

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

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Annexes to Retail Pharmacies as a Source of Essential Medicines for Public Sector Clients in LMICs

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ANNEX I. KEY RECOMMENDATIONS ON OUTSOURCING PHARMACY SERVICES

Source: Santamato V & Pinedo V. Externalización de los servicios de farmacia en el sector público de salud en América Latina. New York: UNFPA; 2017. Available from:

https://www.academia.edu/43536082/Externalizacion_de_de_los_servicios_de_farmacia_en_el_sector_p%C3%ABlico_de_salud_en_Am%C3%A9rica_Latina.

1. *The design of a pharmacy service outsourcing process must start from a public policy perspective linked to the modernization and reform processes that the States are experiencing. The public administration must adapt itself to facilitate the attention of social demands and needs without losing coherence with its global strategy and governance values.*
2. *Effective interventions for the outsourcing of pharmacy services need a clear diagnosis that assesses the context by addressing socioeconomic and market aspects without overestimating their potential or underestimating their limitations.*
3. *Outsourcing can make pharmaceutical services more expensive by incorporating more transaction costs, and to the extent that it includes economic incentives, it can introduce risks of over-provision, diversions, and scams.*
4. *Pharmaceutical services can be outsourced in whole or in part, delivered to public or private companies, and implemented progressively based on criteria that prioritize areas with high population density, the poor, rural, and those at risk. The main thing is to maintain the public nature of its delivery and management.*
5. *To guarantee the proper delivery of outsourced services, it is necessary for the public sector to develop capacities and instances of its own or by third parties, to carry out monitoring, supervision, and control of operations, both at the administrative and assistance levels.*
6. *The design and implementation of an appropriate information system that collects quality data and provides timely information to support decision making is key. The characteristics of the outsourced service must be technically specified to achieve the acquisition of quality products and services and not only the delivery of products (pharmaceutical assistance).*
7. *The inclusion of co-payments is an alternative to alleviate public financing; it makes the user responsible and discourages the misuse of the system. Its acceptance can be positive if awareness and publicity campaigns are incorporated. Another mechanism that contributes to financial sustainability is the definition of public financing mechanisms through protected budgets, and selective taxes, among others, to create a revolving fund.*
8. *To design and facilitate the implementation of an outsourcing process, it is better to clearly define a public (or private) body that leads the process to preserve its value and health interest, without losing sight of the economic one. In addition to an implementation instance, it adds value to create a steering mechanism that is made up of different key actors to lead the process and promote the articulation of the technical level with the political level.*
9. *A broad participation of partners (pharmacies) should be guaranteed or encouraged in such a way as to promote competitiveness and avoid monopolies or oligopolies.*
10. *An efficient and effective payment mechanism for the service must be defined, so that over-prescription, over-dispensing, and/or use of higher-cost or lower-quality products are discouraged.*
11. *Efficiency mechanisms should be incorporated, for example, purchases at scale.*

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12. An *internal communication strategy* (in the institutions) and external communication (to the users) must be designed to publicize the program and its results.
13. Consider the *participation of civil society* in the oversight and transparency of the process.
14. The *list of products to be selected should be based on the identification of priority problems*, the scope of the program, a national list of essential drugs, and the guidelines or standards of care that define how it will be prescribed. The same information generated by the program serves as feedback to the health system itself to monitor and evaluate its operation.

Future changes in reimbursement can also provide a financial incentive for pharmacies and pharmacists to perform more consumer-facing functions. This will likely require retail pharmacies to have physical, virtual/digital, and home health strategies that elevate the human experience and build on what happens in their four walls. Here are four strategies to consider:

