USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

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Use of Retail Pharmacies as a Source of Essential Medicines, including Family Planning Products, for Public Sector Clients in Low- and Middle-Income Countries: A Thought Leadership Paper

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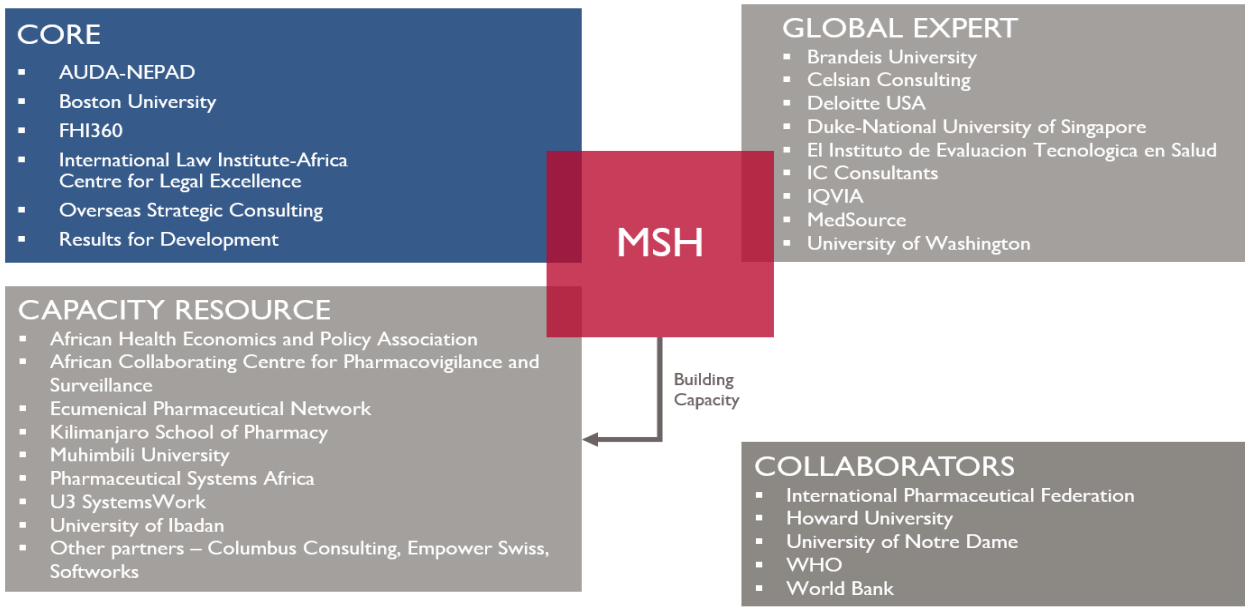
About the USAID MTaPS Program

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to higher-performing health systems. MTaPS focuses on improving access to essential medical products and related services and on the appropriate use of medicines to ensure better health outcomes for all populations. The program brings expertise honed over decades of seminal pharmaceutical systems experience across more than 40 countries. The MTaPS approach builds sustainable gains in countries by including all actors in health care—government, civil society, the private sector, and academia. The program is implemented by a consortium of global and local partners and led by Management Sciences for Health (MSH), a global health nonprofit.

The MTaPS Consortium



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ACRONYMS AND ABBREVIATIONS

AC	Autonomous Community [Spain]
AFP	Private pharmacy component of FPP (Aqui ha Farmacia Popular Program)
ANVISA	National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária)
BMI	Body Mass Index
CBA	Cost-Benefit Analysis
CMS	Central Medical Store
CNES	National Registry of Health Facilities (Cadastro Nacional dos Estabelecimentos de Saúde)
CP	Community Pharmacies
CPCF	Community Pharmacy Contractual Framework
CPD	Continuing Professional Development
CRP	C-Reactive Protein
DATASUS	Department of Informatics of The Unified Health System [Brazil]
DHS	Demographic Health Survey
DMPA-SC	Subcutaneous depot medroxyprogesterone acetate
EC	Emergency Contraception
EM	Essential Medicine
EML	Essential Medicines List
ESPS	Essential Small Pharmacy Scheme
FFS	Fee-For-Service
FP	Family Planning
FPP	Farmacia Popular Program
GDP	Gross Domestic Product
GP	General Practitioners
GPO	Group Purchasing Organization
HbA1C	Hemoglobin A1C
HIC	High-Income Country
HPV	Human Papillomavirus
HR	Human Resources
ICT	Information and Communication Technology
IT	Information Technology
IUD	Intrauterine Device
KI	Key Informant
LMIC	Low- and middle-income country
LNG EC	Levonorgestrel-only Emergency Contraception
MAF	Medical Aid Funds [Namibia]
mCPR	Modern method contraceptive prevalence rate
MoH	Ministry of Health
MPA	Medical Products Agency [Sweden]

NAB	Namibian Dollar
NAMAF	Namibia Association of Medical Aid Funds
NAMFISA	Namibia Financial Institutions Supervisory Authority
NGO	Nongovernmental Organization
NHIA	National Health Insurance Authority [Ghana]
NHIS	National Health Insurance Scheme [Ghana]
NHS	National Health Service [UK]
NHSBSA	NHS Business Services Authority [UK]
NMRC	Namibia Medicines Regulatory Council
NRP	Namibia Reference Price
OOP	Out-of-Pocket
OSN	Obra Social Nacional [Argentina]
OSP	Obra Social Provincial [Argentina]
OTC	Over the counter
PAMI	Programa de Atención Medica Integral [Argentina]
PBM	Pharmacy Benefit Management
PCN	Primary Care Networks
PMO	Compulsory Medical Program (Programa Médico Obligatorio) [Argentina]
PPP	Public-Private Partnerships
PQS	Pharmacy Quality Scheme
PRCP	Private Retail Community Pharmacies
PSAO	Pharmacy Services Administrative Organizations
PSEMAS	Public Servants Employees Medical Aid Scheme [Namibia]
PSNC	Pharmaceutical Services Negotiating Committee [UK]
RENAME	Brazilian National List of Medicines
SCI	Service Coverage Index
SME	Small to Medium Size Enterprise
SNP	Private and public pharmacy component of FPP (Saude Nao tem Preco Program) [Brazil]
SOP	Standard Operating Procedure
SSS	The Ministry of Health's Superintendent of Health Insurance (Supertinendencia de Servicios de Salud) [Argentina]
STG	Standard Treatment Guideline
SUS	Unified Health System (Sistema Unico de Saude) [Brazil]
TB	Tuberculosis
TLV	Dental and Pharmaceutical Benefits Agency (Tandvårds- och läkemedelsförmånsverket) [Sweden]
UHC	Universal Health Coverage
UK	United Kingdom
UNFPA	United Nations Population Fund
UPA EC	Ulipristal acetate Emergency Contraception
VBP	Value-based pricing
WHO	World Health Organization

GLOSSARY OF KEY TERMS

Closed system: A medicine dispensing system where patients may only obtain services and medicines from the same institutions or organizations who are also responsible for the financing of medicines. This system is in place for many low-middle income countries (LMICs), where medicines are dispensed at the public infrastructure of health care units such as hospitals, clinics, and outposts. The cost of the dispensed medicines is often fully covered by the government at these dispensing units, and reimbursement payments are usually not made to providers outside this network (Rankin et al, 2015).

Essential medicines (EMs): According to the World Health Organization (WHO) EMs are:

- Those that satisfy the priority health care needs of the population
- Selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness
- Intended to be available in the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford
- EMs include essential products associated with priority programs, such as FP, HIV, malaria, tuberculosis, and others (WHO 2021)

Family planning: This paper uses the definition of family planning (FP) according to WHO: "Family planning allows individuals and couples to anticipate and attain their desired number of children and the spacing and timing of their births. It is achieved through use of contraceptive methods and the treatment of involuntary infertility. A woman's ability to space and limit her pregnancies has a direct impact on her health and well-being as well as on the outcome of each pregnancy." FP service includes all provisions by a business related to contraceptive methods and the treatment of involuntary infertility including counseling (Shaw 2010).

Online pharmacy: An online pharmacy, also often called an E-pharmacy, is an internet-based vendor of medicines and other pharmacy related products. It sends the orders to the customers either through a courier (a person) or postal mail or other means of shipping (Desai, 2016).

Open system: A medicine dispensing system where patients may obtain services and medicines from a variety of providers who have been contracted to do so. These include public and private hospitals and health centers, private pharmacies and pharmacy chains, e-Pharmacies, and non-governmental organizations (NGOs). These kinds of systems are most often found in high-income countries (HICs), where the cost of medicines dispensed through private community pharmacies are covered, plus a fee, which usually includes all logistic costs (Rankin et al, 2015).

Private health sector: The private health sector is the individuals and organizations that are neither owned nor directly controlled by governments and are involved in the provision health services. It can be classified into subcategories as for profit and not for profit, formal and informal, and domestic and international. For the purposes of this document, the private health sector refers to the private pharmacies and drug shops (Klinton, 2020).

Public health sector: The individuals and organizations directly controlled by governments (national or local), that are involved in the provision of health services (Adapted from Klinton, 2020).

Public payer or public health insurer: A public payer is the federal or local government that finances health services. People have some or all of their healthcare costs paid for by the government. In this document we use public payer or public health insurance interchangeably (National Cancer Institute, 2021).

Public sector client: In this document, we define a public sector client as one who uses health services from a government facility or public sector contracted facility but who may obtain pharmaceutical products, in this case EMs, including FP products, from a private sector pharmacy (authors' own definition).

Retail pharmacies: There are many terms used interchangeably and refer to stores where medicinal products are dispensed and sold, e.g., retail pharmacy, medicine store, licensed chemical seller, chemist, patent vendor, proprietary drug vendor, and accredited drug dispensing outlet. This paper uses the term "retail pharmacies" which are distinguished from other entities in that retail pharmacies are overseen and/or owned by licensed pharmacists or other licensed professionals who sell registered prescription-based medicines. We distinguish these retail pharmacies from drug shops which are lower-tier retail outlets that sell over-the-counter (OTC) drugs, chemical products, and household remedies. Because this paper emphasizes the provision of EMs including FP products, many of which are prescription-based medicines (High Impact Practices in Family Planning, 2021), we focus on retail pharmacies and not drug shops or other establishments such as supermarkets which sell medicines.

Retail pharmacies can be divided into chain and independent pharmacies. Chain pharmacies are defined as "organizations where two or more pharmacies were operating under the same name and the business used distinctive branding across all pharmacies" (Miller & Goodman, 2017). Independent pharmacies are those that operate only one pharmacy under the same name.

CONTENTS

PROJECT SUMMARY

Program Name:		USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program
Activity Start Date And End Date:		September 20, 2018–September 19, 2023
Name of Prime Implementing Partner:		Management Sciences for Health
Contract Number:		7200AA18C00074
MTaPS Partners	**Core Partners**	Boston University, FHI 360, Overseas Strategic Consulting, Results for Development, International Law Institute-Africa Centre for Legal Excellence, NEPAD
	Global Expert Partners	Brandeis University, Deloitte USA, Duke-National University of Singapore, El Instituto de Evaluacion Technologica en Salud, IC Consultants, Imperial Health Sciences, MedSource, QuintilesIMS, University of Washington
	Capacity Resource Partners	African Health Economics and Policy Association, Ecumenical Pharmaceutical Network, U3 SystemsWork, University of Ibadan, University of Ghana's World Health Organizations (WHO) Pharmacovigilance Collaborating Center, Kilimanjaro School of Pharmacy, Muhimbili University, Pharmaceutical Systems Africa
	Collaborators	International Pharmaceutical Federation, Howard University, University of Notre Dame, WHO, World Bank

EXECUTIVE SUMMARY

CONTEXT

Retail pharmacies are an important part of health systems that dispense a large proportion of all health products and related services in many countries. With convenient opening hours, geographic accessibility, and personal familiarity with their clients, retail pharmacies are often a patient's first "port-of-call" with the health system. As such, they can expand access to medicines. It is common in HICs, for retail pharmacies to have a contract or an agreement with public or private insurances to dispense medicines to outpatients in the community. By contrast, in many low- and middle-income countries (LMICs), dispensing of medicines to those who do not have the income to purchase them at retail prices or who need lifesaving medicines is organized using government institutions. However, what many LMICs experience is a lack of investment in supply chain, financial, and human resource (HR)s to guarantee appropriate medicine stock levels and services at government institutions. In addition, public sector facilities often see very high patient numbers which result in long waiting times, that are worsened by restricted opening hours. The high volume of patients allows less time per patient, leading to reduced quality of client-provider interactions and fueling a loss to follow-up.

Countries striving to achieve universal health coverage (UHC) and to implement insurance and other medicines benefits schemes, have an opportunity to incorporate retail pharmacies as an integral part of the public health system supply chain.

PURPOSE

Based on case studies from three HICs (Spain, Sweden, and the United Kingdom [UK]) and four LMICs (Argentina, Brazil, Ghana, and Namibia), and an extensive literature review, we developed this thought leadership paper on the use of retail pharmacies in LMICs as a dispensing source of essential medicines (EM) including family planning (FP) products for patients visiting public sector providers.

The objectives of this paper are to complement previous work by

1. Identifying the advantages and disadvantages of contracting private pharmacies to deliver EM for public sector clients in LMICs
2. Describing promising policies and strategies for using retail pharmacies to deliver EM for public sector clients in LMICs

KEY FINDINGS

The case study analysis illustrates the complexities of developing an efficient engagement between public payers and retail pharmacies. We first outline the general advantages and disadvantages of such engagements.

