology costs.



Private Sector

- The Agência Nacional de Saúde Suplementar (ANS) regulates Brazil's private healthcare system and maintains the mandatory coverage, list, Rol de Procedimentos e Eventos em Saúde (ROL).
- Private sector reimbursement uses CBHPM coding and ROL inclusion for mandatory coverage, but actual payments are negotiated between hospitals / providers and private payers.
- Medical devices and high-cost disposables are usually funded through annual hospital budgets, with pricing determined by private negotiations.

OVERVIEW OF PUBLIC SECTOR REIMBURSEMENT LANDSCAPE IN BRAZIL

Approximately 50% of public healthcare spending is dispensed by states and municipalities and local funding arrangements in wealthier regions are usually a first step in the public reimbursement process.

Brazilian States and Municipalities, by Population



- Although a national SUS listing is the most rapid way of launching many new medical technologies this may not be the ideal first step for many technologies.
- Alternatively, many Brazilian states and municipalities have autonomous budgets within the SUS system, and have the ability to issue tenders and procure technologies within their own budgets.

The Ministry of Health, ANVISA, and CONITEC all play crucial roles.

The Ministry of Health (MoH) provides overall management and provision for healthcare in Brazil.

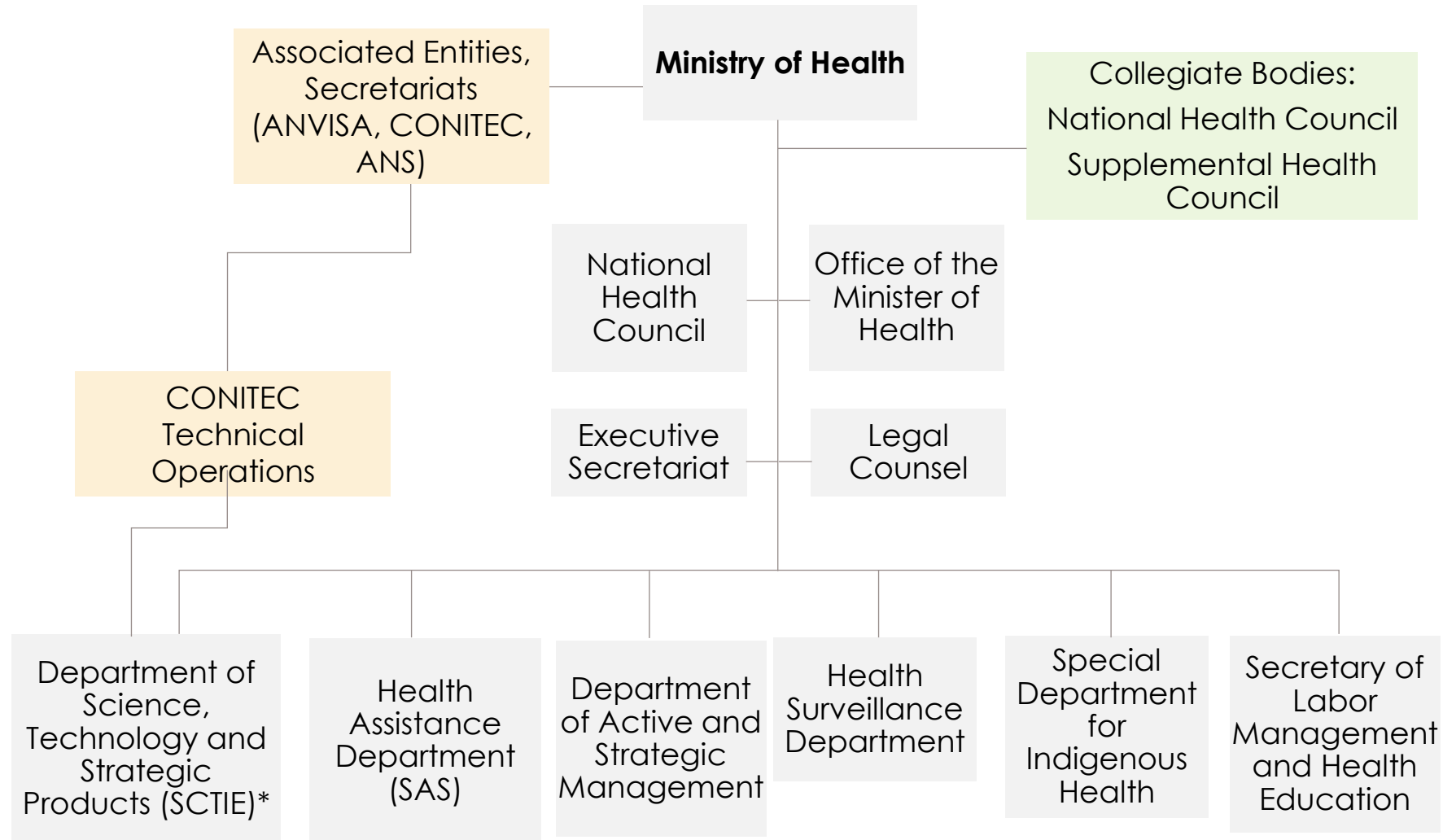
Regulatory Approval: ANVISA approves medical technologies as safe and effective for private or public use, specifically considering international reference prices in their approval of new products for the Brazilian market.