- A. **Use data to personalize interactions:** Integrated data (i.e., medical, pharmacy, lab) can be used to provide intelligent clinical interventions and more personal patient-pharmacist interactions. These types of tailored experiences can help pharmacies create stickiness with consumers and become an integral part of new care models. Pharmacies that can do this successfully will likely emerge as leaders in a post-COVID world, where personalized, in-person care is highly valued.
- B. **Develop actionable and dynamic segmentation:** Technology can be used to segment consumers by demographic and clinical data. It can also be used to leverage genomic, social, and other consumer attributes, as available. The key is to develop actionable segmentation that can adapt with the consumer. Recent Deloitte research shows how actionable segmentation can provide valuable insights about healthcare customers. Once consumers are segmented, pharmacists can tailor the way they engage with each unique group to help create an emotional attachment to the brand. For example, knowing which consumer segments are most susceptible to COVID-19 infections could help improve responses to future infectious diseases. Segmentation could also help pharmacists coach patients in a more culturally sensitive and clinically appropriate way, while also understanding how their needs might vary as their disease progresses or based on other barriers to care.
- C. **Enhance the algorithms:** Algorithms can be used to determine when patients are likely to become non-adherent to a prescription, but they need ongoing input to learn over time (e.g., why a patient is not being adherent). By complementing the data-driven insights with face-to-face discussions, pharmacists can create a memorable and emotional experience for consumers. Pharmacies that use such algorithms could have a meaningful impact in reducing health issues that can result from deferred and delayed care. The algorithms can help pharmacists understanding how to be proactive and when to coordinate care to address key risks for disease progression.
- D. **Localize care:** Healthcare is often local and requires a multifaceted approach to meet consumers where they are. Pharmacists can play a role in helping members of a community understand and improve the drivers of health, such as access to reliable transportation or healthy foods. There is extensive evidence that all these factors have an impact on health. Helping consumers overcome these barriers is important and often requires a hands-on approach.

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Adopting these four strategies will likely require time and attention from pharmacists, which are often in short supply. Around-the-clock service, centralized dispensing automation, and other technologies used by closed-door pharmacies could be perceived as a threat to brick-and-mortar stores. But they could also be an opportunity. Those same technologies could help free up time for pharmacists so that they can focus on the consumer experience to help secure the future of the retail pharmacy.

LITERATURE REVIEW METHODS

Databases and search terms

The literature search was conducted on PubMed, Google Scholar and CINAHL, and consisted of several topics related to retail pharmacy and public payer using a combination of medical subject headings (MeSH) and free text searches.

The Google Scholar search was conducted using primarily free text searches based on key concepts of interest. Full-text articles and indexed Cochrane reviews were identified through these databases and search engines.

The search included the following limits: publication date from 2010 to present, English, Portuguese and Spanish Language. In addition, we consulted with key experts on the topic to obtain additional references.

Inclusion and exclusion criteria

Publications identified during the database search underwent preliminary screening, through which the authors applied the inclusion and exclusion criteria to the titles and abstracts.

Authors included full-text articles which discussed the topics of retail pharmacy and public payer, related to the seven case studies of interest. Other inclusion criteria, as described above, were applied.

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 service public sector clients with regard to receipt of FP and other EMs. We selected the cases based on a mix of the following criteria: evidence of (1) a formal contract or agreement of retail pharmacies with 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 are well documented in terms of the contents of the contract or agreement with the private sector which have to be in place longer than 1 year and have demonstrated preliminary results and achievements. In coordination with the funders of this report we selected Brazil and Argentina, two upper-middle income countries in South America; Ghana and Namibia, two lower-middle income countries in Africa; and Sweden, United Kingdom (mainly England) and Spain, 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 report. We were unable to identify a low-income country that met the inclusion criteria.

Data extraction and analysis

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Once the relevant literature was identified, the data was reviewed to develop seven country case studies. Each case study is divided into two parts. The first part is a brief description of four aspects of the countries' retail pharmacies, and followed the questions:

1. How are retail pharmacies chosen by the public payer?
2. What services are retail pharmacies contracted to offer?
3. How are retail pharmacies paid for their services? Are there any incentives to offer high quality services?
4. How are retail pharmacies accredited, regulated, monitored and audited?

The second part of the case studies was a synthesis of the documents that assessed, monitored or evaluated the impact of policies and strategies on contracting private pharmacies' performance of the pharmaceutical series related to geographical accessibility, quality of pharmaceutical services, affordability, access to family planning.

The writing of each case study was key to the writing of the final report.

