

Disease Control Priorities, Fourth Edition Volume 1, Disease Control Priorities in Practice

Evolution of Health Benefits Package in Colombia: Thirty Years of Successes and Failures

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Preface

Since the early 1990s, researchers involved in the Disease Control Priorities (DCP) effort have been evaluating options to decrease disease burden in low- and middle-income countries. This working paper was developed to support the Fourth Edition of this effort. It is posted to solicit comments and feedback, and ultimately will be revised and published as part of the DCP4 series.

DCP4 will be published by the World Bank. The overall DCP4 effort is being led by Series Lead Editor Ole F. Norheim, Director of the Bergen Centre for Ethics and Priority Setting in Health, University of Bergen. Core funding is provided by the Norwegian Agency for Development Cooperation and the Norwegian Research Council.

More information on the project is available at: <u>https://www.uib.no/en/bceps/156731/fourth-edition-disease-control-priorities-dcp-4</u>.

Evolution of Health Benefits Package in Colombia: Thirty Years of Successes and Failures

Abstract

Over the past three decades, health benefit packages in Colombia have undergone significant transformations. This article outlines the progression of priority setting in Colombia, which can be categorized into three distinct periods marked by substantial reforms, commencing with a major overhaul of the healthcare sector in 1993. Each of these periods presented both advantages and disadvantages, stemming from varying institutional arrangements, processes, and methodologies. The most notable shift occurred when Colombia transitioned from a positive list that included specific services to an approach that covers all services and technologies, except those explicitly listed in a restricted negative list. The evolution of Colombia's healthcare system offers valuable insights for other low- and middle-income countries seeking to establish evidence-based priority setting mechanisms.

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1.0 Introduction

Colombia is an upper-middle income country with an estimated population of 51.6 million, as of 2021(DANE, 2020; UNDP, 2022). Over the past three decades, the country has made substantial progress according to social and economic indicators. GDP per capita reached US\$6418.1 in 2021(World Bank, 2023)¹, life expectancy increased from 69 years in 1989 to 77 years in 2019 (DANE, 2021), multidimensional poverty decreased from 29.7% in 2010 to 16% in 2021(DANE, 2022a), and its score in the Human Development Index improved from 0.610 in 1990 to 0.752 in 2021 (UNDP, 2022).

Nevertheless, inequality remains high. The Gini coefficient for Colombia barely changed between 2009 and 2021 (54.3 and 52.3 respectively) and yawning gaps between urban and rural areas persist. In 2021, departments such as La Guajira and Chocó had poverty rates above 60%, while Cundinamarca and Caldas had rates of 22.8 % and 28.4%, respectively (DANE, 2022b). Current estimates also suggest that around 60% of the workforce is employed in the informal economy (DANE, 2022c).

In 1993, Colombia embarked on a major health sector reform. The country introduced mandatory universal social health insurance financed through a combination of payroll contributions and general taxation. The reform introduced competition into both insurance and the provision of care through a managed care model and created a contributory regime for those able to pay, as well as a fully subsidized scheme for the poor. Central to the health sector reform and the priority setting process was the introduction of a health benefits package (HBP) that included promotive, preventive, curative, rehabilitative, and palliate health services.

This case study will describe and review the evolution of HBPs in Colombia since the major health sector reform in 1993 to date. The case study will first describe the main achievements and challenges associated with the reform after nearly thirty years of implementation. It will then describe the institutional and governance arrangements, processes, methodologies, and implementation pathways that have been used to design and update HBPs, as well as successes, failures, advantages, and disadvantages associated with different approaches used over time. Finally, it will reflect on lessons learned, main challenges, and future perspectives.

2.0 Thirty Years of Reform

Since 1993, Colombia has made remarkable progress towards universal health coverage, financial risk protection and equitable access, regardless of ability to pay. Coverage increased from 23.5% of the population in 1993 to 99% in 2021 - see Figure 1, out-of-pocket expenditure (OOPE) fell from 52% in 1993 to around 15% in 2019, and all citizens within the system are entitled to an equal basket of services. OOPE is very low for the LatAm region and is at similar levels to other OECD countries (2019: Colombia: 14.86%, OECD 13.86%, LatAm 28.35%) (World Bank, 2023).