Health Technology Assessment: CONITEC is an advisory and HTA committee which makes coverage and reimbursement decisions for the public sector.

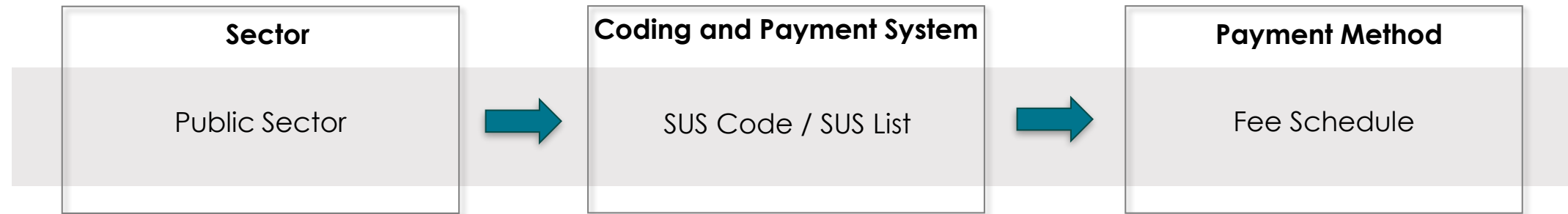


A variety of stakeholders are relevant to the public healthcare sector in Brazil.

Overview of Relevant Stakeholders in Brazil



The public sector is a low-price, cost-constrained market focused on cost-effectiveness for new technologies.

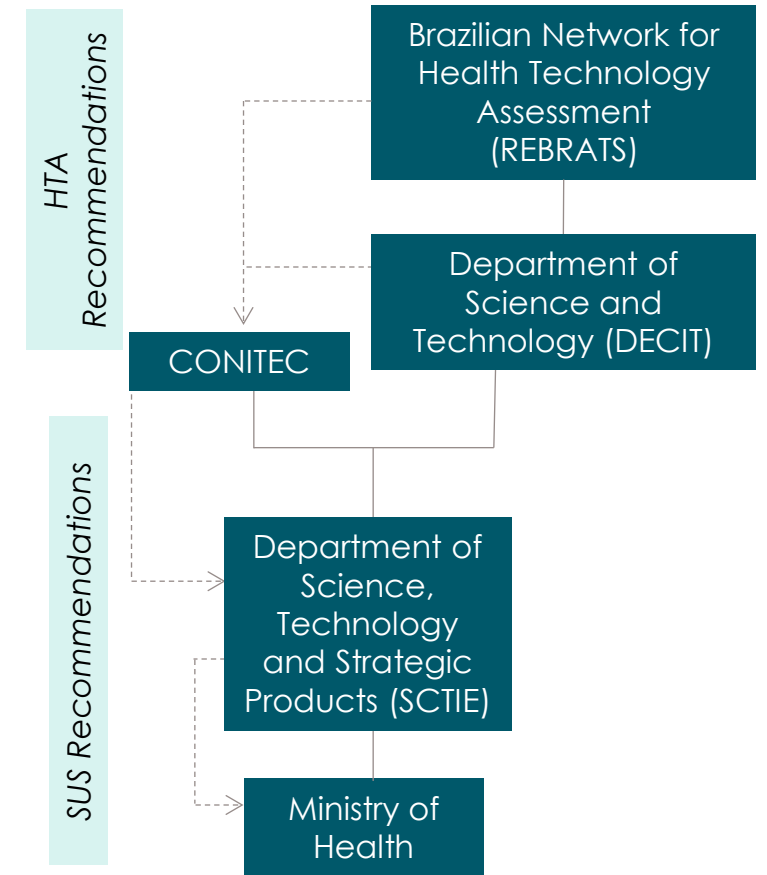


- Reimbursement for procedures in the public sector healthcare relies on inclusion into the SUS coding list and payment according to the SUS fee schedule.
 - Inclusion in the SUS list is not an ideal entry point for new technologies, especially high-cost procedures and devices, due to low reimbursement rates driven by limited public healthcare funding
- New products must first register in *Agência Nacional de Vigilância Sanitária* (National Health Surveillance Agency, ANVISA) to begin selling in the market
- Specific requirements for public sector reimbursement include:
 - Studies in important public hospitals;
 - Demonstrated utilization of device/technology in the public sector throughout Brazil; and
 - A positive CONITEC review, requiring comparative clinical and cost-effectiveness data, for inclusion in the SUS list.