Once the case studies were reviewed by country experts and finalized, we extracted the advantages and disadvantages of contracting retail pharmacies to dispense medicines to public sector clients. For this, we focused on the advantages and disadvantages of such contracting arrangements for the public payer, the clients and the private sector.

This was followed by a thorough analysis of the key considerations that must be made when deciding whether and how contracting retail pharmacies should be conducted. To guide this analysis, we developed a framework which merged the general considerations needed by PPPs when contracting the private sector (2012 Work conducted by Barbara O'Hanlon as Principal Investigator and funded by USAID/SHOPS), with the specific considerations identified by the World Health Organization in its 2017 "Partnering with the private sector to strengthen provision of contraception" document. Six key dimensions were identified (1) Governance including regulation, 2) Contracting and reimbursement, 3) Affordability, 4) Quality of care, 5) Accessibility, 6) Patient-centered pharmaceutical care). We assessed each dimension 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?'

Finally, 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 discussed how they have addressed the related challenges with complimentary policies and strategies. We took into consideration the contextual factors such as the wholesaler and distributor market, the business regulations and incentive structures as well as 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.

Report revisions

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To verify factual accuracy, each country case study was reviewed by country-specific experts, who all provided feedback to be incorporated into the final version of each case study.

The completed report was reviewed by the MTaPS and USAID teams. Any feedback and comments were considered and incorporated into the report by the BU team.

In some instances, country experts and MTaPS/USAID team members provided additional references that were not included through the original literature search. Each reference was carefully reviewed by the BU team and information added or updated, where applicable.

Following a first review by the MTaPS team, an expansion and/or some modifications in some of the aspects of the initial report were requested, particularly relating to the topics of Covid-19 and online pharmacies. The team carefully reviewed each comment and suggestion and updated the report accordingly.

ANNEX 2. CASE STUDY OF ARGENTINA

Abbreviations

ANMAT	Autoridad Reguladora de Referencia Regional para Medicamentos
APE	Administration of Special Programmes
DMPA-SC	subcutaneous depot medroxyprogesterone acetate
EML	essential medicines list
FFS	fee-for-service
FSR	Redistribution Fund (Fondo Solidario de Redistribucion)
IT	information technology
OSN	Obra Social Nacional
OSP	Obra Social Provincial
PMO	Compulsory Medical Program (Programa Médico Obligatorio)
SSS	Supertinendencia de Servicios de Salud (Ministry of Health's Superintendent of Health Insurance)

Regulations, Contracted Services, Payments/Reimbursements, and Monitoring of Pharmacies in Argentina

In Argentina, the decentralized regulatory functions mean that the national health authority is limited in how effectively it can require provincial governments to adhere to new national legislation. The national Superintendencia de Servicios de Salud (SSS), which is the health sector regulatory body, controls the Obras Sociales Nacionales (OSN) portion of the national social insurance scheme funded by a compulsory payroll contribution from employees (3%) and employers (6%). The SSS monitors the OSN's contracts with service providers, including pharmacies. The SSS does not have regulatory authority over provincial social insurance schemes, which can lead to significant variations between regions in regulations and their implementation (Honda & Obse 2020). Overall, there are more than 300 national unions, each of which is associated with a specific trade or industry, and 24 provincial unions, one for each province. Each union contracts private companies, including pharmacies, to provide total or partial coverage for their affiliates (Novick 2017). The institution of the Compulsory Medical Program (PMO) in Argentina forced all health plans to cover a minimum of 40% of the cost of medicines, thus introducing some uniformity across plans. Among others, the PMO covers an extensive drug formulary, applicable to those medicines dispensed at private pharmacies. The reimbursement rate is based on the standard package of services defined by the government. In Argentina, the health subsystems do not pay for the medicines directly to the pharmacy. When patients obtain medicine from a pharmacy, they pay a percentage of the retail price. The difference in price is paid to the pharmacy by their health insurance (OSNs and Obra Social Provincial [OSPs]), through the intermediary of professional organizations, such as the Argentine Pharmaceutical Confederation and the Pharmaceutical Federation of the Argentine Republic (Armando, et al 2020).