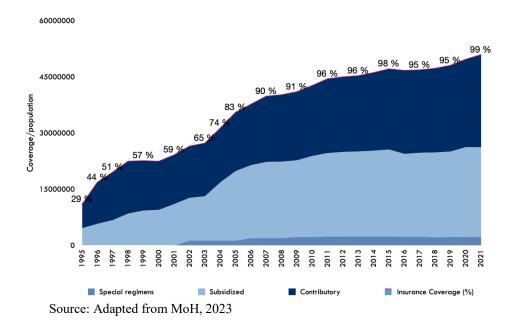


Figure 1. Affiliation regimens distribution to Universal Health Coverage

Despite these impressive achievements, the Colombian health system faces significant challenges including financial sustainability, regional and urban-rural inequities, and an imbalance between primary and specialized care. Insurers, which are mostly private although heavily regulated, often do not manage clinical and financial risk appropriately, and poor employment contracts, inefficient payments systems, and lack of infrastructure in some areas hamper quality of care, especially at primary health care level. Colombia spent around US\$16.6 billion (ADRES, 2021) or 8% of GDP on health in 2021. This is much more than what the country spent a decade before or before the health sector reform in 1993 - see Figure 18.2, but not enough to meet current demands. The current annual budgetary deficit is estimated to be US\$1.1 billion and is mainly associated with a very generous interpretation of the right to health that's enshrined in statutory laws since 2015. According to Colombian law, every health technology and health service must be covered by the system, except in very specific circumstances - see section 3.3.

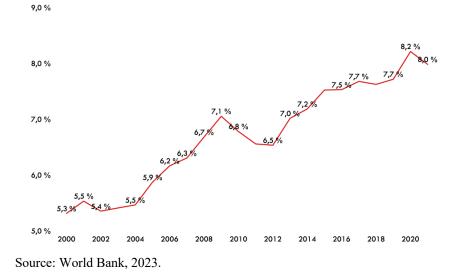


Figure 2. Health expenditure (% GDP) 2000 - 2021

3.0 Health Benefits Package Evolution Since the Reform of 1993

The way the Colombian health care system has made decisions on coverage - what's covered, by whom and at what cost - has evolved over the past 30 years. These changes have been the result of key decisions made by the three branches of the Colombian government - the Congress, the Executive branch, and the Constitutional Court (see Figure 3). Interestingly, and contrary to the experience of other middle-income countries, the Constitutional Court has played a major role in determining the content and the processes by which the Executive branch had to unify the HBPs. For example, in 2008, the Court ruled that the Executive branch had to unify the subsidized and the contributory regimes as stated in the health sector reform law and established a deadline of a year to accomplish this. The Court also mandated the Executive branch to regularly update the HBPs in a participatory, transparent, and evidence-based manner (Colombian Constitucional Court, 2008).

The history of HBPs in Colombia in the past 30 years can be divided into three main periods, based on the shape of the HBP, governance arrangements (i.e., who made what decisions), processes followed (i.e., criteria used for inclusion or exclusion, stakeholder participation, transparency, etc.), and methodologies considered to inform coverage decisions and implementing mechanisms. The first period starts from 1993, when the major health sector reform was passed, to 2007/2008 when the Health Regulation Commission (CRES) was established, and the Constitutional Court issued its major ruling on the right to health (ruling T-760). The second period begins from 2007/2008 to 2011 when the Ministry of Health took several responsibilities from CRES and established a new Advisory Commission. The final period, which begins from 2011 onwards, includes a key milestone - when Congress passed a Statutory Law establishing the right to health as a fundamental human right. This chapter will describe the key features of these three periods, major outcomes, and pros and cons of each institutional arrangement.

Colombian's HBP evolution provides a several lessons for other low- and middle-income countries interested in institutionalizing evidence-based priority setting processes and pursuing universal health coverage. In thirty years, the country went from having two explicit HBPs, with benefits linked to regimen or in other words ability to contribute, to covering in theory everything to everyone, excluding just a narrow negative list of services and health technologies.



Figure 3. Colombia's HBP regulatory milestones

3.1 Period 1: Two explicit HBPs and a multi-stakeholder decision body (1993-2007)

This first period begins in 1993 when the health sector reform was approved by the Colombian Congress and implementation started. A cornerstone of the reform was to guarantee a package of health services for both the contributory and the subsidized regimens.

Governance and institutional arrangements: a collegiate body, the National Social Security Council in Health (CNSSS), was responsible for stirring the system in administrative and financial matters. The CNSSS was very inclusive and was made up of representatives from all interest groups (see Table 1).