CONITEC is an advisory and Health Technology Assessment (HTA) committee that makes coverage and reimbursement decisions for the national SUS system.

- The CONITEC is linked to the Department of Science, Technology and Strategic Inputs (SCTIE) of the Ministry of Health, which is responsible for the incorporation of technology in the SUS.
- The Department of Science and Technology (DECIT) is responsible for conducting HTA analyses and providing recommendations to CONITEC.
- DECIT can also collaborate with members of the Brazilian Health Technology Assessment Network (REBRATS). REBRATS is a network of institutions that work towards promoting HTAs in Brazil.
- All technology reviews should be supported by the applicable specialty society and the society product-specific utilization guidelines.
- Timing of a CONITEC review is crucial. Once a negative review is submitted, it is very difficult to mitigate the consequences.

Public HTA Process for SUS Listing



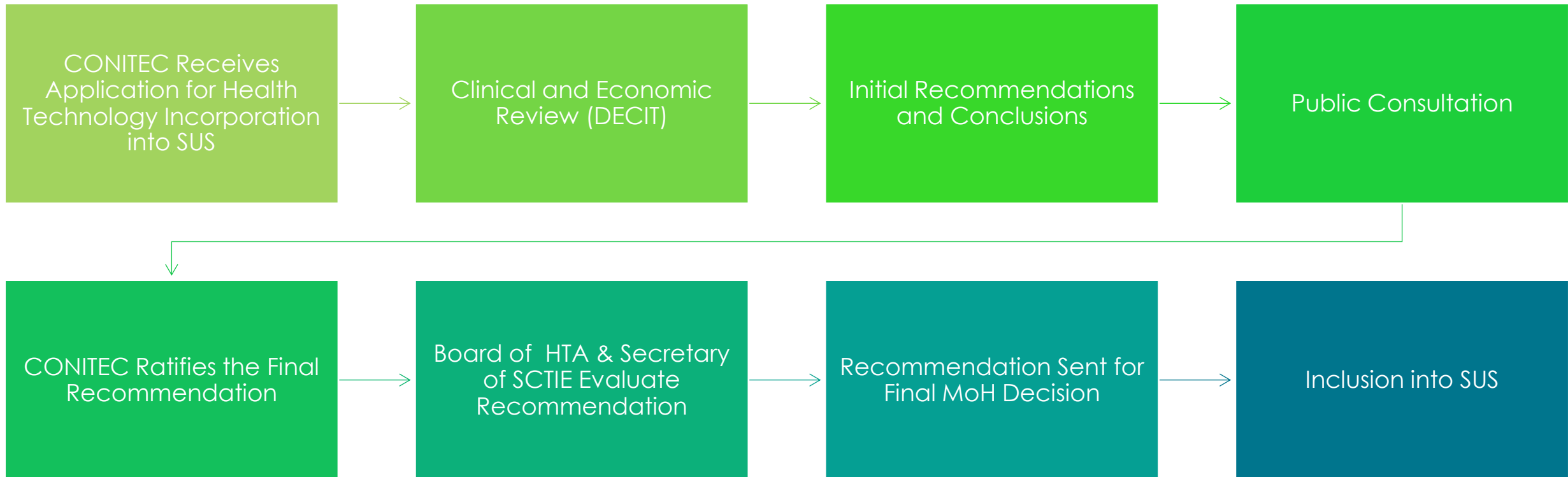
CONITEC weighs evidence levels as part of a systematic review prior to SUS listing.

- Products that are aligned with MoH priorities are likely to be prioritized by CONITEC.
 - More severe health problems that impact large portions of the Brazilian population are prioritized over less severe and impactful indications.
 - The selection and review process can be highly political and driven by support from key medical societies.
- The entire CONITEC process is supposed to take 180 days. It often takes longer in practice.
- CONITEC reviews are evaluated based on the following criteria:
 - Clinical evidence comparing the new technology to existing standard of care technologies in the SUS;
 - Randomized controlled trial (RCT) evidence is strongly preferred but not required;
 - Cost effectiveness study using local Brazilian data representative of the SUS population, with a cost effectiveness threshold of \$8,000 USD per QALY; and
 - Budget impact / total cost to the SUS.