By outsourcing, the public payer benefits from the business acumen and commercial skills of the retail pharmacy, both of which may contribute to improvements in the timely supply of medicines and improved stocks of products. Further, retail pharmacies can leverage private sector information

technology (IT) systems to manage pharmacy operations. By leveraging these retail pharmacy characteristics, public payers can allocate their resources in a more efficient manner, thereby potentially enhancing health system performance and promoting health goals. For instance, outsourcing widens the public payer's talent pool in terms of expertise, and thus allows the existing public payer personnel to focus on other public health issues.

However, public payers must ensure that the retail pharmacies can be held accountable for their performance otherwise such engagements could result in serious disadvantages. An important consideration for public payers then becomes monitoring adherence to the various aspects of the contract, a task that can be costly in terms of workload and workforce time. Public payer outsourcers must also consider the likelihood of facing quality issues, inequities in access and service interruptions.

In deciding whether public payer outsourcing to retail pharmacies is a desirable option, various aspects need to be considered, case by case. Following our discussion of contracting advantages and disadvantages, we identified a set of considerations and corresponding assessment questions that should be carefully considered when deciding whether an engagement of the public payer with retail pharmacies is feasible and the right fit for a specific country context. A (non-exhaustive) summary of the key considerations follows.

1. Governance, including regulation
    a) Capacity for inspection and supervision of pharmacies, e.g., accreditation processes and requirements
    b) Capacity of public versus private sector pharmacies, including number of chains versus independent pharmacies that operate in a country
2. Contracting and reimbursement
    a) Capacity of the public payer to oversee the contracting
    b) Defining the reimbursement level for pharmacies for the medicines and any associated services, e.g., existence of a reimbursement authority that can decide selection of medicines and oversees reimbursement
3. IT management systems to
    a) Provide verifiable evidence of what medicines were dispensed to eligible clients
    b) Facilitate payment
4. Quality of care
    a) Current training and skill level of pharmacy staff
    b) Requirements for retail pharmacies to participate in the contracting out agreement, e.g., accreditation, participation in referral system, etc.
5. Financing and affordability
    a) Costs of supply and dispensing in the public sector
    b) Cost of contracting retail pharmacies
6. Accessibility
    a) Proportion of public health facilities versus retail pharmacies
    b) Geographic distribution of retail pharmacies

7. Patient-centered pharmaceutical care
    a) Patient demand and associated selection of medicines that will be provided by retail pharmacies
    b) Current training and skill level of pharmacy staff to provide patient-centered pharmaceutical care

From the case studies and the literature, we identified a set of enabling policies and strategies for devising a successful contracting model in LMICs. They are summarized as follows:

1. Contract-based business incentives should encourage retail pharmacies to provide the contracted services while also ensuring their own financial viability.
    a) Establish a unit dedicated to setting reimbursement prices within the public payer
    b) Allow pharmacies to participate in the public procurement supply chain, enabling them to benefit from lower purchasing prices that are passed on to patients
    c) Provide incentives for retail pharmacies to obtain EMs inexpensively, e.g., allowing retention of margins
    d) Provide start-up capital, e.g., bank lines of credit and small loans to support new retail pharmacies or for existing pharmacy businesses, access to credit for upgrades to be able to participate in the contractual requirements.
    e) Explore alternative, locally relevant options, such as pharmacy service administrative organizations (PSAO) and digital tools to help manage pharmacy operations
    f) Implementing financial incentive policies so as not to undermine quality
2. Effective governance of the arrangement.
    a) An appropriate legal foundation is required:
        i. To regulate pharmaceutical products so as to prevent fraud (e.g., overcharging for services) and
        ii. To regulate the practice of pharmacy so as to ensure a minimum standard of pharmacy service e.g., accreditation.
        iii. Nimble IT solutions allow public payers greater transparency and integration of all systems, including transfer of payments, and required documentation
3. Market and supply chains that enable retail pharmacies to deliver quality services
    a) Conduct detailed country-specific market studies to generate evidence for decision-making and tailored solutions.
    b) Consider emerging innovations in product supply and distributions that enable quality product and service delivery. This may look different in different country contexts. Some appropriate strategies include:
        i. Centralize dispensing from wholesalers
        ii. Partner with innovators in product distribution that support stock financing, inventory management and group purchasing organizations
        iii. Leverage existing health insurance and procurement policies that may be favorable for the public payer to call upon private sector resources.
        iv. Partner with pharmacy chains when appropriate in order to reap the benefits of lower administrative costs and process streamlining.

4. HRs that assure adequate supply of HR that effectively manage business, health and public services. Some appropriate strategies include:
    a) Implement financial incentives to ensure that qualified HR are retained in the private sector in the long term, while not at the expense of the workforce in the public sector
        i. Ensure that personnel in the public sector/contracting agency are equipped with the necessary skills and expertise to effectively manage their retail pharmacy contracting arrangements. Similarly, encourage capacity building of pharmacy staff e.g., training and continuous education.
    b) Task- shift from primary care to pharmacies to expand access points

Countries and the relevant stakeholders will need to frequently adjust their policies to respond to the various challenges that they will face because of the contracting arrangements between public payers and retail pharmacies. These challenges include ensuring the financial sustainability of the public payer, dealing with non-uniform geographic distribution of retail pharmacies, quality assurance of delivered services and appropriate incentives to promote primary care by pharmacies when required. The case studies in this thought leadership paper show that a series of strategies should be considered to address these existing challenges, from tender and substitution policies to financial incentives for pharmacies in rural areas.

CONCLUSIONS

Overall, contracting with retail pharmacies offers many opportunities for public payers to improve access to EM including FP products. The advantages include due to extended opening hours, stock availability and improved customer service. At the same time, managing the relationship between the public payer and the retail pharmacies in the context of implementing contracts is a complex task influenced by a variety of factors. For the public payer to effectively enter contractual partnerships with retail pharmacies, stakeholders need a systems approach and should consider business, industry and regulatory contexts apart from the health system. It is important for policy makers to understand who their clients are, i.e., which healthcare users obtain medicines from the public sector and which from the private sector. Understanding these distinctions, including what types of FP products are obtained from public and private pharmacies, has significant program and policy implications for governments. Indeed, such client studies are important to understand whether expanding access via contracting retail pharmacies is a promising strategy. Special attention should be devoted to rapidly changing global contexts including those due to the COVID-19 pandemic, such as patient preferences (e.g., preferred products and service delivery points), market developments (e.g., online pharmacies innovative wholesalers and supply chains) and government-led health-related goals (e.g., moving towards patient-centered services at the pharmacy level). Moreover, transformation of health systems due to the pandemic (notably the rise of telehealth and online pharmacies) may require further changes in the mix of physical retail outlets and online pharmacies that are contracted. Finally, to ensure that the private sector remains viable and the public payer remains accountable for safeguarding the health system, it is imperative for both private and public payers to be active contributors and willing to adapt to these changing circumstances over the long term.

BACKGROUND

Retail pharmacies in LMICs have been recognized as an important partner in expanding services traditionally provided by the public sector, such as the delivery of EM, including FP medicines. Compared with public sector health facilities, these outlets may offer clients savings through: a reduction in indirect costs, greater privacy and trust, more convenient locations and scheduling, more consistent stock and availability, shorter wait times, and greater overall client-centered care. The added value of these advantages is they enable more patients to be retained in care, for a longer time (Agrawal et al, 2016; Cameroon et al, 2009; Gonsalves et al, 2020).

In HICs with an open medicine dispensing model, it is common for retail pharmacies to have a contract or an agreement with public or private insurances to dispense medicines to outpatients in the community (Morgado Garcia et al, 2020). These insurances usually cover either fully or partially the cost of the medicines dispensed, plus a fee for the pharmacy costs. There are exceptions to this open model. For instance, hospital inpatients may receive their medicines directly from the institution in which they are treated.

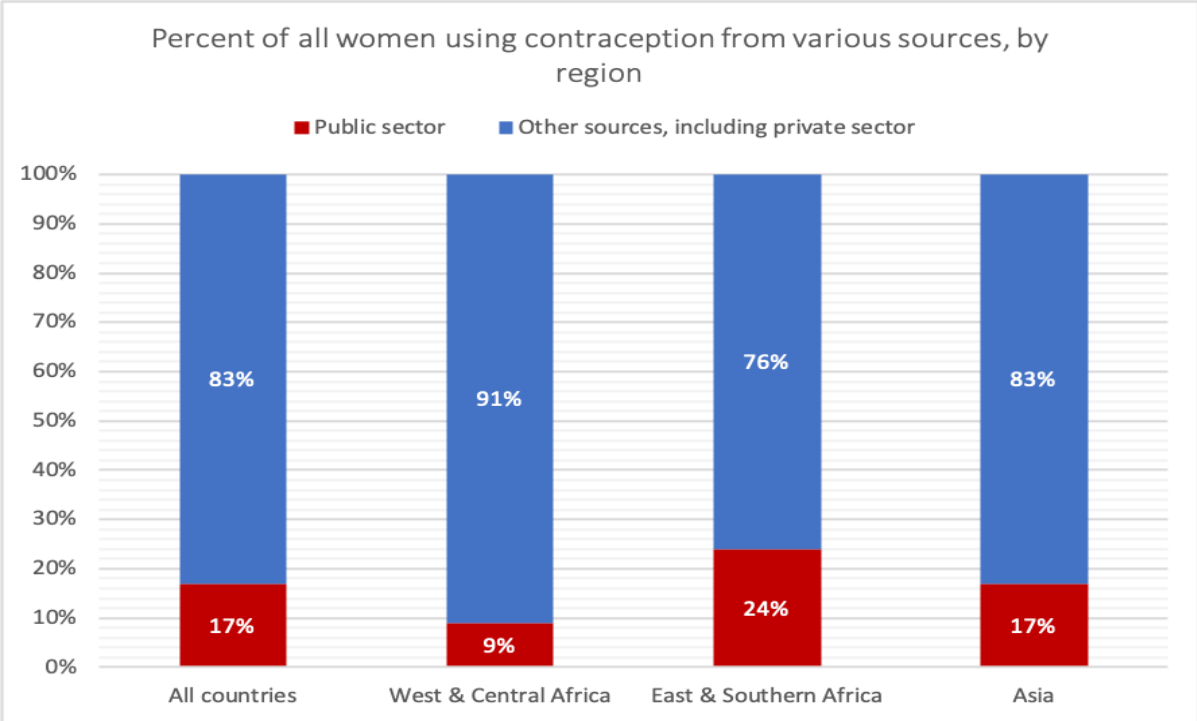
By contrast, in many LMICs, dispensing medicines for public sector users is organized using a closed model in which institutions or organizations financing the medicines dispense them using their own infrastructure (Rankin et al, 2015). For instance, many countries dispense medicines at public health care units such as hospitals, clinics and outposts. In these closed systems, the public sector such as the government and public insurance schemes often cover the costs of the dispensed medicines. In some cases, there is a charge or dispensing fee that the user pays.

The reasons for using either an open or a closed medicine dispensing model are historic and, at least for Europe and North America, are probably due to regulations that forbid doctors from dispensing (Eggleston, 2012) and to the professionalization of pharmacists and their role in the community as preparers and dispensers of medicines (Anderson, 2007). Whatever the historical reasons for their use, each model has advantages and disadvantages.

One disadvantage of the closed model is that many LMICs experience stockouts resulting from poor system governance resulting from a lack of financial and HR investments in their supply chains to guarantee appropriate stock levels. Public sector facilities experience stock-outs much more frequently than their private retail counterparts (Cameroon et al, 2009). In addition, public sector facilities often see very high patient numbers which result in long waiting times, worsened by restricted opening hours. The high volume of patients allows less time per patient, leading to reduced quality of client-provider interactions and fueling loss to follow-up. These disadvantages are not per se caused by a closed model but are observed as associated with such a model in the LMIC context (United States Presidents Emergency Plan for AIDS Relief (PEPFAR), USAID, Meeting Targets and Maintaining epidemic Control [EpiC], 2019).

Given these challenges, in many LMICs pharmacies and drug shops are a significant source for EM including FP products resulting in high out-of-pocket expenditure which can push households into poverty. Using the example of FP, Figure 1 shows that the private sector including pharmacies, drug shops and other non-government outlets is a significant source for FP products globally.

A recent study that analyzed data from 132 LMICs showed that private out-of-pocket (OOP) expenditures for contraceptive commodities represent a heavy burden for women across LMICs. More specifically, private OOP expenditures (% total spent) in 2019 across LMICs ranged from 1% for intrauterine devices (IUD), to 22% for injectables and 55% for the pill (Weinberger et al 2021).



Source: Adapted from Bradley & Shiras 2020

Figure 1: Percentage of all women using contraception from various sources, by region.

Contraceptive stockouts at public facilities are common and pervasive across LMICs; especially for short and long-acting FP methods (Muhoza et al, 2021; USAID, 2019). A few qualitative studies have assessed how women cope with these stockouts (Grindlay et al, 2016).

In many LMICs the private sector plays a very significant role in dispensing and administering contraceptive methods, thus showing the importance of engaging the private sector towards achieving global FP goals. In Bangladesh, for instance, the percentage of women who obtain their contraceptives from the private sector increased from 38% in 2007 to 43% in 2014 and 49% in 2017 (NIPORT/Bangladesh, et al 2016). In Ghana, while the public sector tends to be the primary source of injectables, most-short-acting FP methods including pills, EC and condoms, are dispensed from the private sector (Ghana GSS2014; NPC 2018). A recent USAID study on chain pharmacies reports that for more than 50% of the urban and more than 33% of the rural adolescent population who obtain contraceptives, private pharmacies are the dominant sources for condoms and oral contraceptives (Combet et al, 2020).

When faced with a stockout, FP users with the necessary resources most frequently report going to private facilities to procure their preferred method. Data from Ghana, Tanzania and Kenya have shown

that respectful treatment, shorter wait times, and met expectations correlate with higher client satisfaction. The private sector's responsiveness to these consumer preferences and pervasive stockouts is a critical element in enabling women to switch to the private sector (Grindlay et al 2016; Agha & Do, 2008). Post-partum women in a qualitative study in Kenya explained that choosing private pharmacies not only assured them of medication availability, but also provided them with a high level of customer satisfaction (Keesara et al, 2015).