Permanent members (voice and vote)	Advisors (no vote)
 Chair: Minister of Health The Minister of Labor and Social Security, or his Vice Minister The Minister of Finance and Public Credit, or his Technical Vice Minister Two representatives from the state and municipal governments Two representatives from the employers, one of which will represent small and medium-sized companies Two representatives from the workers, one of which will represent the pensioners One representative from the insurers One representative from the providers One representative from the health professionals One representative from the associations of users of health services in the rural sector 	 One representative of the National Academy of Medicine One representative of the Colombian Medical Federation One representative of the Colombian Association of Medical Schools One representative of the Colombian Hospital Association One representative of the Faculties of Public Health

Table 1. CNSSS members (Law 100 of 1993)

The CNSSS made decisions on the content of the HBPs, as well as several other matters from criteria to identify beneficiaries to value and destination of contributions to the system A few years after the CNSSS was established, the CNSSS established an ad hoc technical secretariat or the Technical Committee on Medicines, which later became the Medicines and Technology Evaluation Committee (CMET). These committees were coordinated by the Ministry of Health, were made up of *ad honorem* members and had the mandate to evaluate any health technology considered for inclusion. These efforts were not successful as committees were not properly funded and did not have all the expertise needed.

Processes followed: The initial HBPs were not designed in a systematic, transparent, or participatory manner. The HBP for the contributing members of the system was based on the tariff manual used by the Social Security Institute (SSI), an insurer covering private workers before the reform. This happened after the CNSSS rejected a proposal developed by a team of world-class experts based on cost-effectiveness criteria. The proposal was rejected for containing fewer benefits than those had had been previously provided by the SSI, and for doubts on the robustness of the data utilized.

During this period, the CNSSS updated the HPBs marginally by including new health technologies 12 times. Moreover, the CNSSS established a taxonomy for medical procedures,

the Single Classification of Health Procedures, or CUPS, which helped them consider and/or include these health technologies into the HPBs. Decisions were made by single majority voting. When necessary, the Minister of Health casted a tie-breaking vote.

Shape of the HBP: the CNSSS established two separate explicit lists of inclusions or HBPs: a larger package known as the Mandatory Health Plan (Plan Obligatorio de Salud; POS), for the contributing members of the system; and a smaller publicly subsidized HBP, known as POS-S (Plan Obligatorio de Salud–Subsidiado), which covered around 50% of the interventions included in the POS, for the lower-income population. When establishing these two regimens and HBPs, the intention was to progressively expand the breadth of POS-S, such that by 2000 it would be equal to the POS health package. Regrettably, this lofty goal was not met due to reduced growth in contributing members and initial projections of public revenue. Beneficiaries also used legal claims that forced their insurers to pay for health services not included in the POS or POS-S packages.

HBP implementation: since the health sector reform passed, the HPBs have been translated into actual health care delivery through the premium or UPC (Unidad de Pago por Capitación). This UPC is paid every year to insurers to provide the services included in HBPs. At first, the UPC for both regimens was calculated on the basis of available funds, guided by the annual increments in the minimum wages. The CNSSS initially calculated the UPC for the SR as a fixed percentage (50%) of the UPC for the CR, mainly due to a lack of reliable information to calculate a separate premium for this regimen. Since 2004, the UPC for the CR was calculated actuarially, considering the frequency of use and the costs reported by the insurers. The CNSSS introduced UPC adjustments by level of care, age, sex, and geography (see box 1). The CNSSS also determined the level of copayments for both regimens.

Box 1. Initial adjustments to the premium (UPC) for the CR

- <u>Age</u>: those under one or over 75 were associated with greater health risks, higher demand for health services and had higher insurance premiums
- <u>Sex:</u> adjusted for conditions related to men (e.g., prostatic cancer) or women (e.g., pregnancy)
- <u>Geography</u>: sought to reflect differences between rural vs urban settings, remote and disperse areas and areas affected by the internal conflict. For example, the value of the premium was around 20 percent higher for dispersed geographical areas for both the CR and SR.

Source: Agreement 254 of 2023 - CNSSS

In this first period, Colombia made notable improvements in expanding coverage, particularly among the poorest segments of the population. Yet during these first two decades of implementation, increasing investment in new and expensive interventions threatened both the sustainability and the equitable distribution of health services. Less than 1% of payments

for new drugs covered people in the poorest quintile of society while 70% of these payments covered drugs for the top two richest quintiles (Gaviria, 2014).

Major pros and cons: In theory, the CNSSS provided an inclusive platform for discussion and a participatory decision-making process. All relevant stakeholders had a seat at the table and were invited to air their concerns and suggestions. In practice, however, effective participation was not easy for certain groups, especially workers and users who were underrepresented, as government and employers had the biggest number of seats and votes (Martínez, 2015). What's more, the CNSSS had too many functions, there were tensions between the CNSSS and the Ministry of Health over responsibilities, and limits and regulation was not appropriately developed and enforced, in part because regulated parties were also acting as regulators.