An overview of the CONITEC process.

CONITEC Process



If CONITEC publishes a review of the product, the ANS will consider its review in publishing their list of covered procedures.

- ANS may independently decide whether to list a procedure on the ROL and provide coverage for a procedure or technology, regardless of whether a public CONITEC evaluation has occurred.
- However, once a CONITEC review has been established, ANS will consider their review in their assessment.
- The ANS has a set of prioritized criteria when considering whether to include a procedure on the ROL:
 - Whether CONITEC has already assessed and approved the technology;
 - Epidemiological data on the disease prevented or treated with use of technology;
 - Recent studies on economic and financial impact of the technology (cost effectiveness using national data);
 - Existing technologies that perform the same function;
 - Existence of skilled labor for use and handling of the health technology; and
 - Existence of inputs and raw materials, the network to provide the services installed, and effective results in clinical outcomes.

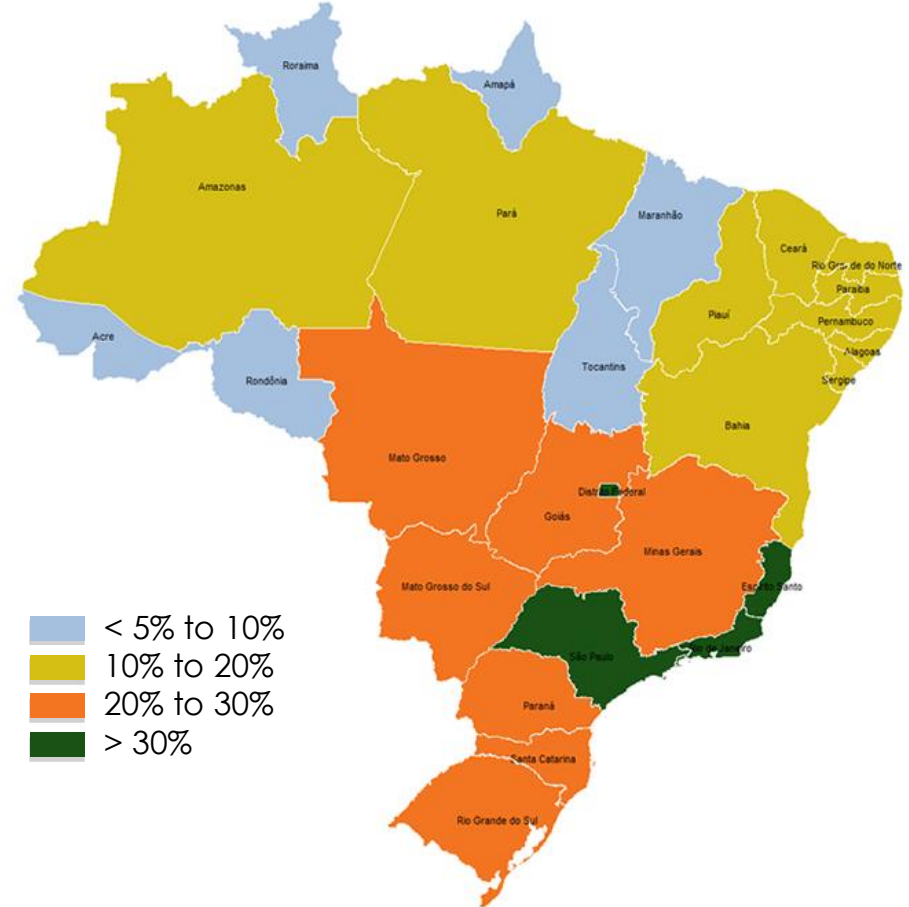


OVERVIEW OF PRIVATE SECTOR REIMBURSEMENT LANDSCAPE IN BRAZIL

Private coverage in Brazil is highly regionalized, with disparate coverage and access to healthcare across the nation.

- More than 23% of the Brazilian population has some form of private health insurance, with more than 51 million private health care beneficiaries as of June 2024.
- Distribution of health plans, by beneficiaries:
 - Business collective: 71.1.6%
 - Individual or family: 17.2%
 - Collective by adhesion: 11.6%
 - Uninformed: 0.1%

Proportion of Brazilian Beneficiaries with Private Health Insurance, by State (2024)



Private Health Insurance Coverage, by State (June 2024)