The movement towards universal health coverage (UHC) and implementation of insurance and other medicines benefits schemes is an opportunity for many countries to consider an open model where medicines, notably EMs, are provided through retail pharmacies as an integral part of the insurance benefits that are financed by the public payer.

Several LMICs have made the decision to contract with the private sector for medicines dispensing, notably for human Immunodeficiency virus (HIV) medicines, FP and to some extent tuberculosis (TB) medicines. Regarding HIV medicines, several countries in sub-Saharan Africa are now incorporating the private sector as part of their medicines distribution system (PEPFAR, et al, 2019). For example, South Africa is providing prepackaged HIV medicines to public sector clients from pick-up points in private sector facilities.

Incorporation of the private sector in delivering HIV medicines is not without challenges. For instance, in Tanzania, stakeholders were resistant to scale up the contracting of the private sector, fearing delayed payment of the private providers which could result in treatment interruptions. Others were concerned that some family members would qualify for private sector use given that their HIV was stable and well managed, whereas others in the same family had to continue to use the public sector (PEPFAR, 2019).

Several LMICs have already engaged retail pharmacies in dispensing TB medicines (Miller & Goodman, 2020). This may be due, in part, to the first WHO guideline on public-private mix (PPM) approaches for TB (WHO, 2006), which clearly spells out a range of interventions specifically needed for non-physicians, such as private-sector retail drug outlets referrals and dispensing (Konduri et al 2017). In some cases, pharmacies were paid for either performing sputum tests or referring patients to public or private clinics with mixed results. Although some studies showed that pharmacies had a higher rate of TB diagnosis, others reported barriers, such as the pharmacist being too busy with other tasks than counselling or referral of patients. In Tanzania, accredited private sector drug dispensing outlets contribute to TB case detection and dispensing of treatment options (Rutta et al 2014).

The WHO's proposed public-private mix pharmacy model could become a scalable reality and a reliable contribution to ensuring access to TB and other EMs. Many countries have tested and scaled up models using retail pharmacies to provide FP. One of these models uses demand side subsidies via vouchers, often for FP commodities. Vouchers are means for governments to flexibly engage private-sector capacity, specifically for beneficiaries who would otherwise have a lower probability of service access and use. As Bellows et al (2017) report, some groups (like unmarried youth) may prefer accessing contraceptive services through private providers due to convenience, and vouchers can enable access to health services in private facilities when public facilities are unable to provide services.

However, there is variation in the evidence regarding the effectiveness of vouchers to improve access to EM. A review of 24 NGO-supported voucher programs across 11 countries in Africa and Asia between

2005 and 2015 found that most voucher programs were successful in reaching subgroups, such as the poor and young consumers (under 25 years old). At the same time, there are limitations to the feasibility and effectiveness of voucher programs. Challenges related to the use of paper vouchers include the administrative burden of forecasting and stock management, and time lags resulting in missing or inaccurate data. On the other hand, use of e-vouchers (which replace physical tokens with a digital value provided to the user through, for instance, an app or text message) face challenges such as a lack of technical capacity and a lack of infrastructure (Riley, 2019). In Zambia, retailers were unable to properly operate point-of-sale card readers or maintain the hardware required for vouchers. In Uganda, the e-voucher platform that was under evaluation faced reliability challenges related to dropped SMS messages and slow internet speed which prevented transactions (Family Planning High Impact Practices 2020; Bellows et al, 2017; Riley 2019).

Several LMICs have already engaged retail pharmacies in dispensing a wide range of EMs for public sector clients - such as in Tanzania (Embrey, 2021), Ghana (Ashigbie et al, 2016)) and in many upper-middle income countries, including Brazil (Emmerick et al, 2015) and Argentina (Villacorta Santamato & Ventura Pinedo, 2017). It is beyond the scope of this thought leadership paper to provide an exhaustive literature review on the experiences of countries contracting private pharmacies.

This document examines the advantages and challenges of public payer contracting with retail pharmacies, the policies and strategies of selected countries to implement such systems, and the policies to address the challenges.

AIMS AND OBJECTIVES OF THIS THOUGHT LEADERSHIP PAPER

The aim of this thought leadership paper is to target influencers such as donor agencies, multi-national organizations, think tanks, country governments, policy makers, academia and other stakeholders who are considering this approach.

The objectives are:

1. Identify the advantages and disadvantages of contracting private pharmacies to deliver EMs for public sector clients in LMICs
2. Describe promising policies and strategies of using retail pharmacies for delivering EMs including public sector clients in LMICs

WHAT DOES THE DOCUMENT ADDRESS AND NOT ADDRESS?

The document starts with a description of how the data were gathered for this document to inform the analysis. Then, its main sections present the advantages and disadvantages of contracting retail pharmacies followed by the presentation of promising policies and strategies for LMICs considering this type of public-private engagement. It concludes by highlighting key recommendations and future research in this area.

This thought leadership paper developed case studies from HICs with decades-long experiences in using private pharmacies in addition to case studies from LMICs with more recent experience in scaling up UHC and developing models of contracting retail pharmacies to dispense medicines for public sector users.

This work does not include key informant interviews and instead focuses on existing literature on this topic. Future work should include a consultation of experts in this area to complement this document and its recommendations.

HOW DATA FOR THIS DOCUMENT WERE GATHERED AND ANALYZED

DEVELOPMENT OF THE ANALYTICAL FRAMEWORK

The collaboration between the public payers or insurers and retail pharmacies is a form of a public-private partnership (PPP) that promises benefits such as leveraging private sector capital, and knowledge and innovation in the supply and sales of medicines. However, there are diverging interests that can jeopardize the values and goals of the public payer, such as equity considerations in which access does not depend on the ability to pay. To understand the overall context of such PPPs, we first identified key general considerations of PPPs. A 2012 literature review on the challenges related to health-related PPPs generally in Sub-Saharan Africa (funded by USAID/SHOPS) led by Barbara O'Hanlon as Principal investigator that was conducted by one of the co-authors of this document (Warren Kaplan) was reviewed (O'Hanlon & Kaplan, 2012).

The WHO review on "Partnering with the Private Sector to Strengthen Provision of Contraception" (2017) was found to be relevant because it summarizes the key considerations for public payers when contracting the private sector to deliver FP products but is also very relevant to EMs more broadly.

To develop a framework to guide the analysis in this document, we merged the general considerations needed by PPPs when contracting the private sector as documented in O'Hanlon's work funded by USAID/SHOPS with the specific considerations that the World Health Organization (WHO) identified in its 2017 document. The compiled list is in Table 1.

Table 1: Key dimensions of contracting the private sector to deliver EMs

Dimensions	Explanation of why each dimension is relevant in the context of contracting the private sector
Governance including regulation	To ensure that governance and associated regulations support private sector provision of EMs/FP and that the private sector complies with public sector health standards and private sector business standards. To facilitate effective governance, regulations and reimbursement via transfer of electronic data between contractor and provider
Contracting and reimbursement	To guarantee timely and efficient service provision by the private sector and the transfer of funds by the public sector payer partner(s)
Affordability	To protect against financial hardship by the end user and the sustainability of the public payer
Quality of care	To maximize health benefits and use resource efficiently through support for patient-centered pharmaceutical service standards, medicine use reviews, and accreditation schemes for private sector pharmaceutical outlets.
Accessibility	To promote equity in accessing retail pharmacies
Patient-centered pharmaceutical care	To increase availability of services and greater provider choice and to improve patient satisfaction, adherence, and outcomes through better patient–provider communication techniques to reduce barriers to information access for pharmacies and patients. To support private sector pharmacies, professional associations, consumer/patient advocacy groups, and civil societies to develop/adapt standards, guidelines, and tools to institutionalize pharmaceutical care as part of essential packages of health services to optimize patient use of medicines.

SELECTION OF CASE STUDIES

For the selection of case studies, we identified and reviewed documents about HIC and LMIC examples under circumstances where public payers in these countries contract retail pharmacies to serve public sector clients for the receipt of FP products and other EMs. We selected the cases based on a mix of the following criteria: (1) evidence of a formal contract or agreement between retail pharmacies and the public payer; (2) an agreement on the provision of EMs or reimbursed medicines including FP; (3) a mix of high, middle and, wherever if possible, low-income countries with single or multiple public payers; (4) case studies that were well documented in terms of the contents of the contract or agreement with the private sector which have been in place longer than one year and have demonstrated preliminary results and achievements. In coordination with the funders of this document we selected Brazil and Argentina, two upper-middle income countries in South America; Ghana and Namibia, two lower-middle income countries in Africa; and Spain, Sweden, and the United Kingdom (mainly England) three HICs countries in Europe. Sweden did not meet the first inclusion criteria of having a formal contract. However, given its history of changing from a public owned pharmacy model to one that allows private ownership and having an agreement with the public payer we included it in the paper. We were unable to identify a low-income country that met the inclusion criteria.

LITERATURE REVIEW

We employed a targeted literature review strategy to conduct this scoping review. The search engines included literature in English, Portuguese and Spanish. We limited the search to the last 10 years (2010-2021). We have created an Appendix in which we further describe the keywords used, the search strategy and list the references for each case study.

1. Google and Google Scholar Search: first 50 cites/ then 'cited by", then 'related references"
    a) Search terms = public private partnership family planning public sector/payer/private pharmacy AND (Argentina, Brazil, Ghana, Namibia, Spain Sweden, United Kingdom)
2. PubMed
    a) ((cooperation, public private sector [MeSH Terms]) AND (medicine [MeSH Terms])) AND (family planning [MeSH Terms] AND (Argentina, Brazil, Ghana, Namibia, Spain Sweden, United Kingdom)
    b) ((cooperation, public private sector) [Title/Abstract] AND (medicine)) [Title/Abstract] AND (family planning) [Title/Abstract] AND (Argentina, Brazil, Ghana, Namibia, Spain Sweden, United Kingdom)
3. CINAHL
    a) AB (public AND private AND (cooperation OR partnership)) AND AB pharmaceutical AND (Argentina, Brazil, Ghana, Namibia, Spain Sweden, United Kingdom)

Each country name was also used alone with the other keywords related to pharmacy and public payer.

Additional sources, including relevant peer-reviewed articles shared by the USAID-MTaPS team and the authors' previous works were reviewed at later stages of writing, for the purpose of enriching this paper.

ANALYSIS

First, from the relevant literature we extracted the advantages and disadvantages of contracting retail pharmacies to dispense medicines to public sector users. We then took each of the dimensions given in Table 1 and identified the assessment questions that public payers would need to ask before deciding about whether or not to contract with retail pharmacies. The advantages and disadvantages, and the assessment questions were general and not specific to any of the case studies.

This was followed by a thorough assessment of each of the dimensions described in Table 1 for each of the seven country cases selected. The question that we asked was: How does the public sector payer in our case studies incorporate provisions and use strategies to achieve its goals with regards to each dimension?

Last, we compared and contrasted the findings of the case studies (found in the Annexes) and drew conclusions and recommendations for the public payer contracting of retail pharmacies. More specifically, we described a series of promising policies and strategies that the public payers in the cases studied have used and we discussed how they have addressed the related challenges with complimentary policies and strategies. We considered the contextual factors such as the wholesaler and distributor market, the business regulations and incentive structures and the most recent developments stemming from the emergence of COVID-19 and other new and existing infectious diseases on the ability of public payers to contract retail pharmacies.

ADVANTAGES AND DISADVANTAGES OF CONTRACTING PRIVATE PHARMACIES

There are several reports that specifically attempt to describe the advantages and/or disadvantages of contracting retail pharmacies for the delivery of EMs including FP or HIV, TB or other specialty medicines for public sector clients in LMICs (Villacorta Santamato & Ventura Pinedo, 2017; Miller & Goodman, 2020; PEPFAR et al, 2019). Although not specific to "advantages and/or disadvantages of contracting for EMs", others discuss outsourcing of healthcare services from the public to the private sector in a way that illuminates these same issues (Skipworth et al, 2020; Kavosi et al, 2018; Moradi-Joo et al 2020; Odendaa et al 2018; Rao et al 2018).

Governments will generally contract private sector pharmacies, and private sector entities generally, for a variety of reasons related to the specific context of their health system. Many actors are involved in the contracting process, including the private retail sector, and central and local governments. Public sector organizations typically have more formal, less flexible and more risk-averse decision-making procedures than do their counterparts in the private sector because they tend to be designed around the principles of the bureaucratic model yet public organizations are often more willing to introduce drastic changes because they do not fear losing their market share and cannot go bankrupt (Skipworth et al 2020).

Although specific contractual design decisions may produce salutary or flawed consequences in a given contract, we summarize below the most frequently mentioned overarching advantages and disadvantages of public sector out-sourcing to the private sector. The provision of services depends on the willingness and capacity of the contractors to offer the service, or the appropriateness of the service and this is largely context-specific.

POTENTIAL ADVANTAGES TO THE PUBLIC SECTOR OF OUTSOURCING TO RETAIL PHARMACIES

- By outsourcing non-core pharmaceutical functions, the public payer can, in theory, reduce its own costs.
- By introducing knowledgeable and competent resources to manage key operational areas, existing public payer personnel can be freed up to focus on other public health issues (e.g., nurses dispensing medicines in health facilities).
- Outsourcing to retail pharmacies may enhance performance including serving more users, promote health goals, reduce costs and increase private sector revenue by creating competition based on patient experience among the multiple service providers.
- Outsourcing, in principle, can widen the public payers' talent pool because it can be difficult to find highly skilled personnel and outsourcing can help health systems bridge that gap.
- Outsourced retail pharmacies can bring business acumen and commercial skills to work alongside the public payer to improve the patient experience and potentially increase the quality of pharmaceutical services to patients.
- Outsourcing can provide more timely supply of needed medicines given retail pharmacies interactions with supply chain stakeholders.