Additionally, the processes followed by the CNSSS had serious shortcomings in relation to using evidence, being transparent, and following standardized methods with clear criteria for decision making. Even though technical committees were created since 1997, these were not set up for success and failed to provide the rigor needed.

3.2 Period 2: unified HBP due to a ruling by the Constitutional Court, gradual dilution of HPBs and creation of a decision-making body attached to the Ministry of Social Protection (2007-2011)

The CNSSS was eliminated as a decision-making body in 2007 and its functions were transferred to the Health Regulation Commission (CRES). CRES was created as part of the first health reform passed by Congress to modify the system since 1993 (Law 1122 of 2007). The new law aimed to improve the system's finances, improve the flow of resources, and clarify roles and responsibilities of the Ministry of Social Protection², especially in relation to regulation and enforcement, among other key objectives.

Governance and institutional arrangements: The CRES was created as a technical institution with regulatory functions, attached to the Ministry of Social Protection. It was in charge of defining the HBP, establishing the value of the UPC for each regime and determining copayments. The CRES was made up of five full-time experts (the Commissioners) and two Ministers, the Minister of Finance and Public Credit and the Minister of Social Protection. It had its own budget and its own staff who supported the Commissioners (Law 1122 of 2007).

Processes followed: As CRES was being established and before it was fully functional, the Constitutional Court issued a seminal ruling that clarified the right to health and provided instructions to the Executive branch. The Court mandated the CRES to unify the HBPs (POS and POS-S), initially for children and later for adults, and develop a participatory, transparent, and evidence-based process to comprehensively update the HPB immediately and on an annual basis. This action by the Court arose in response a wave of litigation to enforce the right to health, with tens of thousands of *tutelas*³ or writs filed by citizens before judges to protect their fundamental constitutional rights. These writs became a systemic problem associated with the lack of clarity, regulation, and transparency in the Colombian

health system at the time. Citizens filed writs to get insurers to pay for health technologies not included in the HBPs, which was particularly out of date for the SR. Writs reached record numbers in 2008 - nearly 35 writs for every 10,000 people (see Figure 4) (Restrepo et al., 2018).

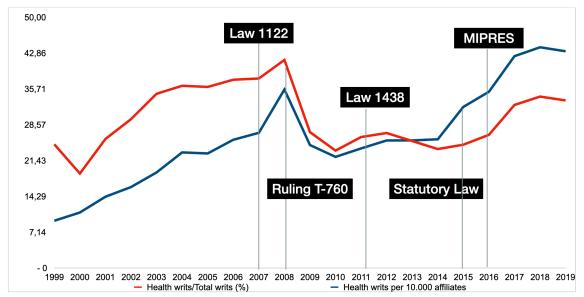


Figure 4. Health writs in Colombia (1999 – 2019)

Source: Adapted from Restrepo et al, 2018 and unpublished information from Jairo Humberto Restrepo Zea.

In response to the ruling, the CRES conducted a comprehensive update of the HBPs in 2009, and as part of it, designed new mechanisms for stakeholder participation and commissioned health technology assessments. Stakeholders including insurers, providers and users were no longer part of the decision-making process, as it was the case with the CNSSS, but were consulted on key stages of the process. The CRES also improved transparency, especially around the benefits covered by the system and launched an app, POS Pópuli, that allowed anyone to search for and identify what health services were covered. The app won many awards, including a prize for best web and mobile-based government application.

Shape of the HBP: The CRES began the unification of HBPs in response to the ruling. Initially, it unified the packages for children younger than 12 years but progressively unified the packages for all ages. Also, the CRES clarified the content of the HBPs and determined the general rules for the system to deal with those technologies not included in the HBPs. It determined that those technologies could be reimbursed ex-post by a separate fund if approved by the technical-scientific committees within insurers.

HBP implementation: unifying both HBPs led to important adjustments to the SR UPC. No changes were made to the UPC calculation method, but its values were significantly adjusted, to consider the additional services included in the HBPs. Ex-post adjustments were also designed to balance asymmetries associated with the number of patients insured with some high-cost conditions such as renal failure.

Major pros/cons: The creation of the CRES, as an autonomous institution, with technical capacity and mechanisms for more expeditious decision-making, brought important advances

to the system. CRES incorporated evidence from health technology assessments into the decision-making process and provided new vehicles for stakeholder participation. Compared to the CNSSS, the CRES had more autonomy and the degree of separation from regulated parties allowed it to be a better regulator. However, the relationship with the Ministries of Social Protection and Finance was not ideal and CRES was to some extent subject to their power and influence. Some authors associate this with "the low profile of Commissioners" and the fact that the decisions of the CRES were tied to the financial balance of the system, which in turn made it subject to the decisions of the Ministry of Finance.