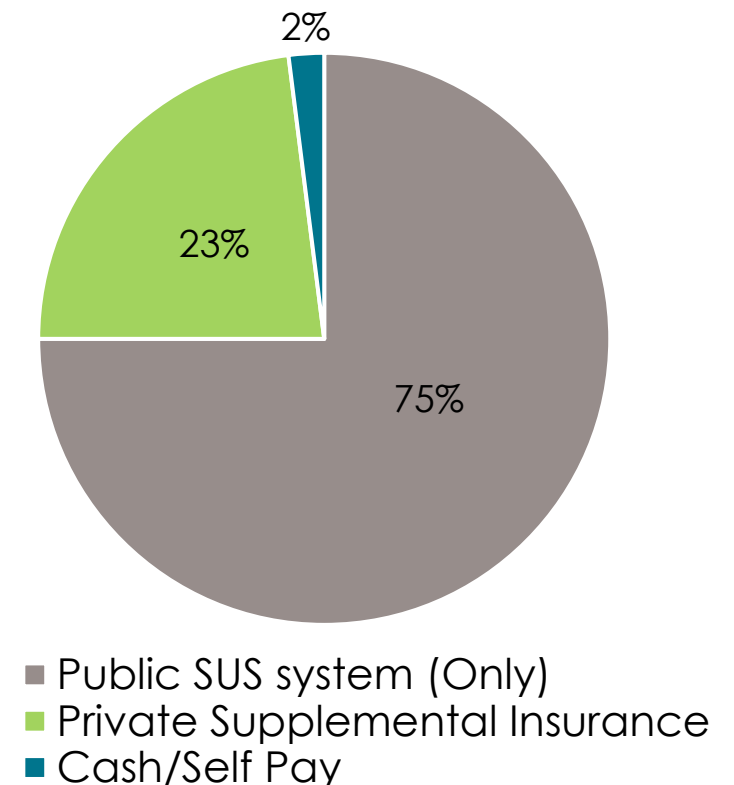
States with Highest Coverage Rate	
State	Coverage Rate
São Paulo	38.9%
Rio de Janeiro	31.6%
Espírito Santo	31.8%
Federal Distrito	30.6%
Minas Gerais	26.8%

States with Lowest Coverage Rate	
State	Coverage Rate
Roraima	4.7%
Acre	4.9%
Maranhão	7.3%
Tocantins	7.8%
Amapá	7.2%

While the national healthcare system covers most beneficiaries, Brazil also maintains a sizeable private sector.

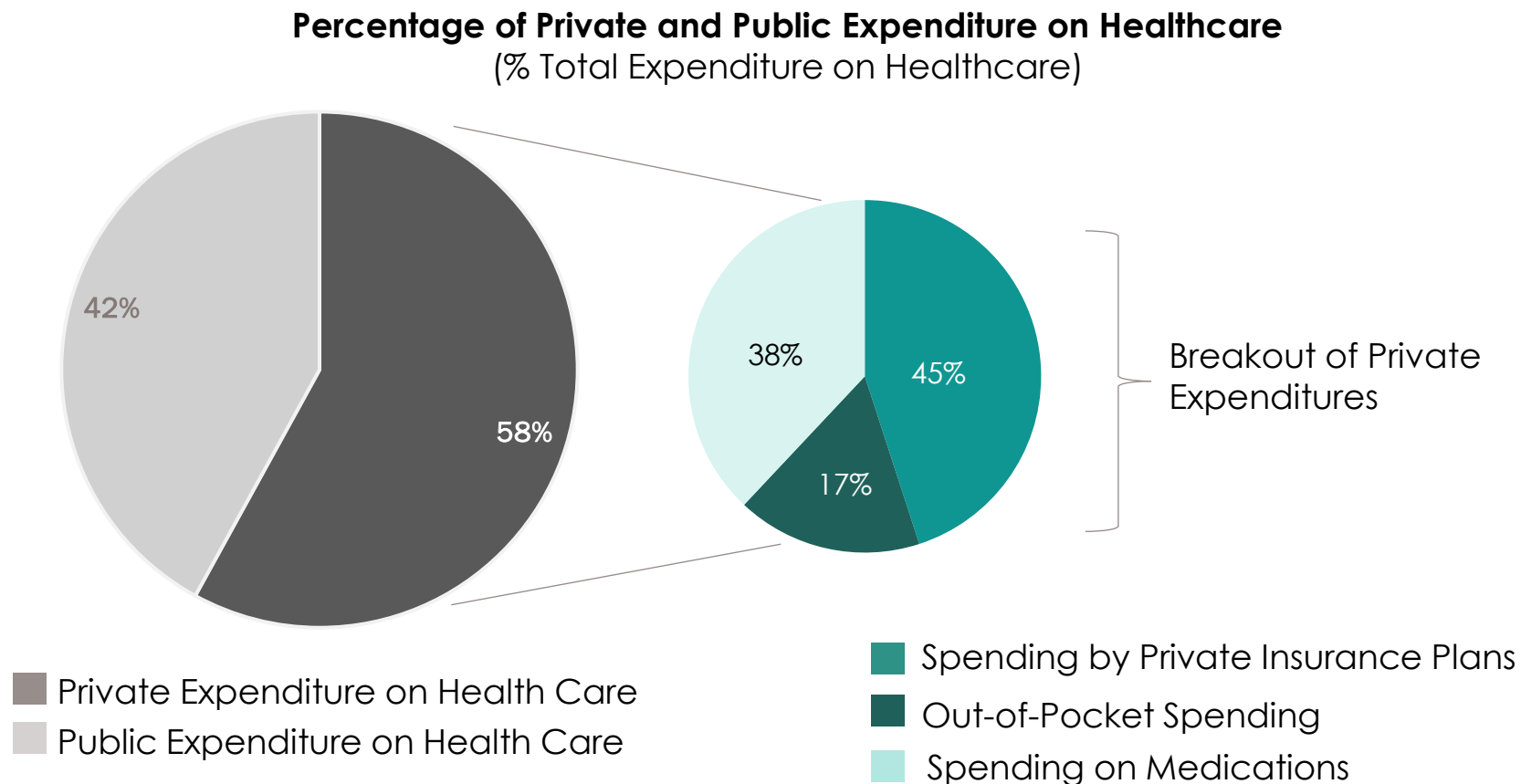
- In 1990, the government established a national healthcare system for the population called the Sistema Único de Saude (SUS).
- The SUS is coordinated at the federal level but administered through overlapping municipal, state, and federal government authorities.
- The SUS offers universal coverage for basic, secondary and tertiary care and rehabilitation to most Brazilians and operates under a fee schedule model.
- Every Brazilian citizen can use the system at no additional costs.