- Outsourcing IT may build intra-organizational systems to gain competitive advantage, maintain it, and provide better retail pharmacy services at a lower cost if it is done properly.
- Outsourcing to retail pharmacies is likely to provide greater ability to dispense multiple months of product (due to better stock situation and better ability to resupply quickly), e.g., for oral contraceptive pills and products for chronic conditions, reducing need for repeated trips to the pharmacy.
- Contracting can encourage cost-effective purchasing which benefits the public payer, (e.g., capping yearly pharmacy "margins" [difference between what the government pays retail pharmacy sector for reimbursement and pharmacy medicine purchase price]).
- Contractually moving pharmacists into delivering primary care, health promotion and/or managing patient devices (e.g., asthma inhaler) can improve public/community health.

POTENTIAL DISADVANTAGES OF PUBLIC SECTOR OUTSOURCING TO RETAIL PHARMACIES

- Public payers' outsourcers must also consider the likelihood of facing quality issues. Poor quality often stems from misunderstandings around the scope of the work being provided and the full costs of the services.
- Public payer may lack proper control over retail pharmacies and with a lack of timely evaluations by either the public payer and/or retail pharmacies. Ensuring compliance with contracts for medicines procured can be workload intensive and can add costs.
- Public payers must ensure that the retail pharmacies can be held accountable for their performance.
- There may be substantial costs incurred by the public payer in overseeing and auditing retail pharmacy services outsourced to a third-party provider. This relates not just to standards of professional service but also checking of medicines procurement and service charges.
- Outsourcers may experience service interruptions when contracts expire, an unstable workforce (limited availability of staff and/or high turnover), and difficulty switching vendors, should that become necessary.
- Additional effort required to monitor adherence to aspects of the contract.
- Long outsourcing contracts can result in inflexibility for both contractual partners.
- The contents of the contract not being updated and being inconsistent when new guidelines are established by the government.
- Although outsourcing can increase efficiencies in the medium to long term, using an intermediary to manage public payer contracting with retail pharmacies creates a substantial up-front and transaction costs.

Although this document focuses on the public payer perspective, it is relevant to mention that there are also advantages for private pharmacies to engage into an "outsourcing" or contractual agreement with the public payer such as the opportunity to increase their client pool, which can subsequently result in higher profits.

Various other aspects need to be considered when stakeholders including public payers decide whether dispensing medicines via retail pharmacies is a desirable option. For instance, 'how big is the population that would benefit from the services?' or 'How much would contracting of retail pharmacies cost compared to dispensing medicines in public sector facilities?' Table 2 summarizes the relevant aspects to

consider in each of the assessment areas mentioned in the previous section. Table 2 is not comprehensive; instead just key aspects identified through the literature review are considered. There is some overlap of key aspects which are relevant across the assessment areas. For example, the selection of medicines is relevant to ensure both patient-centered services as well as reimbursement considerations.

As for the dimension of governance, a detailed situational analysis of the pharmacy and supply chain sector including HR is critical. Such analyses should deal with the geographic distribution and size of the pharmacy sector (and a whether chain pharmacy or independent), and the capacity of the public payer or the government to regulate and supervise the pharmacy sector, including current pharmacy staff training regulations.

Any situational analysis must include key information about the supply chain. The oversight and supervision of pharmacies, wholesalers and distributors are a critical component of the capacity of a public payer to ensure that the contracted retail pharmacies adhere to the contractual obligations. Generally, chain pharmacies are at an advantage over independent pharmacies in terms of dispensing efficiency. Chains can centralize dispensing within their own networks. Independents need to rely on wholesalers to deliver central dispensing services or develop cooperative or in joint-partnership models. In principle, chain pharmacies would be in a better position to achieve both scale economies in dispensing and provide an improved approach to delivering nationally commissioned, (i.e., contracted) services. Smaller independent pharmacies do have an apparent advantage in that they can tailor their offering to local priorities. Independent pharmacies also have an advantage in their geographical distribution of being in suburban and rural locations, whereas chain pharmacies may be limited to urban locations.

With respect to the contracting and reimbursement dimension, the public payer must have the capacity to manage contracts and efficient reimbursement of retail pharmacies. Does the public payer have the capacity to determine reimbursement prices? What other institutions exist that the public payer can collaborate with in determining the medicine benefit package?

Management systems are another critical element to ensure the efficient execution of contracts between the public payer and the retail pharmacies. IT can greatly enhance efficiency but often requires large upfront investments.

As for the quality of care, to ensure quality of dispensing and service delivery alongside dispensing, the current skills of pharmacy staff and the potential training requirements need review. Training of pharmacy staff is of particular relevance when extending services to administer injections. For example, if a pharmacy is contracted to provide FP, do they have the necessary counseling skills? Do they have space for privacy? If they are allowed to administer injectables, have they received the appropriate training? Do they have the appropriate measures for sharps disposal? The ability of pharmacies to provide contractual services needs assessment. If pharmacies need to make large investments without sufficient returns to meet their accreditation requirements, it will deter them from participating (see also Section Necessary legal foundation for effective governance, page 41).

As to financing, the public payer needs to assess both the current costs of providing EMs via a closed model and the open model of contracting retail pharmacies. The public payer needs to understand the

ability of financial resources to support either an open model or a closed model, or a combination of both.

In other words, as governments consider public-private partnerships in light of limited health care resources, economic evaluations of hospital and retail pharmacy services become increasingly important to enable an understanding of which health care services provide value for money and to inform policy makers as to which services will be cost-effective.

Economic evaluation studies of private versus public pharmacy dispensing would be helpful to understand the clinical and societal benefits of these contracting models, as well as their value for money (Gammie et al, 2017). For instance, Garcia and colleagues (2020) conducted an economic evaluation of Brazil's national health system (NHS) and found that facilitating negotiation of medicine price, and thus improving access to medicines across all income classes with the greatest benefit to the poorest families, would be an optimal model of contracting retail pharmacies. (Countdown 2030 Europe, 2018)

However, measuring societal benefits is very difficult. In fact, cost-utility analyses are more often employed than cost-benefit analyses (CBA) are. The limited use of CBAs is likely a result of technical challenges in quantifying the monetary cost of clinical benefits, risks, and outcomes (Gammie et al, 2017). In the future, more widespread use of economic evaluations, notably CBAs, should become increasingly commonplace to enable understanding of what outsourcing models provide the best societal benefit for money.

Obtaining physical access to pharmacies is a key dimension: it is critical to assess where retail pharmacies are located. Regardless of whether the public payer is considering contracting chain or independent pharmacies, a situational analysis should assess where such pharmacies are located (see Hafner et al, forthcoming). The public payer would need to examine whether new access points are to ensure accessibility.

Finally, public payers need to assess the current demand for services, users' expectations and how these needs can be addressed through adequate contractual conditions. For example, what is the medicines benefit package that is offered to users through retail pharmacies? Will it include an adequate choice of products that satisfy users' needs? Offering a range of products but also a range of formulations and features is especially relevant in the area of FP. Who will be left out if EM and FP are predominantly offered through retail pharmacies? Partners and stakeholders' roles, as well as what they expect to benefit weighed against what they can bring to the contract must be kept in mind throughout the balancing act of devising these contracts.

Before deciding about contracting retail pharmacies, it is important to consider that a market approach - a deliberate plan for provider contracting- is only one way to increase access to EMs by public sector users. Many other factors come at into play. A low percentage availability/use of FP could also be attributed to low demand, from either the LMIC government or user side. For most LMICs, the specific allocation or budget line items dedicated to FP are not well delineated. If for instance, financing of EMs is the limiting factor for access to medicines in the community, contracting retail pharmacies will not solve the lack of access to medicines. A complete and thorough analysis assessing the underlying barriers to access is therefore critical before deciding whether contracting retail pharmacies will resolve a particular problem (e.g., low utilization of FP products and services).

Furthermore, understanding what group of public sector users obtains what kinds of EM from retail private pharmacies has significant program and policy implications for governments. For instance, many studies conducted in the past have indicated that retail pharmacies and drug shops are often preferred by young, single, and other underserved populations (Corroon et al 2016). There are many reasons for this, including that retail pharmacies are often open and accessible at various times or the fact that retail pharmacies sell a variety of products in addition to contraceptives, and this makes young and unmarried women feel more comfortable obtaining their contraceptive methods there. If this specific population group is to be the target of expanding access to EM and FP products and services, then contracting retail pharmacies may indeed be a viable strategy. However, if the target group prefers other outlets including public sector facilities, contracting retail pharmacies may not have the desired effect of changing the group's access to EMs.

Table 2: Key considerations when deciding whether and how to contract retail pharmacies

Dimensions	Feasibility aspect	Sample assessment questions
Governance including regulation	• Capacity of inspection and supervision of pharmacies • Issuing of licenses • Registration of pharmacists • Ownership of pharmacies • Number of trained pharmacists and other trained professionals such as technicians • Number and types of retail pharmacies in the country • Structure and regulation of the supply chain of pharmacies • Number of licensed distributors and wholesalers • Market share of distributors and wholesalers	• What is the capacity of public sector vs private sector pharmacies? • What is the proportion of public health facilities versus retail pharmacies? • How many chains versus independent pharmacies are operating in the countries? Generally, contracting chains is easier than contracting many independent pharmacies. • Will there be an increased documentation burden for both public payer and retail pharmacies due to contracts? • Is there capacity to prevent contracting from steering beneficiaries to politically connected and/or favored providers, because this may adversely affect both access to and costs of, medicines? • What is the impact of supply chain and/or managerial intermediary partners on retail pharmacy transaction costs and operating costs?
Contracting and reimbursement	• Capacity of the government or the public payer to contract and oversee the contracting • Selection of medicines that will be provided by the retail pharmacies • Defining the reimbursement level of pharmacies for the medicines and any associated services • Capacity of the government or the public payer to pay retail pharmacies for their services	• What is the governance capacity of the public payer? • Has the public payer the capacity to develop a contract with retail pharmacies? • Has the public payer the capacity to enforce the contractual obligations if needed? • Is there a reimbursement authority deciding on the financing of medicines and setting reimbursement prices? • Has the public payer an established mechanism of selection of medicines for reimbursement? • Has the public payer an established mechanism to set reimbursement levels/ prices for medicines and related services?
Information technology management systems	• IT tools that allow public payer to pay retail pharmacies for their services efficiently • IT tools that allow supervision of retail pharmacies in contract implementation	• What are the Information Technologies that are available by payers and retail pharmacies to transfer or receive money? • Do the IT tools support monitoring and evaluation activities carried out by the public payer? Are both products and services monitored? • What does the IT infrastructure look like locally (e.g., is there access to network coverage that is good and makes servicing easier)?
Quality of care	• Current training and skill level of pharmacy staff • Requirements for pharmacies to participate in providing services under the scheme, including accreditation • Supervision of service quality provided by retail pharmacies	• What is the pharmacy education curriculum? • Are there sufficient public payer resources to carry out monitoring, supervision and control of operations, both at the administrative and assistance levels?

Dimensions	Feasibility aspect	Sample assessment questions
		• Is there a sufficiently strong referral system between public facilities and private retail pharmacies? • What are the current standards on quality of dispensing and pharmaceutical care? • What is the capacity of the public payer to supervise retail pharmacies?
Financing and Affordability	• Costs of supply and dispensing in the public sector • Cost contracting retail pharmacies	• Is the contracting of retail pharmacies affordable to the payer at all? • How will the costs of the open system compare to that of the closed system? • Is receiving medicines from retail pharmacies affordable to the user? • Is there an entity responsible for the selection of medicines in the benefit package? • Does the public payer have the capacity to decide on its own that a pharmacy under contract may be neither necessary nor desirable for a given community/location?
Accessibility	• Number and types of retail pharmacies in the country • What is the proportion of public health facilities versus retail pharmacies? • Geographical distribution of public and private pharmacies in the country	• How accessible will retail pharmacies be nationwide? What will the geographical disparities be? • From where do users obtain their medicines? • From where is the demand for pharmaceutical care? • What users are in need of receiving medicines and care who are not served by the current medicines access points?
Patient-centered and pharmaceutical care	• Selection of medicines that will be provided by the retail pharmacies • Current training and skill level of pharmacy staff	• How will the contracting of retail pharmacies ensure patient-centered care? • How will quality of care and products be ensured?

PROMISING POLICIES AND STRATEGIES FOR USING RETAIL PHARMACIES TO DELIVER ESSENTIAL MEDICINES IN LMIC

Based on the seven country case studies that were chosen for this thought leadership paper (Argentina, Brazil, Ghana, Namibia, Spain, Sweden and the UK) the promising policies and strategies fall into four areas: contract-based business incentives; effective governance; market and supply chains; and HR (Figure 2).