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Argentina's national SSS controls and monitors the OSNs and their contracts with service providers but does not have regulatory authority over OSPs at the provincial level (Honda & Obse 2020). OSP monitoring efforts are spread throughout 24 jurisdictions and various subsectors. The SSS also does not monitor the Programa de Atencion Medica Integral, the fund for pensioners and retired persons that covers more than 40% of the pharmaceutical market.

Effects of the Information Technology Management Systems on Access to Services

Argentina serves as a successful case in the information technology (IT) systems realm. For the purpose of ensuring the control of medicines and contributing to eradicating the flow of illegal medicines, the Ministry of Health established, under the provisions of [Resolution 435/2011](#), a Traceability System that is to be implemented by all persons and companies involved in drug products marketing, distribution, and dispensing chains (GSI Argentina 2014; Autoridad Reguladora de Referencia Regional para Medicamentos [ANMAT] 2011).

In addition, to improve patient experiences with universal healthcare, the Ministry of Health recently completed a three-year project of creating a national digital health network that aims to automate the flow of public health statistics and manage underlying systems. However, it is unclear if this will include pharmaceutical service information (RedHat Summit 2021).

Effects of Contracting and Reimbursement on Access to Services

Argentina's OSNs contract private providers to offer total or partial coverage to their affiliates. Each year, the affiliates can choose the union that best fits their service expectations and preferences (Novick 2017); therefore, contracts vary across OSNs and OSPs from region to region. Lack of formal clearing or reimbursement mechanisms for any services in any of the segments of coverage leads to duplicity of provision of services and reimbursement inefficiencies. Individuals with formal coverage can receive healthcare from a public facility at no cost, burdening the public health system further, and its insurance company may never receive a bill for it (Novick 2017).

Geographical Accessibility

In Argentina, social and private health insurance coverage is positively correlated with the use of private facilities. In addition, economic development differences across provinces are correlated with availability of pharmacies and pharmaceutical products (Cavagnero, et al. 2006). A 2014 study that analyzed the accessibility of pharmaceutical products in the Buenos Aires region, including at private pharmacies, revealed the top reasons for non-availability of medicines as being errors in processes, ranging from issuing prescriptions, improper filling of forms, to non-availability of medicines at pharmacies (Parodi et al. 2014). This review found that geographical accessibility of pharmacies in Argentina has not been well documented.

Accessibility of Private Pharmacies Related to Insurance Coverage

According to the 2010 Argentine Population Census, 46.4% of the population have coverage of OSNs, while 36.1% do not have formal health coverage. In general, the Argentine system is an uncoordinated model where the greatest financial contributions are not directed to those subsectors that absorb the most significant financial and health risk (Palacios et al 2020).

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Not everyone in Argentina has access to the same health benefits and services. Coverage varies by plan (different unions offer different packages), and by region (economic development differences from region to region related to differences in availability and coverage). However, to compensate for the differences that may result in potential health inequities due to the disparities in earnings for each of the OSNs, a redistribution fund (Fondo Solidario de Redistribución [FSR]), composed of 10%–20% of each payroll contribution, transfers money from the wealthier to the poorer OSNs. It compensates low-salary workers who do not achieve their minimum contribution. The FSR also pays for the administrative costs of the SSS and for the Administration of Special Programmes (APE), which covers ex-post risk sharing in the OSNs covering high-cost and low-probability health events. In an effort to improve coverage equity, the national health authority ensures the population's access to the PMO, which covers outpatient visits, diagnostic testing, rehabilitation, hemodialysis, palliative care, prosthetics and orthotics, inpatient care, mental healthcare, interfacility transfer, extensive drug formulary, and high-cost care services, among other things (Rubinstein et al. 2018).

Quality of Pharmaceutical Services

Argentina does not have a general framework for collaboration among pharmaceutical organizations, regulatory entities, organizations of health professions, and universities to provide quality standards and guidelines of practice. This hampers the ability to effectively implement and enforce quality standards in the provision of pharmaceutical services at private pharmacies (Armando et al 2020).