Sources of Brazilian Healthcare Coverage (Covered Beneficiaries), 2018



About half of private health expenditures are addressed by private health plans.

- Private spending accounts for nearly 58% of the total healthcare expenditures while 42% is from public expenditure.
- Spending by private insurance makes up nearly half (45%) of the total private expenditures, with the remaining 55% split between out-of-pocket and medication payments.

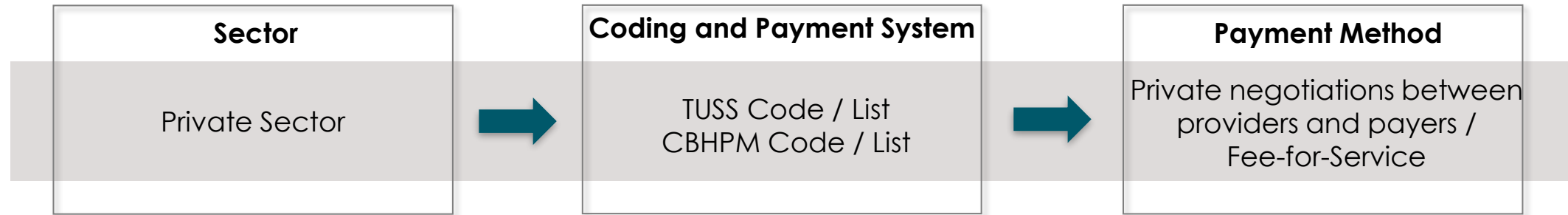


ANS is the agency that regulates the private healthcare system.