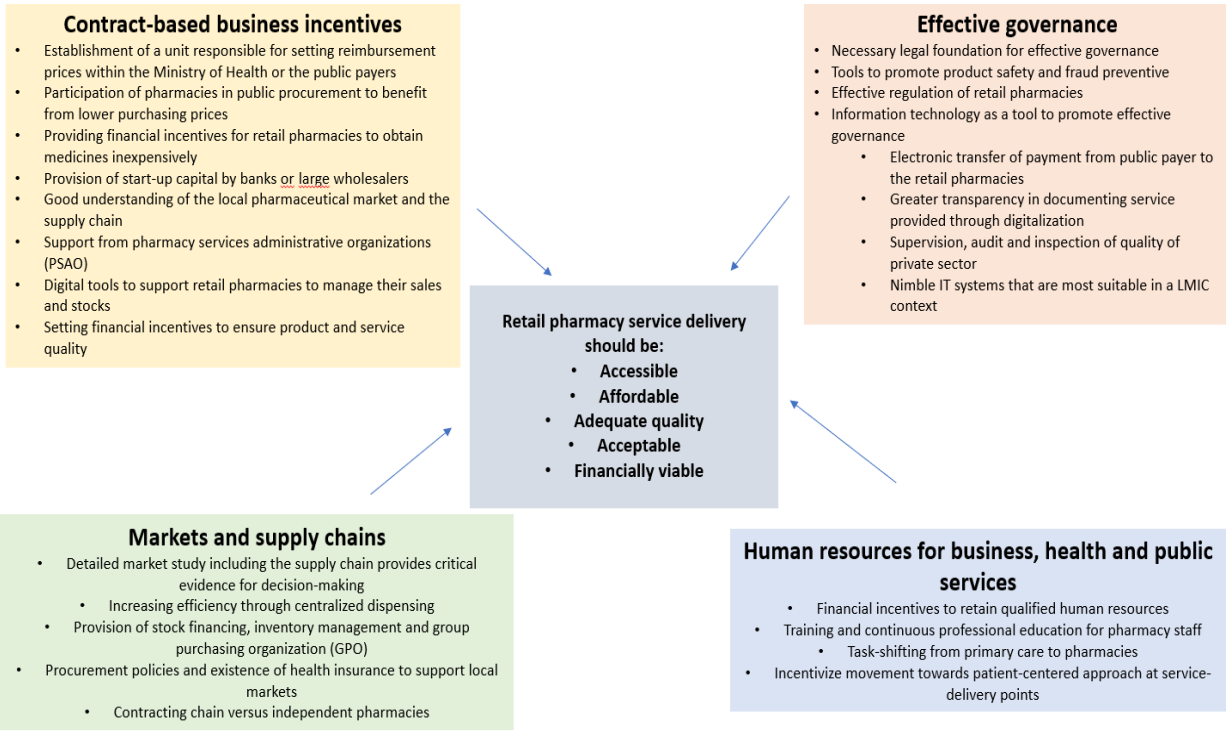


Figure 2: Enabling policies and strategies for contracting private pharmacies

CONTRACT-BASED BUSINESS INCENTIVES

Financial incentives for the private sector to participate are critical. The incentives should be 'built-into' the public-private contract. The level of reimbursement for the services provided and the amount reimbursed for the product dispensed will ultimately determine whether the private sector business is able to provide the service while at the same time ensuring its own financial viability. It is a difficult balance to maintain over time. The case study in Ghana illustrates that when the National Health Insurance Scheme (NHIS) reimbursement prices were lower than the patient price (wholesale price plus mark-ups), private pharmacies took a loss. This is because retail pharmacies incur additional expenses, whereas in the case of public pharmacies, are paid by the government. Moreover, public facilities benefit from lower prices of medicines made possible by competitive tender purchasing, which private Ghanaian pharmacies were unable to do (Ashigbie et al, 2016). Similarly, in Brazil, after lowering the amount of reimbursement that retail pharmacies are paid that take part in the private arm of Farmacia Popular in

2018, private pharmacies were less attracted to enroll in the program (Honda & Obse, 2020; de Oliveira et al, 2018). On one hand, if the reimbursement margin is low, private sector providers may incentivize users to increase consumption of the products and services which can have a negative effect on health or waste resources. On the other hand, private pharmacy providers may also decide to stop providing services under the public system altogether if the reimbursement for their services is considered unattractive from a business perspective.

For this reason, when working on the design of an outsourcing contract, it is important to understand the attitudes of major stakeholders involved, which typically include government ministries, regulatory agencies such as price control boards, insurance companies and their associations, health care organizations and pharmacy associations. Understanding these stakeholders' roles and engaging them in dialogue and decision making is critical as it can help facilitate a productive and mutually-beneficial partnership between the payer and the pharmacies.

Establishment of a unit responsible for setting reimbursement prices within the Ministry of Health or the public payers

An important strategy to ensure adequate reimbursement is the establishment of reimbursement prices by dedicated units within the Ministry of Health (MOH) or the public payers. Many LMICs with a closed medicines distribution system do not have dedicated units to set reimbursement prices because medicines are purchased directly by the government, and are distributed and provided for free at the point of dispensing (usually at public health facilities). Other distribution systems have reimbursement agencies that do set reimbursement prices (such as those in England for branded, prescription medicines) and they must take into consideration the price the pharmacies are paying when the pharmacies purchase from the manufacturer distributors and wholesalers. Agencies can benchmark prices by comparing them between countries and should be analyzing any taxes and tariffs imposed on the relevant EMs.

Unless LMICs want to assume the costs of maintaining a large and separate supply chain of EMs, they may have to transfer some of the distribution to the private sector. Higher patient convenience associated with retail pharmacies can result in quicker treatment initiation and better adherence, generating savings from avoided in-patient episodes when a patient's disease progresses to advanced stages (Yadav and Glassman, 2019). Considering the move towards UHC, and the transition out of donor financing, some firms in Sub-Saharan African, Southeast Asia, and other regions are getting ready for a future where medicines will be reimbursed at a larger scale by national insurance schemes.

However, shifting the purchase of these products to retail pharmacies may lead to higher mark-ups on these types of commodities. Fragmented wholesale and distribution markets are often the root cause of higher distribution channel markups (Yadav & Glassman, 2019). Setting reimbursement prices at retail pharmacies requires the public payer to factor in the mark-up costs for delivery or shipping of those products.

Participation of pharmacies in public procurement to benefit from lower purchasing prices

Private sector stakeholders usually procure directly from manufacturers' distributors or agents. In some countries private retail pharmacies have successfully participated in the national public procurement and supply chain, enabling the pharmacies to benefit from lower purchasing prices which can then be passed

on to consumers. Given that donor financing of FP products is unlikely to increase, out-of-pocket spending will have to cover a larger share (Family Planning 2020); therefore, passing along lower prices to consumers is critical.

This was a key idea promoted by the USAID DELIVER program's work in the Americas. Coordination mechanisms (including with the public sector, NGOs, donors and the United Nations Population Fund [UNFPA]) were set up in several countries, and non-public sector participants benefited from the access this gave them to supplies from the public sector supply chain. It goes without saying that for this to work sustainably, excellent coordination between sectors (which can be difficult to achieve) is required (Countdown 2030 Europe, 2018).

Providing financial incentives for retail pharmacies to obtain medicines inexpensively

Public payers use reimbursement prices as a measure of cost containment. Some countries have successfully set these reimbursement prices at such level that it incentivizes business to get the medicines at a low price but still be able to remain financially viable. This system is not fool-proof, e.g., in the UK since pharmacies are thus incentivized to obtain generic medicines inexpensively as they get to keep any difference between their procurement price and the NHS price (King's Fund, 2020), for smaller, independent pharmacies, however, this 'margin' tends to make up the majority of their income and if these margins decrease, their very existence may be in doubt. Further, the challenge for UK pharmacy has been that an increase/introduction of fees for pharmaceutical services has been linked to a reduction in dispensing fees.

In Sweden, the pharmacy margin is similarly regressive, so pharmacies receive a higher compensation for higher-priced products, but only up to a ceiling (Westerlund & Markland 2020. In Spain, although there is also a statutory regressive margin scheme for all outpatient medicines, community pharmacies have to make "claw back" payments to the national governmental health service based on their annual sales (Vogler 2020). The case studies from Europe show that even in countries with comparatively high investments in health, offering sufficient remuneration not only for the medicines but also for the additional clinical service is still challenging (Garattini et al, 2020).

Having fewer quality checks combined with downward pressure on price may result in compromising the quality of the private sector distribution channels (Hasnida et al, 2021). This is an additional consideration for LMIC governments to keep in mind when devising contracts with the private sector, such as ensuring resources are dedicated to ensuring lower-quality, substandard or falsified medicines do not enter the system.

Setting financial incentives to ensure product and service quality

The literature shows that the management of co-payments is another factor that is critical to understand (Kanavos et al, 2011). When customers are paying for a product that is set at different price points, the incentive is to dispense the most expensive products. When the payment is per person/client/customer, the incentive is to have more customers at a higher price but not always to provide better quality service. The pharmacy's incentives to sell a certain product may also influence the medicine user. For instance, their choice may be affected by the pharmacy counselling received. Publicly insured populations encompass vulnerable patient groups, including those who need family planning medicines and who may

be especially susceptible to medication non-adherence when required to pay (Sinnott et al, 2013). Non-adherence to FP has potential consequences and costs elsewhere in the system (Luiza et al, 2015).

Provision of start-up capital by banks or large wholesalers

Actors in the pharmaceutical supply and distribution chain must have sufficient financial expertise and capital available to them to open new outlets and to survive their initial growth period. For instance, banks that understand the pharmaceutical business and their attendant services could provide lines of credit and small loans. Pharmacists in LMICs may well need business training either as a part of their academic training or their accreditation/ licensing. The business environment and government regulatory frameworks play an important role in creating a favorable context for the private sector to flourish. For instance, in Mali, the opening of new retail pharmacies was promoted and facilitated by the provision of start-up capital by large wholesalers (McCabe et al 2011; Estevez et al 2020).

Although the topic of creating a context where private businesses such as retail pharmacies can grow is not the focus of this document, we would like to briefly discuss its relevance here. First, increasing investment in private retail pharmacies generally requires at least some understanding and overcoming of perceived/actual barriers to the contracting relationship in LMICs, including mistrust of the private sector; lack of business/management skills in public and private sector; poor information networks; poor monitoring/lack of HRs; lack of business management and marketing skills. Increasing investments can be improved by making it easier for the private sector to access loans (Barnes et al, 2010). All tiers of government could provide annual grants to serve as financial buffers to these private sector partners. Such grants will be conditional on: (a) grantee accounts to be available for annual auditing; (b) funds to be allocated according to either the numbers of people served and/or the packages of services provided; and (c) specific minimum service accreditation criteria to be met (Barnes et al, 2010).

Altering taxation rates will likely also be favorable for the expansion of the private sector. Various financing options might include tax exemptions or imposition of a minimum tax rate on the amount invested by various individuals, financial institutions and joint ventures setting up community pharmacies. Governments may support a partnership by providing revenue subsidies or by providing guaranteed annual revenues for a fixed period. Further, risks could be mitigated by providing market information on health care businesses and credit scoring.

Support from pharmacy services administrative organizations

Pharmacy services administrative organizations (PSAOs) provide a wide range of business services to all member pharmacies, often including the management of the business and operational aspects of the pharmacy, such as inventory, sourcing, working capital credit and invoicing. Their impact on considerations regarding contracting is worth noting. Independent pharmacies are more adaptable to their local context than chain pharmacies, yet independents often lack the tools required to deliver effective services, manage their operations, support patients who wish to pay cash and rely on fragmented and cash-based supply chains for medication of unknown quality. PSAOs can allow pharmacy owners/pharmacists to focus on customer service, while PSAOs manage the business and operations aspects of the pharmacy. This arrangement can allow for market access of a more varied portfolio of medicines, as well as improved quality of care (Health Evaluations, n.d.).

Digital tools to support retail pharmacies to manage their sales and stocks

The ecosystem of supply chain innovations in medicines distribution is growing. These include both consumer-facing offerings such as digitally enabled direct-to-consumer models for delivery of OTC and prescription medicines, but also provider-facing innovations which include inventory-management software and tech-enabled inventory services (Adeseun et al, 2021).

A provider-facing supply chain innovator worth highlighting here is Maisha Meds, which operates in East Africa and builds digital tools to help providers better manage their pharmacies. For instance, pharmacies can order medicines through the Maisha Meds' platform, which leverages sales data to design "smart" order packages based on prior sales volumes. In addition, Maisha Meds leverages the pharmacy point of sale (POS) system as a digital reimbursement platform to help global health funders and pharmaceutical companies subsidize products for high risk or low-income patients using mobile money, in this way improving market access. This latter capacity is especially noteworthy for the provision of medicines like FP, which are often understocked by retail pharmacies (Maisha Meds 2021).

EFFECTIVE GOVERNANCE

Necessary legal foundation for effective governance

Any public payer interested in contracting retail pharmacies at scale to deliver EMs and health services needs to set up an appropriate legal framework. A legal framework is necessary for the effective governance of a contractual relationship between the public payer and the retail pharmacies.

Part of this framework is the accreditation process for pharmacies which, in principle, should also form part of a contract or agreement with the public payer (Riley et al, 2017). The accreditation process often focuses on checking for inputs such as facility size, supplies and equipment, etc. It often oversees the assessment of the skills required to deliver services beyond initial professional licensure.

For example, accreditation requires were created when the Brazilian FPP program was extended to the private pharmacy sector. These included having a Health Surveillance Functioning Authorization, being compliant with commercial regulations presence of a certified technically responsible pharmacist, fiscal capability and infrastructure for a computerized system to issue invoices and receipts and be registered with the MoH. Despite its achievements in improving access, the program has been audited a number of times due to issues that compromise service quality, such as weak internal and administrative controls and lack of monitoring (Emmerick et al 2015).

To assure quality of service delivery, additional measures need to be implemented (see also Quality Assurance Section on page 53-54). This document does not focus on the requirements for such legal frameworks including the requirements for accreditation. We refer the reader to other publications such as the recent World Health Organization publication on the legal and regulatory framework for community pharmacies in the WHO European Region (WHO, 2019) or work by the United Nations Population Fund (UNFPA) in Latin American countries on contracting retail pharmacies (Villacorta Santamato & Ventura Pinedo, 2017).

Tools to promote product safety and fraud prevention

Ensuring product quality is critical for public payers contracting retail pharmacies because without ensuring quality, the public payers are wasting public resources in addition to risking the lives of users and patients. In terms of efficiencies but also ethically it would be difficult to defend any public payer contracting retail pharmacies without the payer also promoting product and service quality.