Choice of Family Planning Methods

OSNs in Argentina provide coverage for medicines that are on the essential medicines list (EML) for inpatients and outpatients, including family planning. Regarding OSPs, coverage levels offered vary from province to province. The lowest coverage is in the Buenos Aires province. There is no common benefits package across the OSPs (WHO 2010).

In 2019, both Argentina and Namibia added subcutaneous depot medroxyprogesterone acetate (DMPA-SC; injectable contraceptive) to their national list of contraceptives, and they are now available at public facilities, private clinics, and private retail pharmacies, including for self-injection (UNFPA 2019).

Affordability

The initiation of the PMO in Argentina forced health plans to cover, at a minimum, 40% of the cost of medicines prescribed in the treatment of its policy holders. The PMO covers outpatient visits, diagnostic testing, rehabilitation, hemodialysis, palliative care, prosthetics and orthotics, inpatient care, mental healthcare, interfacility transfer, extensive drug formulary, and high-cost care services, among other things. Most of the ambulatory drugs for chronic conditions have a 70% discount, and some critical drugs, such as insulin and cancer drugs, are 100% covered. Implementing this program ensures that any entity that takes part in the dispensing of medicines wishing to be reimbursed adheres to the predefined list, and thus works as a means of ensuring more equity across the various OSNs and OSPs (PAHO 2012; Rubinstein et al. 2018).

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Although healthcare services are purchased using a range of payment mechanisms, in an attempt to improve efficiency in resource use, many mandatory insurance mechanisms have shifted or are shifting away from fee-for-service (FFS) to close-ended payment systems (i.e., capitation and case-based payments). Many Argentine OSNs have shifted from FFS to capitation payments (Honda & Obse 2020). This shift is of importance because capitation payments are a more sustainable and timely payment option (Rowan et al. 2019).

ANMAT is Argentina's independent government agency responsible for controlling the safety, efficacy, and quality of medicines, and their commercialization, registering, and/or granting authorizations. Each province has its own health authority that works jointly with ANMAT and can issue regulations. ANMAT has not issued specific regulations for fixing the prices of products under its control (Marval et al, 2018). This has resulted in the setting of prices at artificially high values. For instance, social security patients pay a percentage of the price of medicines that is calculated on the basis of the retail price, not the percentage actually paid by the consumer, which is much lower. In this regard, there is a cross subsidy from beneficiaries to the social funds.

Procurement and Supply Chain Management Challenges

Argentina's decentralized system contributes to procurement and supply chain challenges because medicine purchase prices are published across different government sources, and some of the sites contain information that does not appear in others. Overall, there is a lack of standardization of contracting data and vague descriptions of purchases (Colman 2018).

Vision for the Future of Pharmaceutical Services

Improvements in the implementation of a basic service package and in the quality of services may lead to some reduction in disparities in the use of public versus private insurance schemes due to the perceived quality of care, thus improving the use of private pharmacies.

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ANNEX 3. CASE STUDY OF BRAZIL

Abbreviations

AFP	Aqui ha Farmacia Popular Program (private pharmacy component of the FPP)
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)
CNES	Cadastro Nacional dos Estabelecimentos de Saúde (National Registry of Health Facilities)
DAF	Departamento de Assistência Farmacêutica (Pharmaceutical Policy Department)
EML	essential medicines list
FPP	Farmacia Popular Program
IC	injectable contraceptive
MOH	Ministry of Health
OC	oral contraceptive
OOP	out-of-pocket
SNP	Saude Nao tem Preco Program (private and public pharmacy component of the FPP)
SUS	Sistema Unico de Saude (Unified Health System)

Regulations, Contracted Services, Payments, and Monitoring of Pharmacies in Brazil

Although Brazil has a decentralized public healthcare system, known as the Unified Health System or Sistema Único de Saúde (SUS), it is the municipal government that is largely responsible for its implementation. However, the Farmacia Popular Program (FPP) was a centralized program (Luiza et al. 2018) established in 2004 as a government-subsidy system to expand the Brazilian population's access to medicines (Emmerick et al. 2015). The FPP had three modalities: (1) the FPP in public pharmacies (including university hospitals and nongovernmental organizations) selected via public tender; (2) the Aqui ha Farmacia Popular Program (AFP) in accredited private retail pharmacies that expressed interest in the program; and (3) the Saude Nao tem Preco (SNP), which was implemented in both public and private pharmacies (Emmerick, do Nascimento JM Jr, Pereira, et al. 2015). On financial sustainability, corruption, and public health grounds, the public arm of the FPP was terminated in 2018, closing 400 public service delivery points and shifting access to 32 essential medicines to the AFP arm, which had 34,000 private service delivery points (Governo Federal, Ministerio da Saude 2018).