3.3 Period 3: Elimination of explicit HBPs and a new institutional framework based on the right to health (2011-2023)

In 2011, a new Health Technology Assessment Agency, the Instituto de Evaluación Tecnológica en Salud - IETS, was created as part of the second reform to the system since 1993 (Law 1438 of 2011). This reform came as a response to the wave of litigation to enforce the right to health, the institutional and technical limitations of CRES and the international move to establish HTA agencies. IETS was established as a non-profit organization, governed by a Board of public and private entities including the Ministry of Health, the Administrative Department of Science, Technology and Innovation, the National Institute of Health, the National Institute of Drug and Food Surveillance and the Colombian Association of Medical Schools. IETS was created to generate evidence to support decision-making within the health system, especially in relation to the HBP and Standard Treatment Guidelines.

In addition to the creation of the HTA agency, CRES was eliminated, and a new Directorate was established within the Ministry of Health. Decision making was also transferred to the Minister of Health and an Advisory Commission to the Ministry on issues related to benefits, costs, and tariffs was created (Decree 2562 of 2012).

In 2015, Congress passed the third reform to the health system since 1993 when it established the right to health as an autonomous fundamental human right. The law known as the Statutory Health Law 1751, linked this right to public health interventions and health services and established that financial or fiscal sustainability could not become a barrier to fully exercise the right to health. It mandated the Executive to move from marginally expanding the HBP with inclusions to assuming that all health services and interventions were covered except in specific circumstances (Law 1751 of 2015).

Governance and institutional arrangements: since 2012, decisions related to the HBP are made by the Minister of Health and Social Protection, following the advice of an Advisory Commission. This Commission is made up of the Minister of Health and Social Protection, the Minister of Finance and Public Credit, the Director of the National Planning Department, a delegate from the Presidency, and the Director General of IETS. Decisions within the Commission are made through consensus and to date, the Minister has always followed the Commission's advice (Decree 2562 of 2012).

The new Directorate created in 2012 within the MoHSP (DRBCTAS) functions as the technical and administrative secretariat of the Commission. MoHSP/DRBCTAS works in

coordination with IETS to build the evidence necessary for the Commission to make decisions. Representatives from the other members also provide technical contributions before formal submission and decision-making take place. The Commission may invite other stakeholders to its sessions where they can participate without voting rights (Decree 2562 of 2012).

Processes followed: since the elimination of CRES in 2012 and until the Statutory Health Law was implemented in 2017, the process to update the HBP was aimed at including new health technologies in the package and was done at least every two years as mandated by law. Stakeholders including clinicians, users and the pharmaceutical industry would nominate health technologies not included in the HPB and therefore not included in the UPC calculation. MoHSP/DRBCTAS would implement a topic selection process to determine the technologies that would be assessed, IETS would conduct the health technology assessments (HTA), focusing on comparative effectiveness and budget impact, and the Commission (CABCT) would appraise the evidence and issue a recommendation to the Minister on the basis of the appraisal (see Figure 5). Explicit criteria including weights, built after a long participatory process, would be used as part of the topic selection process and the appraisal. HTA would follow methodological guides developed by IETS, and stakeholder participation would be primarily conducted during the technical assessment and before the MoHSP/DRBCTAS would submit the evidence to the Commission.

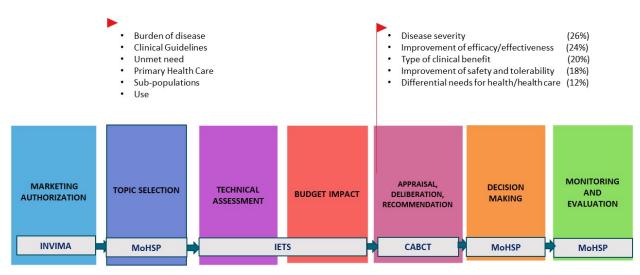


Figure 5. Health Technologies Assessment Process and Key Actors before Statutory Health Law

Source: IDB, Colombia priority setting of public expenditure project, 2011 (modified)

However, once the Statutory Health Law was implemented in 2017, the process changed completely, and exclusions rather than inclusions became the focus. An abridged form of the old process was still used to make decisions on how the system would finance health technologies that were not explicitly included in the HBP and financed through the UPC, but a negative list following an exclusion process was the goal.