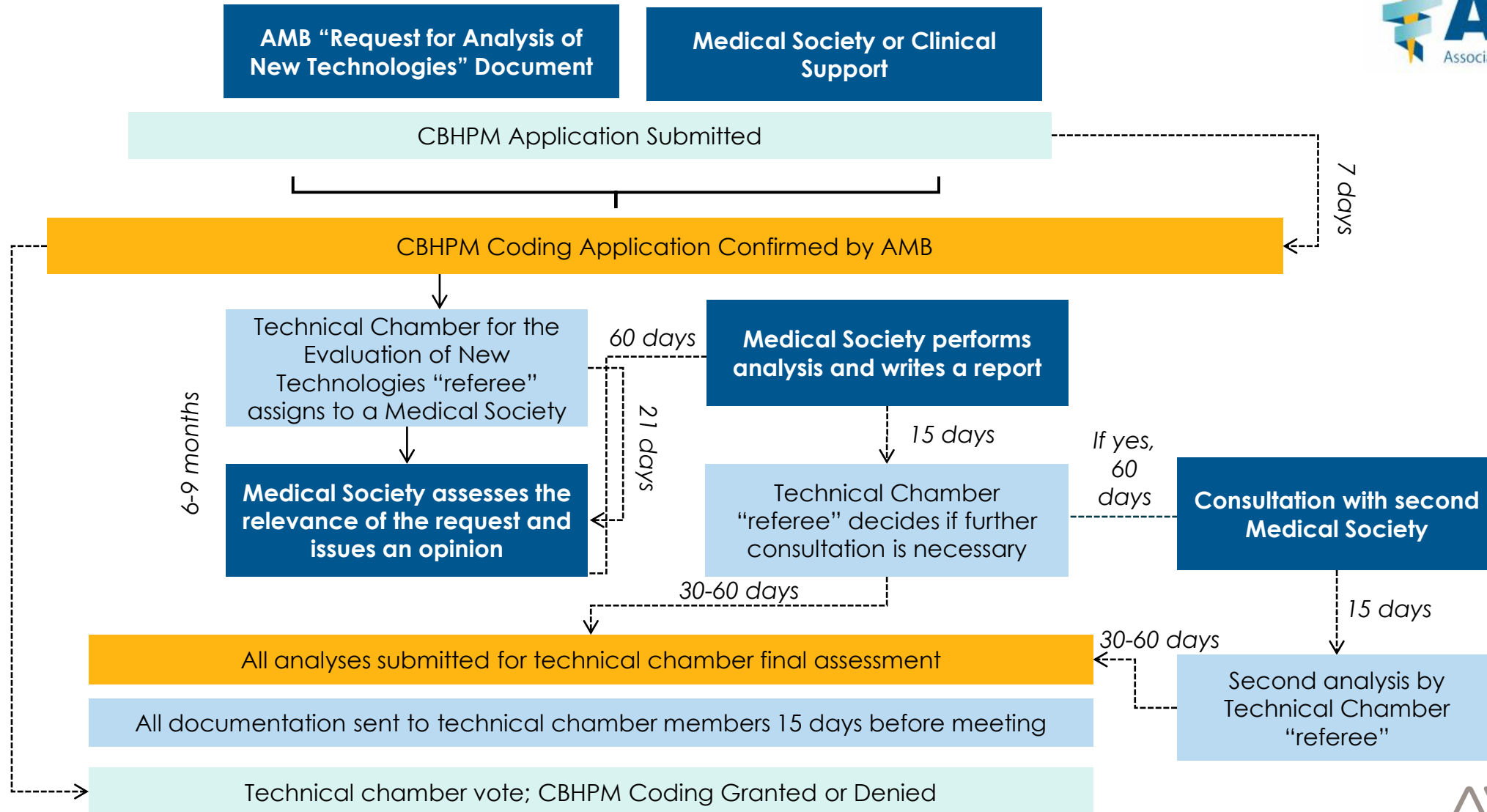
- In June of 1998, the Brazilian government launched Law 5696, which establishes the regulation of the private sector.
- As a result, the National Regulatory Agency for Private Health Insurance and Plans, *Agência nacional de saúde suplementar* (ANS) was created by the Brazilian Government under the Ministry of Health (HoM).
- The ANS operates nationwide to regulate, standardize, control and inspect the supplementary healthcare system (private system).
- Overall, objectives of the ANS are to establish rules in order to:
 - Ensure good quality of care;
 - Monitor prices; and
 - Provide coverage of services.
- In 2010, ANS launched the *Rol de Procedimentos e Eventos em Saúde* (ROL), a list of procedures that private insurance plans must cover.

In the private sector, CBHPM codes are issued by the Brazilian Medical Association (AMB) and the ROL list for mandatory coverage is maintained by ANS.



- The *Classificação Brasileira Hierarquizada de Procedimentos Médicos* (CBHPM) list of codes is issued by the Brazilian Medical Association (*Associação Médica Brasileira*, AMB) and is used to define the private sector procedure nomenclature.
 - The list provides recommended medical fees for each procedure to orient private payers. However, these are suggested values and payers are free to negotiate with providers in the free market system.
- The *Rol de Procedimentos e Eventos em Saúde* (ROL) is a list of codes mandatory for private insurance coverage maintained by the ANS.
 - The ROL is continuously updated. However, there is no pricing associated with ROL listings, and it is simply a list of procedures with mandatory coverage by private insurance. Certain procedure codes have guidelines for use, or additional indications / criteria for coverage.
 - Providers will have different agreements with private payers, typically based on volumes. The associated payment rates are the result of negotiations and are not publicly available.

The process for obtaining a novel CBHPM code can take between 6 and 9 months. A medical society must apply for CBHPM coding for a product on a company's behalf.



The application for new CBHPM coding consists of four distinct sections, along with a subsection dedicated to describe the procedure's guidelines for use.