With respect to end-use dispensing strategies to prevent fraud, the Argentinian MOH, established a traceability system to be implemented by all persons and companies involved in drug products distribution and dispensation chains, including private retailers (GS1, 2014; ANMAT 2011).

In 2012, Turkey became the first country in the world to implement comprehensive legislation on the traceability of all medicines sold in its territory. Although stakeholders experienced both physical and software-related problems in its implementation, the alignment of incentives among all stakeholders with the power of the state, along with leeway for adaptations, ultimately resulted in a successful process. This "Pharmaceutical Track and Trace System" allows for the tracking of each drug unit at all phases from production to consumption, thereby ensuring the reliable supply of drugs to patients and the prevention of theft and scams. As an added benefit of this system, staff that were previously engaged in pharmacy inspections are now reallocated to ensure production quality, which reduces the risk of substandard medicines (Parmaksiz et al, 2020). For context, other countries and regions have enacted legislation that will require the traceability of all medicines. For instance, the United States implemented such legislation in a phased manner by the year 2023 (Riley et al 2017).

Effective regulation of retail pharmacies

Regulating the practice of pharmacy itself is different than regulating pharmaceutical products. The Medicines Regulatory Authority has the responsibility to regulate products but regulating pharmacy practice is often split between different agencies, including self-regulation by professional bodies. These professional bodies can either be federal or decentralized. Their capacity in overseeing pharmacy practice varies.

Although pharmaceutical product regulation may be similar across countries, the regulation of pharmacies is not (Riley et al, 2017). There are multiple reasons for this. Pharmacy councils are often self-regulating. Compromises have been made where pharmacy regulation is managed locally making it more difficult to provide federal oversight. This is especially relevant when public payers are contracting via locally managed retail pharmacies.

IT as a tool to promote effective governance

Governance requires effective tools to enact strategies such as oversight, monitoring, and reporting. The public payer needs to have information on the services provided to verify compliance with the contractual arrangements and to reimburse for the services. European countries have contracted private pharmacies for decades and IT systems have had many decades to mature. By contrast, many governments in LMICs, having not yet contracted third parties for the provision of services at a large scale, do not necessarily have IT capacity to enable efficient dispensing verification, invoicing, and payment, which are critical to efficiently contract these services.

In Brazil there is no robust IT system for the tracking of medicines to avoid issues like fraud and illegal commodities. This eventually contributed to the termination of the FPP (Governo Federal, Ministerio da Saude 2018). It has been documented that during the implementation years of the Aqui ha Farmacia Popular (AFP) (i.e., the private pharmacy component of the Farmacia Popular Program (FPP)) years in Brazil, medicine dispensing occurred without accompanying key documents, such as copies of prescriptions, and there were no intelligence activities to detect possible fraudulent conduct (Luiza et al, 2018). The lack of such a system may lead to discrepancies in pharmaceutical health system management performance and, consequently, to inequalities in population health outcomes (Emmerick et al 2016).

Electronic transfer of payments from the public payer to the retail pharmacies

One of the reasons of why reimbursement of pharmacies took so long in Ghana was the extensive labor involved in processing claims due to the absence of sophisticated information systems (Ashigbie et al, 2019). For countries with a very large number of small retail pharmacies (e.g., Bangladesh, India) building an adequate IT system is critical. Many small businesses rely on prepayment digital wallets (e.g., M-TIBA[1] which means that they can receive payments. Building those into IT systems is important because they are also very data-rich platforms (Yadav and Glassman, 2019). Tapping into these platforms brings important benefits but also requires governments to rapidly scale up their applications to make it possible to electronically send payments to small businesses and to check claims and approve them in a timely manner. Moreover, there is a need for HR in the area of health IT and the necessary legal framework for such systems.

Greater transparency in documenting services provided through digitalization

mClinica serves as another technological tool used to manage supply chains in an attempt to improve markets struggling with inefficient supply chains, poorly trained pharmacists and legal bottlenecks. mClinica's system now reaches more than 100,000 pharmacy professionals across Indonesia, Malaysia, the Philippines, Thailand, and Vietnam. To date, mClinica has offered a mobile application that electronically digitizes prescriptions using machine learning and image recognition to address challenges at the pharmacy level. mClinica provides critical information on drug distribution and dispensation in what were previously non-transparent markets (Koh, 2018).

Nimble IT systems that are most suitable in a LMIC context

It is important for any contract to enable quality services. To do so, pharmacies need information about their clients (e.g., risk factors, past service use). Scaling up information technology systems does not come without with data privacy concerns and other legal issues. Models in HICs with vast electronic medical record systems and decades of maturity will not serve many LMICs. More nimble IT systems are needed. For example, in Spain, in recent years there have been various technological advances and pilot schemes for community pharmacies. There is an app for the management of professional services for community pharmacists which enables them to visualize and monitor the health problems of their patients (Matarranz & Satue, 2016).

Leapfrogging- i.e., jumping development stages that other countries had to go through, seems more realistic in the case of LMICs using IT systems that are flexible and do not rely on constant electricity. Many applications for mobile phones already allow pharmacies to be in constant communication to

[1] M-TIBA is a mobile-based health wallet which is popular in Kenya. https://mtiba.com/

exchange information. These applications are thought to be the future of rapid information exchange. It is important to note that although a step in the right direction, not all functionality is able to get onto a mobile application, and that not all LMICs have access to good network coverage.

MARKET AND SUPPLY CHAINS THAT ENABLE PRIVATE PHARMACIES TO DELIVER QUALITY SERVICES

Detailed market study, including the supply chain, provides critical evidence for decision-making

When LMIC governments plan to contract retail pharmacies to deliver EMs, a thorough market study on supply chain security in the country is essential. For instance, Ghana's national health supply chain system was assessed in 2019, in a joint effort by the Ministry of Health (MOH), Ghana Health Service and USAID. Although the focus was on the public sector, the assessment provided details on the current state of Ghana's health supply chain in terms of its capability, functionality and performance (USAID Global Health Supply Chain Program and Supply Management, 2020).

An analysis of the public sector system can help determine its existing capabilities and performance weaknesses. To understand whether some of the needs can be met through a contracting-out model, it is critical to obtain an accurate picture of the private health sector. Based on its work conducting private health sector assessments across 32 countries, the SHOPS PPLUS Project standardized a tool to help capture key private sector information. The tool's elements are : 1) policy environment and regulatory issues, 2) health financing opportunities, 3) documentation of provision of health services, 4) mapping the supply of commodities, and 5) analyzing the demand for priority health services and products. Private sector analyses allow for an understanding of the key stakeholders, preference and source of products. These factors help identify opportunities for and maximize public-private sector collaboration for health (SHOPS Plus, 2016).

Although not systematically used across the globe, such situational analyses recognize the importance of considering the context in which new contracting models are to be implemented and how they aid the development of targeted, actionable recommendations across the entire supply chain to achieve its goals (USAID GHSC-PSM, 2020).

Increasing efficiency through centralized dispensing

Although research has traditionally focused on retail pharmacy chains to drive improvements in access to medicines, it is worthwhile to consider the role private wholesalers and distributors could play in partnership with governments to increase health care product availability in selected country markets. In countries that are showing rising dispensing volumes in a fixed budget, pharmacies need to improve their efficiency in filling prescriptions. Pharmacy chains may need to centralize dispensing within their own networks. Independent pharmacies may need to rely on wholesalers to deliver central dispensing services or develop cooperative or in joint-partnership models if wholesalers do not assist in this regard. In the UK, some pharmacy chains with repeat prescriptions are connected to regional, centralized dispensing of such prescriptions (Kearney, 2021).

Centralized dispensing, such as for example using e-pharmacies with courier services, is essentially a transformative process which will require significant capital investments, changes to regulations, and development of IT systems to support the new operating model. Any savings generated for the

healthcare system should be reinvested back to the relevant stakeholders to ensure sustainability (Kearney, 2021).

Provision of stock financing, inventory management and group purchasing organizations

Without access to a regular supply of working capital, retail pharmacies can struggle to maintain an adequate inventory of drugs and other supplies. In Nigeria, one of the most consistent financing needs is to avoid stockouts. A SHOPS Plus activity that expanded financing to smaller pharmacies and drug shops allowed Nigerian pharmacies to expand volume and the range of pharmaceutical products they offered, thus increasing client visits, including those for FP (Estevez et al 2020).

The capabilities of private wholesalers and distributors are impacted by the environment in which they operate (e.g., regulatory hurdles). However, many wholesalers also have the capacity to offer high-quality services to companies that want to distribute their products in these markets. For instance, several emerging innovators in product distribution, mainly in Africa, are seeking to disrupt markets for health product provision and improve provision at scale by lowering the mark-ups along the supply chain, reducing the transaction costs required to get products and reducing the variability in prices for their consumers (Hansen & Eldridge, 2019). They do this by offering strategies such as providing consumer information and direct- to- consumer distribution, and supporting stock financing, inventory management systems and group purchasing.

In Kenya, the first private commercial group purchasing organization (GPO), MedSource, was introduced in 2017 by MSH. MedSource bridges the gap between pharmacies and suppliers' aggregates purchasing volume and uses the economies of scale it creates to negotiate discounts. MedSource allows its member pharmacies and pharmacy chains to buy medicines at better prices than would otherwise be available to them, and ultimately provide affordable, quality medication to the population at large (MedSource 2021).

Some companies offer a blend of consumer- and provider-based strategies. For example, Advantage Health Africa offers stock financing and vendor-managed inventory services to hospitals and pharmacies and digitally enabled direct-to consumer services (Adeseun et al, 2021)

By adopting these strategies, these product distribution companies, in principle, offer transparency with respect to movement of products from the manufacturer down to facilities and pharmacies. With facilitated product movement, availability is likely increased.

While a lack of accessible technology for rural communities and poor access to products remains a widespread barrier to rural scale, some companies do have the potential to reach rural providers with some level of service (e.g., Maisha Meds, Healthy Entrepreneurs and Copia), and some companies have even made this their explicit focus (Hansen & Eldridge 2019; Adeseun et al, 2021). Public payers selecting with whom to contract with should consider contracting companies that adopt such purchasing strategies.

Procurement policies and existence of health insurance to support local markets

Government procurement policies and the availability of health insurance are important factors that determine the size of the pharmaceutical market and the country context. They need to be taken into

consideration. With health insurance and procurement policies that allow the public payer to call upon private sector resources, Ghana was to develop a relatively large pharmaceutical market. By contrast, in Mali there is no local manufacturing sector. However, the dominant private sector wholesalers have close ties to France so that relatively efficient global supply and national distribution networks can supply public sector outlets (McCabe et al 2011). In Malawi, there are no such close ties to outside governments and the Malawian government offers little support to local private sector manufacturing or local wholesalers. It therefore relies on procurement and supply through international tenders and international donors (McCabe et al 2011; Estevez & Griffith 2020). Public payers planning to contract retail pharmacies need to take the local supply chain structure into consideration as mentioned earlier in the section on the advantages and disadvantages of contracting retail pharmacies. Contracting retail pharmacies in Malawi will be more challenging because there is little support from local wholesalers.

Contracting chain versus independent pharmacies

When a government chooses to contract with a pharmacy chain, rather than dealing with multiple separate companies, it deals with only one administrative body that covers many pharmacies. By decreasing administrative costs and streamlining the process, this contracting model is less expensive than multiple contracting and easier to monitor, notably for quality assurance and other regulatory issues. In LMICs, contracting with pharmacy chains offers an opportunity to address issues of fragmentation in pharmacy retailing, poor quality monitoring and high prices that have not yet been fixed. This model has already been recognized by start-ups like MPharma in Ghana, which has acquired some of the largest pharmacy chains in Africa and is planning to leverage this by working with African governments to improve drug availability through better centralized systems (Adegoke, 2019).

In principle, pharmacies organized in a chain can impact brand visibility and centralized management systems which could encourage self-regulation and improve regulatory efficiency if government authorities focus regulation on central management structures. In practice, a recent study in India found, however, few differences between chain and independent organizations in these areas. Not all chains were operating with a qualified pharmacist. Drug control authorities did not take advantage of the existing chain architecture to enforce regulation. Chains did heavily self-regulate but their focus was on customer service, rather than on aspects of quality relevant to health outcomes. The incentives faced by chain employees tended to reward sales targets. A shift in focus from customer satisfaction to outcomes of public health concern is unlikely without either financial incentives or strengthened external regulation (Miller et al. 2017).

HUMAN RESOURCES FOR HEALTH, BUSINESS AND PUBLIC SERVICES

Financial incentives to retain qualified HR

The availability of capable HR is a key factor to ensure that contracts with private pharmacies support expanded access. However, HR and capacity development are areas that are lacking across LMICs such as in Ghana, where there is a clear divide with regards to career progression between pharmacists in public and private pharmacies. In fact, as of 2010 in Ghana, both the minimum and maximum annual pharmacy salaries were lower in the private retail sector than in the public sector. Not only were they lower, but they stagnated over an employee's life, posing a risk to retention in this sector (Ghana Pharmacy Council 2010). In other LMICs, the private sector may be more desirable to pharmacists.

Identifying and supporting these kinds of incentives is important for the public payer to successfully contract with private retailers.

At the same time, a contracting-out agreement that leads to efficiency and improvement in access, should not be undertaken at the expense of HR in the public sector. For a successful shift to a contracting-out model, the implications related to the loss of jobs in the public sector should be considered. For instance, a strategy to counteract this may be to develop HR capacity in the public sector to manage these kinds of contracting-out agreements.