The 14 years during which the public arm of the FPP was active were marked by significant achievements, including expanded access, decreases in mortality and hospitalizations, capacity building, and improved relations with the private pharmaceutical sector (Alencar et al. 2018).

Eighteen cities in the Brazilian Northeast were dependent on the public arm of the FPP, so when the termination was announced, a process to contract private pharmacies was initiated (Governo Federal, Ministerio da Saude 2018).

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When the program was extended to the private pharmacy sector, accreditation and dispensing requirements, and fiscal monitoring systems were devised.

Although geographic location and demographic density were not regulated, all participating retail pharmacies had to be accredited. (Non-accredited pharmacies were explicitly forbidden to use any originator in the FPP.) The minimum requirements for participation in the AFP program included having a Health Surveillance Functioning Authorization; compliance with commercial regulations; presence of a certified technically responsible pharmacist; fiscal capability and infrastructure for a computerized system to issue invoices and receipts; and being registered with the Ministry of Health (MOH) (Emmerick et al. 2015). FPP facilities are included in the National Registry of Health Facilities (Cadastro Nacional dos Estabelecimentos de Saúde; CNES). Inclusion of FPP facilities in the CNES means that they are recognized as health facilities and not just a common retail pharmacy (Emmerick et al. 2016). In the AFP, 90% of the reference price of a limited list of medicines is subsidized by the government, and the remaining 10% is paid by consumers out-of-pocket (OOP) and health insurance. Most items reimbursed by the government are included in the national essential medicines list (EML, known as RENAME). The AFP has its own reimbursement list and there is no regulation on the obligation to fit in the national EML (Bertoldi et al. 2019). The MOH makes payments directly to the accredited retail pharmacies after receipts of expenses are checked against dispensing information contained in the country's electronic authorization system (known as DATASUS). From these data, it is possible to retrieve information about each individual dispensation, including date of dispensing, name and quantity of the medicine dispensed, daily prescribed dose, MOH expenditure, and patient co-payment. It is also possible to identify gender, age, and geographical information at the patient level (Mendes da Silva & Caetano, 2015). In the event of any proven irregularities, and if no actions on the implementation and maintenance of the FPP were performed within 30 days, financial incentives were suspended and resources returned to the Health National Fund. Since 2005, Brazil's MOH ordinance subordinated the FPP to a specific MOH agency: the Science, Technology, and Strategic Health Products Secretariat. This MOH agency and the SUS Audit Department (known as DENASUS) are responsible for monitoring the program. In addition, the AFP is monitored by a committee consisting of government representatives, the Agência Nacional de Vigilância Sanitária (ANVISA; the National Health Surveillance Agency), and the private sector (Emmerick et al. 2016).

Challenges in the Regulation of Pharmacies in Terms of Access to Services and Medicines

Despite its achievements in improving access, the AFP has been audited in the past because of accreditation process issues, weak internal controls, lack of monitoring, and insufficient administrative control.

Inadequate or lack of inventory management have been reported. The Brazilian Federation Court of Accounts inspected the FPP and reported very weak internal controls for the 2006–2009 period. For example, medicine dispensing occurred without enclosing key documents, such as copies of prescriptions, and there were no intelligence activities to detect possible fraudulent conduct. Weak resource tracking was also seen in the financing of pharmaceutical services to FPP establishments. Payments to pharmaceutical retail establishments were recorded as Health National Funds (Fundo Nacional de Saúde) direct transfers. This system identifies which federation units have the highest

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number of pharmacies and highest payment volumes. However, specific medicines provided by the AFP-private program and the amounts spent on each medicine are still missing from the database (Luiza et al. 2018).