MoHSP/DRBCTAS established the exclusion process following the clear mandate included in the Statutory Health Law. The law required a scientific and technical process that would also be participatory, public, and transparent. Potentially affected groups would also have to be consulted before decisions on exclusions were made. Following on these requirements, MoHSP/DRBCTAS established a four-step process including nomination, evaluation, consultation, and adoption and publication (see Box 2). The evaluation is now focused on establishing the rationale for exclusion, using six potential reasons included in the Statutory Health Law, which can be summarized as follows:

The health technology:

- i) is indicated for cosmetic purposes;
- ii) does not have scientific evidence on safety and efficacy;
- iii) does not have scientific evidence on clinical effectiveness;
- iv) has not been authorized by the regulatory agency;
- v) is still in under clinical development;
- vi) is not available in the country.

Box 2. Exclusions process phases

- 1. <u>Nomination and prioritization</u>: stakeholders including the MoHSP and medical associations nominate technologies for exclusion. MoHSP/DRBCTAS prioritizes nominations using criteria such as public health interest, population affected, and budgetary impact.
- 2. <u>Analysis</u>: IETS with participation of independent experts from health care associations, the National Academy of Medicine, and association of schools with different health care programs, among others, assesses and appraises the information collected and makes recommendations on how convenient it is to exclude the health technology. Decisions are made by consensus.
- 3. <u>Consultation</u>: potentially affected patients and the public are consulted through virtual surveys, events, and the My Vox Pópuli app.
- 4. <u>Adoption and publication</u>: MoHSP adopts, publishes, and implements the recommendation made during the analysis and verified during the consultation.

Source: Resolution 330 of 2017

Shape of the HBP: the HBP evolved from being a positive list with inclusions (Resolution 5261 of 1994) to cover in theory everything to everyone, excluding a negative list of 18 procedures and 55 medicines (Resolution 2273 of 2021). Since the times of CRES to 2020, technologies included in the HBP were financed ex-ante through the UPC, while technologies excluded were reimbursed ex-post by a separate fund if certain approvals were met. However, since March of 2020 any technology that's not explicitly included in the UPC calculation is also covered ex-ante by a prospective budget cap mechanism (Law 1955 of 2019). Budgets caps are calculated by insurers, based on the historical spending on, and the number of patients receiving the health technology. The number of technologies included in the UPC have increased steadily and in 2022, 97% of procedures and almost 94% of medicines approved and available in Colombia were financed through the UPC (see Table 2) (MoH, 2022a).

Financing mechanism	Number of Procedures covered	%	Number of Medicines covered	%
UPC	9.197	96,90%	61.056	93,70%
Budget caps	275	2,90%	4.079	6,30%
Exclusions	18	0,19%	55	0,10%
Other	4	0,04%	10	0,0%
Total	9.494	100%	65.200	100%

Table 2. Medicines and procedures included/excluded by financing mechanism

Source: Ministry of Health, 2022a; Resolution 2273 of 2021; Resolution 2292 of 2021.

HBP implementation: The UPC continues to be calculated actuarially, considering the frequency and severity of the health services covered in the HBP and historically provided, adjusted by level of care, age, sex, and geographical area. The UPC is calculated using the loss ratio method, which seeks to find the necessary increase on current premiums to ensure that the fundamental insurance equation is balanced, in addition to IBNR (incurred but not reported) and IBNER (incurred but not enough reserve) adjustments. These analyses are conducted by the MoHSP/DRBCTAS based on the information reported by insurers. Over time, this Directorate within the MoHSP has become incredibly good at collecting relevant data and calculating and adjusting the insurance premium.

Expectedly, and in alignment with the gradual expansion of health services included in HPBs, the UPC has grown substantially in the past thirty years. In 2022, the average UPC was COP 1.109.221,20 (US\$246) for the CR and COP 964.807,20 (US\$214) for the SR⁴ while in 1995 and 1997 when the two regimes were first established⁵ UPCs were COP141,600 or US\$31.46 for the CR and COP 108.464 or US\$24.10 for the SR.

Age and sex adjusters are now defined in 14 groups as opposed to 7 as was the case in the past. Geographic adjusters are defined in 4 categories, based on accessibility to health care services and supply conditions. Insurers for Indigenous people get an extra 4.81%, which covers traditional medicines and procedures. The high-cost diseases ex-post adjusters have evolved. Adjustments are now made for chronic kidney disease, HIV, Hemophilia and 11 types of cancers, based on prevalence and health outcomes (MoH, 2022b).

Major pros and cons: Colombia established a more stable, coherent, and mature priority setting system, especially in the first part of this period. This positive development included the creation of IETS, the HTA agency; MoHSP/DRBCTAS, the Directorate within the MoHSP responsible for carrying out clear, specific stages of the process; and CABCT, the Commission responsible for making the final recommendations to the Minister of Health. Over time, these institutions have also become stronger. For example, the IETS has conducted around 200 budgetary impact analyses and 50 economic evaluations in the past ten years since it was created (IETS, 2022).