- Before submission to the AMB, there are four distinct sections of the application form that must be filled out, along with a subsection designated for usage guidelines for the procedure:

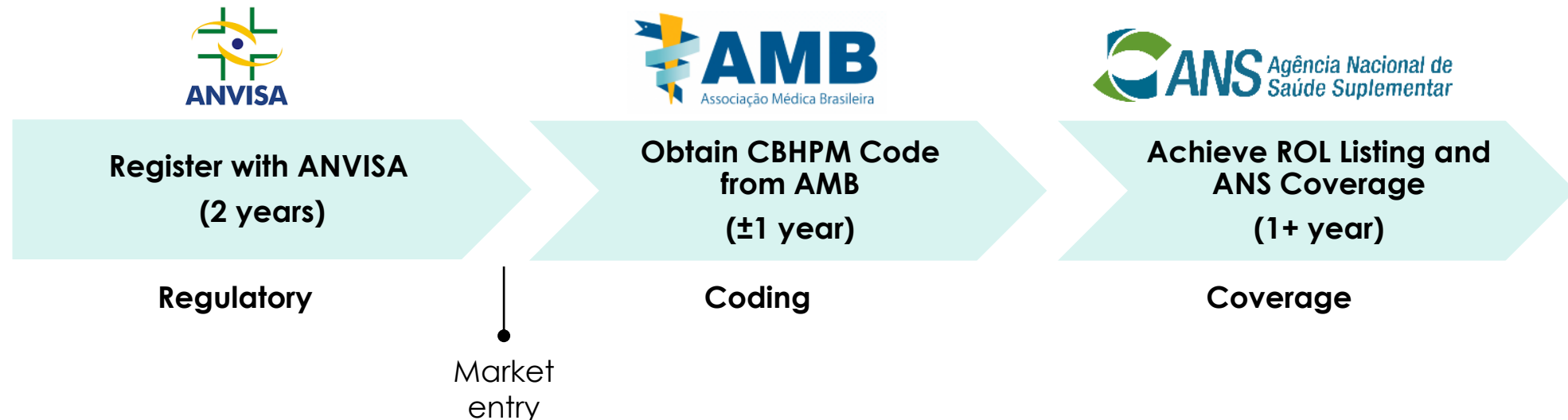
Application Form for Inclusion of Procedures in CBHPM			
Section 1	Section 2	Section 3	Section 4
<ul style="list-style-type: none"> • Name of the procedure • TUSS coding, if applicable 	<ul style="list-style-type: none"> • Description of procedure • Purpose of the procedure and importance for inclusion • Advantages over the existing procedures with the same purpose, if any • Information on the size, auxiliaries, anesthesia requirements, and operational cost 	<ul style="list-style-type: none"> • Description of professionals or services trained to carry out the procedure at the national level 	<ul style="list-style-type: none"> • Identify guidelines on the procedure, accuracy, and degree of evidence of therapeutic and / or diagnostic effectiveness • Confirm criteria that must be followed for your appointment and exclusionary procedures
DUT (Usage Guidelines)			

- The CBHPM coding application requires the submitting party to describe usage guidelines for the procedure.

Achieving a new listing in the ROL is process and it results in mandatory private insurance coverage.

- The process to achieve ROL listing requires compelling clinical and local economic and is subject to a vote of healthcare stakeholders in the Commission and a public hearing.
- After registering with the Brazilian regulatory agency, Agência Nacional de Vigilância Sanitária (ANVISA), a company will need to approach the AMB to apply for and obtain a private CBHPM procedure code. This process can take up to a year.
- Upon issuance of a novel CBHPM code, achieving ROL listing and mandatory coverage will take up to 3 years total.
- CBHPM codes are device-agnostic.
- **Once ROL coverage is issued, private payer rates still must be negotiated.**

Overview of Key Steps and Timelines for a Novel Device in the Private Sector



APPENDIX

Key Acronyms and Terminology

Acronym	Definition	Translation
AMB	<i>Associação Médica Brasileira</i>	Brazilian Medical Association
ANS	<i>Agencia Nacional de Saúde Suplementar</i>	National Supplementary Health Agency
ANVISA	<i>Agência Nacional de Vigilância Sanitária</i>	National Health Surveillance Agency
CBHPM	<i>Classificação Brasileira Hierarquizada de Procedimentos Médicos</i>	Hierarchical Brazilian Classification of Medical Procedures
CONTIEC	<i>Comissão Nacional de Incorporação de Tecnologias no SUS</i>	National Commission for the Incorporation of Technologies in SUS
SUS	<i>Sistema Único de Saúde</i>	Universal Health System
ROL	<i>Rol de Procedimentos e Eventos em Saúde</i>	List of Procedures and Events in Health

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