Training and continuous professional education for pharmacy staff

Studies have shown that many pharmacists have poor knowledge of medicines and associated practices, especially for contraceptives. In Ghana, fewer than 50% of pharmacists attend courses on appropriate medicine use, medicines management and Standard Treatment Guidelines (STGs) (WHO, 2010). A 2016 systematic review of the performance of pharmacies across Asia's LMICs found discrepancies between knowledge and actual practice, suggesting a cause for the mismanagement of patients (Miller & Goodman, 2016). Similar issues are seen in Namibia, where development partners have been supporting the government with long-acting planning of pharmaceutical HR and building capacity of training institutions for pre-service and in-service pharmaceutical management training (Systems for Improved Access to Pharmaceutical and Services, 2016).

Task-sharing from primary care to pharmacies

The dispensing and administration of some EMs may require special training. For instance, injectable contraceptives that must be administered intramuscularly are often provided in health facilities whereas many client-initiated forms of contraception such as emergency contraception, combination oral contraceptives, progestin only pill, diaphragms or cycle beads tend to be provided at retail pharmacies (NIPORT/Bangladesh, et al 2016; Ghana GSS2014). Tash-sharing policies may allow, for example, trained community health extension workers or pharmacy staff to administer injectables. This task sharing to lower-level trained providers presents an opportunity to continue to expand access points for injectables to pharmacies (WHO, 2017). However, it should be noted that such task sharing programs are not trivial to implement because many countries require significant legal reforms, extensive training programs and the establishment of supervision and inspection systems if they decide to provide permission and allow retail pharmacies to administer long-acting contraception (Peterson et al, 2018).

Incentivize movement towards a patient-centered approach at service-delivery points

In HICs, there seems to be growing recognition that moving towards patient-centered pharmacy services holds great potential for improving access to services. Perhaps the best example of this is Sweden's pilot program in developing clinical counseling by community pharmacies (Dawoud et al 2019). Those in favor point to increased competition between retail pharmacies and primary care points leading, in principle, to better service to the public and more financial sustainability by attracting and keeping patients (Westerlund & Marklund 2020). However, if customers have a limited awareness about the medicines they are visiting the pharmacy for, it may well be difficult to build a pharmacy brand on this basis.

With this in mind, and the fact that knowledge of medicine types and management is a salient predictor of dispensing, the training and support of pharmacy staff are crucial aspects of effective implementation of contracting for expanded access such as for FP (Family Planning High Impact Practices, 2013), and should be extended to public and retail pharmacies alike. This can only happen if retail pharmacies are proactive in this area (Westerlund & Marklund 2020). As for FP, training should span FP methodologies and practice, as well as counseling and education, which are especially important in poorer, more underserved areas that may not be aware of existing FP options (Family Planning High Impact Practices, 2013).

EXISTING CHALLENGES OF CONTRACTING RETAIL PHARMACIES

Given these promising policies and strategies described above, there still remain challenges before these policies and strategies can be fully implemented at scale. The seven country case studies reviewed for this document demonstrate that a constant adjustment of contracts with retail pharmacies, laws and regulations, and market shaping mechanisms are necessary to ensure that the public payers' objectives of enhancing health, equity and financial protection are met. The for-profit model of retail pharmacies may well increase costs, and the inappropriate use of medicine, including FP products. Notably, the public payers' desire for financial sustainability can be in conflict with the need to expand patient-oriented service delivery via pharmacies. Figure 3 below illustrates four areas of existing challenges that were identified: 1) public payer's financial sustainability; 2) geographical accessibility; 3) quality assurance of services; and 4) patient-centered clinical services. These will be discussed in the following section.

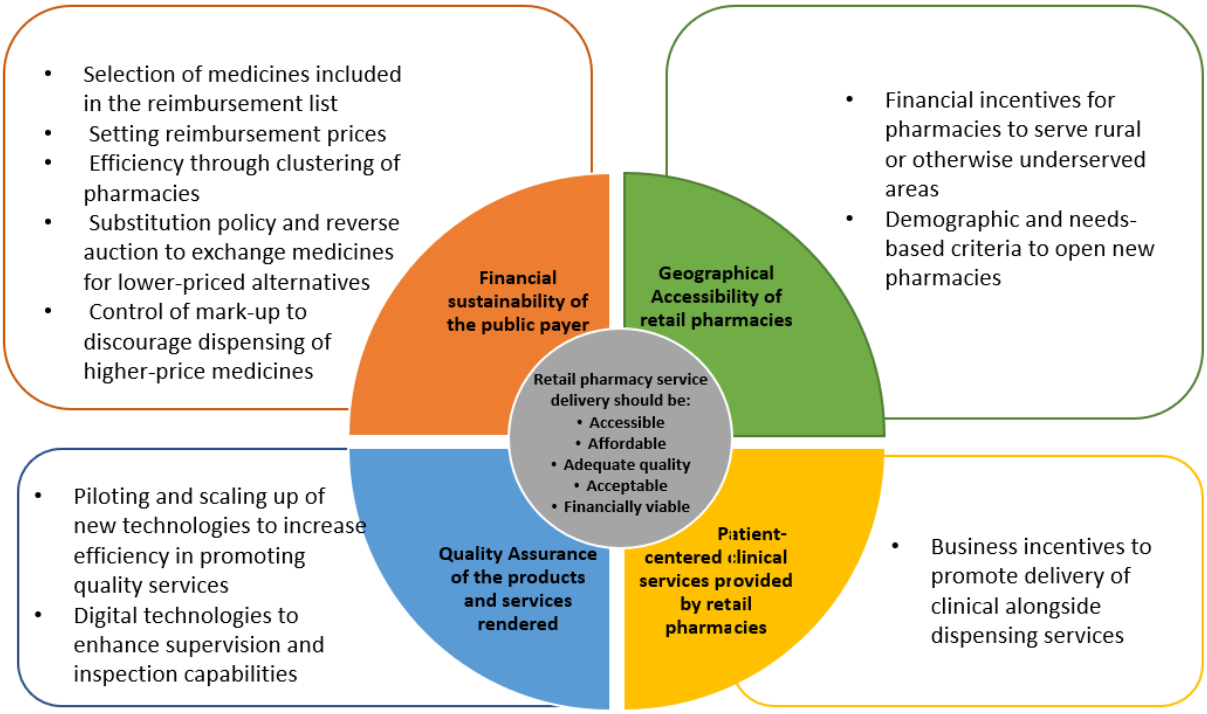


Figure 3: Existing challenges of contracting retail pharmacies

FINANCIAL SUSTAINABILITY OF PUBLIC PAYERS

The case studies highlight the difficulty of balancing financial sustainability of the public payer program with ensuring the affordability of the products offered to patients by retail pharmacies. For instance, in Brazil under the FPP the MOH set reimbursement prices for a limited list of medicines to be offered at accredited private pharmacies contracted under the program. The government agreed to pay up to 90% of the reimbursement price (da Silva & Caetano 2015). If the selling price was higher than the reimbursement price, the patient needed to pay the rest which meant increasing co-payments for patients. Many retail pharmacies kept the sales price higher than the reimbursement price to ensure

their financial sustainability and profitability but this affected the patients' affordability of the medicines. The Brazilian Government later decided to offer a limited number of chronic disease medicines free of charge at the point of dispensing in FPP affiliated pharmacies. However, the financial sustainability of offering chronic disease medicines for free without any copayment seems challenging for many countries given their current financial investment in pharmaceutical benefit packages. The case study from Brazil illustrate that the governments have to be mindful to create regulatory and policy environment that allows businesses to be profitable while ensuring affordability of essential medicines for the system and their users.

To that effect, a set of policies is necessary to ensure the financial sustainability of public payers including selecting medicines to be included in the reimbursement list and setting reimbursement prices as previously discussed. In the following section below, we highlight the case of Sweden which illustrates policies to ensure the financial sustainability of the public payer while maintaining business incentives and the affordability of medicines and services (TLV, 2020).

Substitution policy and reverse auction to exchange medicines for lower priced alternatives

Sweden introduced a substitution policy (pharmacies being allowed to exchange medicines for cheaper alternatives- this procedure commonly called "Products of the Period"). Briefly, under the medicine exchange program, the government decides which generics are exchangeable. Such exchange groups are selected on a monthly basis and the company with market authorization of a selected product is required to enter into a contract in which the company attests to specific stipulations regarding the company's financial and logistical capacity in order to be able to participate in this pricing and purchasing mechanism. The final selection mechanism uses a reverse auction approach where the company with the lowest bid is chosen in the exchangeable program (TLV 2020; Chivi 2020).

This exchange/auction system has its own advantages and disadvantages. From the perspective of the end-customer, the system provides lower prices and more affordable medication. However, there is a lot of up-stream logistical and administrative work needed to support the system. Each month, forecasts must be made and stocks filled with the new medicines that have been assigned to be exchanged. Managing all this is considered time consuming and inefficient because much logistical supports are needed to cover several deliveries of potentially new products each month. There is also a perception that some pharmacy chains are more prioritized than others by the wholesalers, resulting in backorders at some specific pharmacies (TLV 2020).

Control of mark-up to discourage dispensing of higher-priced medicines

Controls on mark-ups to discourage the dispensing of higher-priced medicines were introduced in Sweden using a regressive formula (Yadav, 2015). The formula determined that the mark-ups for higher priced medicines should be less than for lower-priced medicines.

Since Sweden's deregulation, over time, the number of pharmacies increased, the opening hours were longer, and patient satisfaction scores were higher. According to Bergman et al (2014), the deregulation context (including regressive mark-ups) not only reduced the cost for consumers, and also maintained a financially sustainable market for retail pharmacies, wholesalers and pharmaceutical companies.

Overall, the Swedish experience suggests that a set of complementary policies that aim to make medicines affordable to the public payer and the user while providing sufficient business incentives are required to promote the sustainability of contracting retail pharmacies long-term.

GEOGRAPHICAL ACCESSIBILITY OF RETAIL PHARMACIES IN LOW INCOME AND RURAL AREAS

Strategies to incentivize the use of retail pharmacies in less wealthy or less populated areas is one way to allow for sufficient equitable access. Brazil's Farmacia Popular Program provides an important lesson that the inclusion of more retail pharmacies does not necessarily result in the desired level of equity in geographical access. Although it first used public pharmacies to dispense a list of subsidized medicines that were purchased by the federal government, the program was broadened by contracting accredited, retail pharmacies to allow greater expansion and geographical coverage. Including accredited private pharmacy outlets in the Farmacia Popular Program led to a considerable increase in the number of pharmacies, although the geographical distribution was still skewed towards the wealthier South and Southeast areas of the country and equity concerns remained. (Emmerick et al, 2015).

Financial incentives for pharmacies to serve rural or otherwise underserved areas

Sweden makes funds available to support rural pharmacies. (WHO Europe- Legal and Regulatory Framework 2019) and Scotland, Northern Ireland and Wales guarantee a minimum monthly pharmacy income. They are way in which public payers can promote geographical accessibility. In Spain, access to new licenses for retail pharmacies entails public tendering. However, once the pharmacist has won the license for a specific location, the license becomes a commodity and this sets up a market for pharmacies/licenses, though only another pharmacist can buy a retail pharmacy (García-Armesto et al, 2010).

Demographic and needs-based criteria to open new pharmacies

The evidence about policies incentivizing equitable accessibility suggests that arrangements for retail pharmacy funding that rely solely on distance from one pharmacy to another as the means of determining funding allocation are ill-advised because this could penalize community pharmacies in the most deprived communities, and potentially have a negative effect on other healthcare providers, such as general practitioner and accident and emergency services (Todd et al, 2018). In Spain, equity and access to pharmacies seem to be better achieved by establishing demographic or needs-based criteria to open new pharmacies including "farmacia-botiquin" (pharmacy outlets) in rural areas, i.e., where pharmaceutical services are provided by one of the pharmacies in the nearer towns or villages. Amongst those nearby pharmacies, one of them is designated and this one will be the only one eligible to cater to that portion of the population that is geographically isolated (Lluch & Kanavos, 2010; Barbarisi et al 2019).

Nevertheless, in principle, pharmacies in more rural areas should be able to join together to benefit from joint deliveries to their community. This cooperation should also be extended to the purchase of medicines. Although others have highlighted the potential benefits of greater use of technology to strengthen and secure pharmaceutical supply chains (such as bar codes, RFID [radio-frequency identification], e-procurement or e-payments) (Parmaksiz et al 2020), such technological initiatives may be difficult to implement in country contexts where many of the retail outlets are simply too small.

QUALITY ASSURANCE OF PHARMACIES

There is a history of countries having attempted to extend access to medicines by allowing those with no or limited training in healthcare or pharmaceutical dispensing to sell certain limited selection of medicines (usually anti-malarial medication, analgesics and other over the counter medicines (OTCs)). Often these outlets including pharmacies are small single owner-run businesses with high overheads. This model proves problematic because knowledgeable staff are not present to advise patients. This is relevant to the issue of contracting out to private pharmacies, because when doing so, public payers have a strong financial interest in ensuring that the pharmacies provide quality products and services. If the products and services provided are of low quality, the payers would waste their resources. Hence the need for monitoring and accreditation requirements.

Piloting and scaling up of new technologies to increase efficiency in promoting quality services

New technologies may provide the means of providing medicine security (i.e., quality, safe medicines) and improved access (see the Section on Lessons from the COVID-19 Pandemic below). In many HICs (e.g., Spain and Sweden, among others) electronic prescribing has been widely used, but it is relatively new in many middle- income countries such as India. For example, online pharmacies in India require the customer to send their prescription electronically (Sajeet 2021). The increase in prescription data would allow easier review and quality checks by the public payers than paper records from retail pharmacies: Does the prescription match the dispensed medicines? How many prescriptions have been dispensed? When diagnosis is recorded on the prescription, does it match the medicine prescribed? With using a system where a physical copy was shown at the pharmacy or retained at the pharmacy, auditing of these records was very time intensive and hence, not the most efficient method.