Separation in key roles and responsibilities between those conducting the evaluation, those appraising the evidence, and those making the decisions was fully established. Methods to evaluate potential inclusions were also more robust by the end of the first part of this period. Finally, transparency and stakeholder participation continued to improve to some degree in some stages, but decision-making was solely done by the Executive branch.

Despite this progress, the system did not fully incorporate the concept of opportunity cost, and economic evaluations including cost-effectiveness analysis were rarely conducted and/or used to make coverage decisions, inform price negotiations, or incentivize quality improvements. IETS was also unable to receive funds directly from the national budget and instead depended on funds linked to projects financed by MoHSP and the Ministry of Finance. The absence of direct funding from the national budget undermined the institution and had adverse repercussions on its interactions with other stakeholders in the priority-setting process, including the Ministry of Health. Additionally, this situation impeded the growth of organizational capabilities and the retention of skilled staff.

In the second part of this period, the implementation of the Statutory Law substantially changed the concept and goal of the priority setting system. On the positive side, it provided clarity to all stakeholders on the mandate to protect and deliver on the right to health (i.e., users now knew insurers could not deny health services because these were not listed in the HBP); protected medical autonomy (i.e., health care professionals could prescribe the best care for their patients without additional bureaucratic and administrative barriers); reduced transaction cost (i.e. patients would not need to go to the courts or through lengthy approvals to access care) and empowered insurers to better manage clinical and financial risk (i.e., insurers got all the funding ex-ante and no longer had to rely on ex-post reimbursement).

However, questions on financial feasibility remain, as neither health care expenditure nor the premium paid to insurers increased to cover a scenario where, in theory, all services covered would translate into services that patients actually receive. Furthermore, as the process for exclusions is limited by the criteria mandated by law which is typically slower and more cumbersome than the process for introducing new technologies, insurers are now more exposed to increased, early demand for high-cost technologies and interventions. This

challenge persists even though the Colombian regulatory agency, INVIMA, experiences delays in reviewing and granting marketing authorization for new technologies. In response to this new reality, some insurers might have imposed access barriers and/or resorted to implicit rationing or low quality of care. Implicit rationing coupled with lack of essential services in some regions and the risk of favoring new, high-cost technologies in urban areas might lead to increased inequity.

Finally, overall value for money might have decreased as funds are spent on services that do not provide the biggest benefit for society (i.e., there is not any signaling on essential, most cost-effective interventions and cost-effectiveness can't be used as one of the criteria for the negative list of exclusions).

4.0 Lessons Learnt, Main Challenges, and Future Perspectives

Explicit priority setting via a HBP was one of the key policy instruments used by the Colombian health system to improve coverage and work towards universal health coverage since 1993. The Colombian government successfully used HBPs to determine what services would be available to whom, calculate the premium paid to insurers and signal priority services to clinicians and patients. Over time, institutional arrangements became clearer and more stable and processes and methodologies more robust. However, as insurers were not always able to adequately deliver the services included in the HBPs, the system was unable to ensure timely delivery of an equal basket of services regardless of type of affiliation. In addition, as Colombians grew richer and embraced the right to health, the knowledge of and exposure to new health technologies increased and a very strong human rights framework was established in the country, explicit priority setting in the form of a HBP was no longer a viable option. The Constitutional Court and Congress mandated the Executive branch to move away from explicit priority setting and HBPs, to delivering on the idea that every health technology and health service is covered by the system, except in very limited circumstances.

This move has made explicit a clear tension between two views: one that embraces health as a fundamental human right and when taken to the extreme argues that health care must be guaranteed regardless of funds available and financial considerations, and another which argues that funding available must determine what's covered, and allocative efficiency or value for money should be maximized for any given budget envelope.

As Colombia has already leaned towards the former, and key challenges such as financial sustainability, weak primary health care, and access to quality care in remote, poorer regions remain, alternative policy options are needed to maximize health benefits, improve health outcomes within current health expenditure, and guarantee that the system delivers on the promise of universal health care and health as a fundamental human right within existing financial means.

These alternative policy options are imperfect. No country can possibly offer access to all available health technologies and services. Agreeing on the need to have limits and the process to decide on coverage - what's covered, by whom and at what cost is essential for the

Colombian society. Unfortunately, that means explicit priority setting at the central level and that's what Colombia decided to leave behind a few years ago. Amid this backdrop, a few potential policy options include:

<u>Strengthening priority setting at lower levels within the system</u>: in the absence of a centralized priority setting process including health technology assessments, insurers and health care providers could conduct their own evaluations and make their own decisions regarding what products and services to procure, prescribe and pay for, and at what price. This move, although suboptimal and less efficient, could increase health care quality and make these stakeholders better stewards of public funds. Insurance, hospital, and medical associations and networks could play a vital role in running these processes on behalf/with their members. This would reduce duplication and increase reach and impact (Giedion et al., 2028).