The FPP has been criticized about its reimbursement list, which is not regulated to fit in the national EML. In fact, inclusion and exclusion criteria for the FPP list are unclear, and some formulations included are not registered with ANVISA (Alencar et al. 2018).

Effects of the Information Technology Management Systems on Access to Services

There is no robust national information system used to track medicines in Brazil. The MOH launched HORUS, an information system that allows the control and distribution of medicines available at the SUS. The purpose is to enable the identification and registration of medicines taken by patients, and to facilitate electronic inventory management, expiration dates, screening, and pharmacoepidemiologic control of dispensed medicines. However, HORUS is not mandatory and still has low coverage. Accreditation for private pharmacies that want to be part of the FPP in Brazil requires information technology infrastructure, allowing for more efficient, streamlined processes among these pharmacies. These differences in policy implementation may lead to discrepancies in pharmaceutical and health system management performance and, consequently, to inequalities in population health outcomes (Emmerick et al. 2016).

Geographical Accessibility

In an attempt to counter equity challenges, Brazil is incentivizing the expansion of its FPP in the municipalities included in the “Brazil without Extreme Poverty” (“Brasil sem miséria”), a governmental effort to reduce disparities in the country (Emmerick et al. 2015).

A 2015 document review and ecological study described changes in geographic accessibility of medicines during the FPP in Brazil and showed that following the start of the private pharmacy component (AFP), FPP coverage increased in most Brazilian regions. However, those pharmacies remain unequally distributed across the regions. Specifically, the wealthier South and Southeast regions have higher coverage, whereas the relatively poorer North and Northeast regions have lower coverage (Emmerick et al. 2015). This consideration is particularly important in light of the recent termination of the public arm, which was the primary provider for 18 cities in the Northeast.

Beyond geographical distribution of private retail pharmacies, issues at the point of delivery pose barriers to access. Non-availability of medicines is also prevalent in Brazil, where stock availability does not meet the challenge of supplying essential medicines to the entire population (Bertoldi, Chaves, Ross-Degnan, et al. 2019).

Quality of Pharmaceutical Services

Despite a set of policies in place to improve access to medicines, such as the FPP, lack of human resources remains one of the main barriers to the expansion and improvement of this program (Emmerick, et al. 2016). Among the criticisms of the AFP arm for being profit-oriented, the FPP accreditation requirements have been able to preserve hygiene and, thereby, the quality requirements

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for participating pharmacies. However, AFP's business aims mean that clinical pharmacy services, such as counseling, health education, and appropriate use of medicines, are often not provided at these facilities (Alencar et al. 2018).

Choice of Family Planning Methods

Overall, it is clear that the AFP's focus remains on non-communicable diseases. However, in 2007, contraceptives were included in the AFP, and prescriptions for these medicines had a validity of 12 months (Emmerick et al. 2016). As of 2016, medicines that were applicable for AFP reimbursement that were also included on the EML were: medroxyprogesterone acetate; norethisterone enanthate + estradiol valerate; ethinyl estradiol + levonorgestrel 0.03 mg + 0.15 mg; and norethindrone 0.35 mg. Public health services also supply emergency contraceptives: levonorgestrel 0.75 mg and misoprostol 0.025 mg and 0.2 mg.

Emergency contraception is mostly accessed from private pharmacies. A 2015 cross-sectional descriptive study found that the highest prevalence of oral contraceptives was in the South region (37.5%) and the lowest in the North region (15.7%). For injectable contraceptives (IC), there was no difference between the regions. Access was higher for oral contraceptive (OC) users (90.7%) than for IC users (81.2%), as was direct payment (OC 78.1%, IC 58.0%). In the case of direct payment, 95% and 86.6% of OC and IC, respectively, were obtained from retail pharmacies.

The number of users who paid for contraceptives but tried to obtain them from SUS is important because it represents a need unfulfilled by the public service and that is often disregarded in medicine programming. About 1.4 million OC users and 200,000 IC users reported having tried to obtain medicines from SUS, accounting for 17.5% and 17.0% of OC and IC users, respectively, who paid for the contraceptives (Farias et al. 2016).