Digital technology to enhance supervision and inspection capabilities

Scaling up the delivery of services and products via retail pharmacies requires enhanced supervision and inspection capabilities. There are opportunities to use digital technology smartly to lower costs of in-person inspections and supervisions. However, there is much room for development and current systems in many LMICs are underfunded in this regard. The LMICs surveyed for this document should have requirements aimed at supporting supervision and inspection efforts specified in the pharmacy contracts. These requirements should include the presence of technically responsible staff, and infrastructure for monitoring, such as computerized systems. However, this is often not effectively enforced. In Brazil, the national information system is not mandatory and still has low coverage (Emmerick & Luiza, 2016). Argentina does not have a framework for collaboration between regulatory entities and pharmaceutical organizations, seriously hampering the ability to enforce quality standards and control in private pharmacies (Armando et al 2020). Ghana and Namibia also face challenges, mainly due to the scarcity of resources and HR capacity (Ghana Pharmacy Council 2010; Eghan et al 2014).

HICs may provide some lessons about increasing the efficiency of inspection of pharmacies and their services. For examples, in Sweden, the pharmacy license holder must self-monitor its own pharmacy practice and ensure that there is a suitable self-monitoring program in place that has been customized for the specific pharmacy. One part of self-monitoring is conducting internal inspections on a regular basis. In the UK, pharmacies must have appropriate standard operating procedures (SOPs) for dispensing, repeat dispensing and support for self-care. The public sector requires only the determination of whether the pharmacy has an appropriate SOP but it does not require the government

to carry out a detailed analysis of the content of the SOPs. The UK's NHS suggests that the most appropriate way to determine whether the private retail pharmacy has an appropriate SOP is for the government inspector to ask to see it during a monitoring visit (but without reading it in detail), then to ask appropriate members of staff suitable questions about their procedures to establish the level of understanding and compliance with the SOP.

It would appear that, for LMICs, there is a limited menu of evidence-based options for professional bodies and policy makers to inform the improvement and development of pharmacy services (Miller and Goodman, 2016). This is due to many factors but certainly in part to HR limitations and the profit incentive. Studies on regulatory enforcement of pharmacy services in LMICs are not extensive. The efficiency of retail pharmacy inspection in LMICs could be improved by using digital technology. Moreover, other solutions such as improving market incentives for quality and a developing better-quality benchmarking in-country should be explored concurrently with regulatory enforcement (Van Assche et al, 2018).

PATIENT-CENTERED CLINICAL SERVICES PROVIDED BY RETAIL PHARMACIES

Looking ahead, in most countries the healthcare system needs to be able to do more with less—improving healthcare outcomes while increasing system efficiency. We suspect that in all countries, new responsibilities placed on retail pharmacies may not be associated with more public funds because there are longer-term funding pressures to deal with an ageing population (Solanski et al 2021). LMICs are not immune from this fiscal pressure which means that providing sufficient financial incentives to retail pharmacies to expand their role to counsel and provide patient care will be challenging. The concern around delivering patient-centered clinical services is relevant when public payers contract retail pharmacies to provide products and services. How will the public payer ensure that the services provided are patient centered? What incentives does the public payer provide to pharmacies to deliver those services? In the following section we summarize the conclusions of our case studies, notably from the UK, which that illustrate the trade-offs that public payers face when deciding which services retail pharmacies are expected to deliver and which will be delivered via primacy care clinics.

Business incentives to promote delivery of clinical services alongside dispensing services

Physicians are often viewed as superior to pharmacists in knowledge and training and their perceived authority can impact patients' views about pharmacists making medication recommendations (Stewart et al, 2020). This creates a division for patients between health-care providers, with physicians considered for diagnostic roles and more serious conditions, and minor issues more suitable for pharmacists. The potential conflict that the current- primarily business-oriented commercial environment- poses also need to be addressed because numerous reports show that patients and the public are suspicious of pharmacist commercial affiliations and financial motives (Hindi et al, 2018). On the one hand, large pharmacy chains, however convenient and accessible, will still need to transform patients' perceptions if they are to be considered trusted clinical advisers as much as independent pharmacists. On the other hand, independent pharmacies will have to find innovative models of cooperation to enable the evolution into a more clinical model. These new models will take many forms, and some are already emerging. For example, in the UK clusters of independent pharmacies are coming together under limited liability partnerships to tender for certain services (NHS Digital, 2019). Therefore, many independent

pharmacies will need to consolidate to survive, align themselves to local needs and become better integrated with other players in the healthcare system. In Scotland, national specification and commissioning of services have resulted in an enhanced role for pharmacy through the introduction of four core contract-based pharmacy healthcare services that were specified, commissioned, and negotiated at a national level but with great importance on adapting local delivery to the needs of the community (NHS Lothian, 2012).

LESSONS FROM THE COVID-19 PANDEMIC FOR CONTRACTING RETAIL PHARMACIES

Although this thought leadership paper focuses on the contracting of retail pharmacies for the provision of EMs for public sector users, it is essential to situate this topic in the broader context of health system strengthening and the current COVID-19 pandemic. The pandemic has brought a seismic change for health systems around the world including disruptions to the delivery of medicines and vaccines. For example, the WHO national survey on the continuity of essential health services during COVID-19 found that 94% of 135 countries reported some kind of disruption to sexual and reproductive health care in early 2021, and 40% reported disruptions to FP and contraception services (UNFPA 2021).

The COVID-19 pandemic has forced public payers of health care to re-think the delivery of public health services by pharmacies (Hamid et al, 2020). The rethinking also includes the re-assessment of what type of retail pharmacies to deliver EMs and FP are actually effective in improving medicines access. For instance, during the pandemic many countries have seen large shifts from in-person consultation services to telehealth services which providers plan to maintain for the coming years (Hamid et al, 2020). Similarly, many retail pharmacy businesses from small to large have transformed service delivery, offering delivery services or contract with other business to have their medicines and other products delivered to their customer's home or close to their homes (Miller et al, 2021). Online pharmacies have seen a large boost during the pandemic. These trends are expected to increase over time. Consequently, the shift from in-person pick-up to an increasing number of online pharmacies with home delivery would mean the need to consider contracting such pharmacies in certain locations to deliver medicines to public sector users. With respect to contracting services, online pharmacies that provide delivery through courier services hold potential for some market consolidation, leading to procurement economies of scale.

Contracting online pharmacies platforms with medicines delivered via courier services

One country in which online pharmacies has grown fast is India. PharmEasy, 1mg Practo, Netmeds, and Medlife are only a few examples of large enterprises offering services to a growing number of customers. All of them have developed applications for mobile phones. Orders get delivered within a day or two. PharmEasy and other applications offer a free doctor consultation at the end of the electronic check out process for customers who do not have a prescription. With respect to the focus of this document two key requirements stand out. First, if public payers contract these online pharmacies, it is necessary that these pharmacies accept third-party payments. Second, there needs to be a mechanism of verification that services were rendered in adherence with established safety and quality standards (see also the sections on Promising policies and Strategies, and Effective Governance above).

Decoupling dispensing services from advice and care services

Some aspects of online pharmacies contracted by public payers may facilitate regulatory control and thus improve access to medicines. For instance, if online pharmacy records were to be made available to regulators, traceability would improve, allowing the public payer to gain insights on the authenticity of prescriptions and compliance. Another advantage of the online pharmacies model is the decoupling of pharmacy dispensing advice from physical dispensing of products by using digital technology. This means

less investment in the training of thousands of pharmacy staff at retail pharmacies; instead, only the staff in call centers would require high-level training and could be supervised through audio recording of the calls or observation of calls in the centers. One example of such digital platforms for FP health information is AskNivi used by Pathfinder. Such decoupling of location would provide public payers the ability to contracting online pharmacies for the dispensing and shipment of medicines and contract another provider, such as AskNivi, to ensure access to high quality pharmaceutical care. The pandemic has accelerated the demand for contactless health information and service delivery which will influence public payers in their decisions about whether to contract retail pharmacies and which type and mix of providers to choose for service delivery (Oxford Business Group 2020).

Identification of target populations of virtual versus in-person services

Although online pharmacies offer convenience, time savings and possibly lower prices, their limitations should be noted. Well documented is the issue around patient data privacy, and that financial transactions should be secured through adequate use of encryption technology. Another well documented issue that will be relevant to public payers' obligation to ensure adherence to regulations is the lack of physical evaluation in place for online pharmacy providers (Chordiya & Garge, 2018).

When public payers consider contracting online pharmacies instead of retail pharmacies with physical location in the community, it is important to identify those patients who are most likely to benefit and those who are most likely to be excluded from the benefits of the online pharmacies model. Would vulnerable populations such as the elderly, poor people, and people with low education have more or less access to online pharmacies that provide delivery via courier services or some other form of shipping?

Contracting retail pharmacies to deliver vaccines and other public health interventions to address the pandemic

The COVID-19 pandemic has also resulted in many public payers contracting retail pharmacies for additional services to promote public health, such as the administration of COVID-19 vaccines. For example, pharmacies in the UK can enter into a sub-contracting arrangement to serve as a vaccination site and are remunerated for each vaccination administered (NHS 2021). Several other European countries have contractual arrangements with pharmacies to administer vaccines (Paudyal et al, 2021). It has been argued that pharmacy staff are especially well placed to address misinformation about the COVID-19 vaccine given the trust that many of them have in the community (Appiah et al, 2021; Maidment et al 2021). Therefore, contracting retail pharmacies to dispense medicines including vaccines could help booster dissemination of trustworthy health information to public sector clients.

FINAL REFLECTIONS ON THE ROLE OF PRIVATE PHARMACIES IN DELIVERING EM, INCLUDING FP, TO PUBLIC SECTOR CLIENTS

In this thought leadership paper we examined the advantages and disadvantages, and the promising policies and strategies of contracting retail pharmacies to provide EMs including FP products to public sector clients. In many LMICs the public sector supply of medicines has suffered from chronic underfunding, stockouts, long-waiting times, inconvenient opening hours and low user satisfaction. In addition, a substantial number of LMICs rely on donors to sustain their public sector supply chain. Unless these LMICs want to assume the costs of maintaining a large and separate supply chain they may have to transfer some of the distribution to the retail pharmacies. This transfer comes with benefits and costs.

The case studies and the complementary literature presented in this document show that by contracting retail pharmacies, public payers can tap into the expertise of the private sector in medicine supply, distribution and dispensing. It also shows that contracting retail pharmacies when facilitated by IT and alongside new business models could offer potential game-changing opportunities to increase access to medicines including to population groups that previously struggled to access the public sector. These opportunities include the business model of product stock financing by wholesalers, inventory management, GPOs, participation in public sector procurement and decoupling dispensing from delivering counselling and care services. It is essential that donors and governments alike invest in evaluating these new business models and in bringing them to scale if they successfully meeting their objectives.

The contractual relationships described here need to deal with the special nature of EMs which are different from selling non-essential goods such as clothes. Medicines including, FP products, require retail pharmacies to ensure the safety, quality, and appropriate use of their products. They require pharmaceutical services that dispense medicines, to follow SOPs to ensure product quality and safety, and quality service, including maintaining physical privacy and have attentive, understanding and knowledgeable personnel, some with training (e.g., safety of emergency contraceptives, using long-acting methods, such as injectables). As this document discusses, this requires that the public payers have the capacity to develop, implement and enforce the contracts. In some cases, this will require changes in the legal framework that underpins the operations of both public payers and retail pharmacies. It may also require changes in the management of professional associations that have a role in overseeing retail pharmacy standards and individual professional standards.

If the public and private sectors want to successfully adopt new policies, they need to target particular profiles of users to increase access to medicines, and should assess the performance of contracting retail pharmacies, especially on access to medicines at the household level. This may require adding questions to routine household surveys, such as the national Demographic and Health Survey (DHS) that is carried out with the support of USAID in collaboration with other organizations. Collecting information on EMs, in addition to FP products, would be at marginal cost because the DHS already collects information on FP products. We recommend doing this routinely for all countries where the survey is conducted. The evaluation of policies is critical to learn from their achievements and to adjust them to improve their performance.

Looking into the future of public payers contracting retail pharmacies is a complex exercise. Contractual relationships as described must continually balance how responsibility for service delivery can be shared between the public payer and the retail pharmacies so that the retail pharmacies as businesses remains a viable or attractive option and the public payer remains financially sustainable and accountable for safeguarding a comprehensive UHC service delivery system that ensures equitable access to affordable EMs.

Not everything can be "resolved by contract" as it were. The relationship between a public payer and retail pharmacies must be specific to the particular context. For example, it is certainly possible that LMIC governments considering contracting retail pharmacies can lower barriers to entry of pharmacies in rural areas by outsourcing their operations to private providers. But this is likely to fail if the resulting retail business is not incentivized to initiate operations in the first place. Providing multiple purchasing functions (e.g., broadening the market to have various wholesalers or have public-sector managed supply systems) so as not to rely on only a few wholesalers might also encourage retail competition but possibly at the expense of the smaller business' return on investment. This highlights the importance of LMIC governments interested in contracting retail pharmacies to conduct a thorough situational analysis, and to consider and devise locally appropriate policies to create a context in which contracts can truly be efficient.

Such contracting must therefore be seen within the entire health, financial and business "ecosystem". This balancing act is, in our view, the key to understanding how public payers can effectively enter contractual partnerships with private retail sector pharmacies. Examples from Brazil and Ghana are insightful in this respect because they illustrate that the public payers had to make a series of adjustments over more than a decade to carefully calibrate strategies that were appropriate for both, the large health system and the market sector context. This requires recalibrating roles and accountability over time and changing circumstances. Some of the challenges and potential solutions described in this paper may offer some insights on how public payers can successfully contract retail pharmacies.

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