<u>Implementing alternative processes to deal with health technologies with high-cost and low-value</u>: despite the fact that economic evaluation cannot be conducted and used by the MoHSP to exclude products on cost-effectiveness grounds, these methodologies should be applied for other purposes, including price regulations and negotiations, as well as the development of standard treatment guidelines and protocols. The MoHSP would benefit from deploying horizon scanning and early negotiation techniques, such as managed entry agreements, to avoid high-cost products from entering the Colombian market without adequate stewardship. The MoHSP could also apply co-payments to services and technologies with low health value to signal the market and stir demand.

<u>Deploying alternative options for funding insurers</u>: adequate incentives to stir insurers to manage clinical and financial risk better and deliver high value quality care should be put in place. These could include changing the way the premium (UPC) is calculated by incorporating outcome-based indicators and conditions. Also, it involves better ex-post adjustments to reduce risk asymmetries and address risk concentration in the populations covered by certain insurers.

<u>Increasing efficiency in the system</u>: productive inefficiencies or inefficiencies in the form of excess costs in producing a given output should be tackled. Demand aggregation and centralized procurement of expensive technologies, increased use of generic and biosimilar medicines, tackling waste, corruption and fraud, etc, would help the system achieve more health for the money.

<u>Improving monitoring and evaluation</u>: systematically and routinely measuring the services provided, and the quality of such services, would help the MoHSP measure effective coverage, identify, and address implicit rationing or signal inadequate or inefficient consumption patterns. The MoHSP already collects information on services provided to calculate the premium (UPC) but capturing additional attributes and improving data quality and timeliness is needed.

<u>Strengthening stakeholder participation</u>: despite improvements in engaging stakeholders in certain processes such as determining exclusions, it is vital to increase their effective engagement in fundamental discussions such as the financial sustainability of the system, the

importance of maximizing health benefit, and the need to incorporate new technologies at adequate prices, etc.

In early 2023, the Colombian government introduced a significant healthcare reform bill to the Colombian Congress, with primary objectives centered on expanding healthcare access in rural areas, prioritizing preventive and primary care, and enhancing fund management. While there is widespread agreement on these objectives, considerable controversy surrounds the proposed strategies for their achievement. The reform suggests significant alterations to various aspects of the Colombian healthcare system, including the transition to a National Health System with a single public insurer, increased support for public healthcare provision through funding for public hospitals and the establishment of more primary health care clinics throughout the country. In terms of priority setting, the reform proposes to revive the CNSSS, a participatory body established after the 1993 reform, as described at the outset of this chapter, and integrate the IETS into the government. There are no other changes proposed concerning the processes and methodologies for defining healthcare benefits. The perspective that views health as a fundamental human right is embraced despite budgetary constraints.

The fate of the health reform's approval by Congress remains uncertain, as the government does not possess the majority vote. Consequently, it is probable that the draft reform will need to undergo amendments to secure successful approval.

5.0 Conclusion

Over the past three decades, priority setting in Colombia has undergone a significant evolution. The country has established more transparent and stable governance arrangements while refining and strengthening its institutions and processes. During this transformative period, Colombia shifted its approach from explicit priority setting, featuring a positive list of health services, to an inclusive approach covering all services and technologies, except for those explicitly listed in a restrictive negative list. This transition brought about certain advantages but also significant drawbacks, particularly concerning financial sustainability and value for money.

Colombia's progression offers valuable lessons for low- and middle-income countries aiming to establish evidence-based priority setting mechanisms. The successes and failures in Colombia's journey can serve as instructive insights for ongoing and future discussions on achieving universal health coverage.

Notes

- 1. GDP expressed in constant 2015 US\$
- 2. The Ministry of Social Protection was the result of a merger between the Ministry of Health and the Ministry of Labor between 2002 and 2011.
- 3. The 1991 Constitution created a Constitutional Court, together with mechanisms such as the tutela (protection writ) to protect individual rights, and greatly enhanced the public's access to the courts through unfettered standing and lack of procedural requirements (Yamin et al, 2009).
- 4. This gap is explained by different administrative efforts as the insurers in the CR manage sick leave compensations.
- 5. Although approved in December 1993, the Subsidized Regime did not begin until 1996.

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