Affordability

In Brazil, zero copayments for asthma, hypertension, and diabetes drugs (through the SNP portion of the FPP) have led to more patients filling prescriptions through the FPP and, in turn, the proportion of days covered per patient (a proxy measure for adherence) has also increased (Bertoldiet al. 2019; Emmerick et al. 2016).

Two years after the implementation of the public arm of the FPP, the program was extended to include private pharmacies, where patients would be able to obtain medicines for hypertension and diabetes. In this plan, the MOH reimbursed 90% of the medicine price, and patients would be responsible for 10%. In 2011, the "Saude Nao Tem Preco" program was established, which made hypertension, diabetes, and asthma medications free of charge at all FPP service delivery points, including at private pharmacies. As expected, this significantly increased access to medicines, especially those for hypertension, diabetes, and later, asthma.

FPP has improved access to medicines in Brazil, offering better affordability in relation to OOP (Emmerick et al. 2016). For instance, the zero copayments in the SNP acted as an incentive for more patients to fill through the FPP. In particular, the FPP improved the affordability of hypertension and

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diabetes treatment (through the SNP arm of the FPP) after 2011, when those medicines became free (Emmerick et al. 2016). It has been shown that the FPP also led to large increases in the generics market share; generic use in FPP is greater than the national average. The reason for this is that generics have been prioritized in the program, meaning that providers, including private ones, are required to prioritize dispensing of those products. This supports the fact that policies that promote the use of generics offer a way to increase the efficiency of expenditures on medicines by encouraging the use of quality-assured medicines at lower costs (Bertoldi et al. 2019).

An important determinant of affordability is availability. A good example is Brazil. Although the availability of medicines in the public sector does not meet the challenge of supplying essential medicines to the entire population (Bertoldi et al. 2019), availability in the FPP was adequate ($\geq 90\%$).

As discussed in the geographical accessibility section, many patients (especially those in the Northeast) now face pricier medicines and longer commutes to a pharmacy that will cover their needs. The Brazilian MOH has analyzed price differences between the public sector and the AFP. In 2018, it introduced price adjustments to products dispensed through the program (Alencar et al. 2018). However, pricing concerns remain. Government data show that reimbursements to private pharmacies have been superior to the market prices of asthma, hypertension, and diabetes products. For example, the price of insulin in the private sector is 175% higher than when procured by the SUS (Governo Federal, Ministerio da Saude 2018).

Procurement and Supply Chain Management Challenges

Some individuals with prescriptions from Brazil's public sector and who could get them free-of-charge at the public dispensary (SUS) go to the FPP to obtain them instead. The reason for this might be the low quality of public sector services, medicine shortages, and factors relating to geographical proximity (Emmerick et al. 2016).

In Brazil, the FPP was jointly managed by the Departamento de Assistencia Farmaceutica (DAF; Pharmaceutical Policy Department of the MOH) and Fiocruz (The Oswaldo Cruz Foundation, a scientific institution for research and development in biological sciences functioning as a national institute of health for the Brazilian government). Although Fiocruz and public manufacturers were responsible for producing and distributing medicines for the public sector arm of the FPP, DAF managed the retail pharmacy authorization system (Emmerick et al. 2016).

It has been argued that the generics market played a key role in the success of the AFP arm. In 2011, generic medicines made up 51% of the medicines dispensed by the private sector. This share grew to 65% in only a few months (Alencar et al. 2018).

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ANNEX 4. CASE STUDY OF GHANA

Abbreviations

EML	essential medicines list
FFS	fee-for-service
FP	family planning
ICT	information and communication technology
IUD	intrauterine device
LMIC	low- and middle-income countries
NHIA	National Health Insurance Authority
NHIS	National Health Insurance Scheme
PRCP	Private Retail Community Pharmacies
WHO	World Health Organization

Regulations, Contracted Services, Payments, and Monitoring of Pharmacies in Ghana

Ghana's National Health Insurance Scheme (NHIS) was implemented in 2003 by the National Health Insurance Authority (NHIA), which regulates various aspects of the country's NHIS, including those that are pharmacy-related. The NHIA accredits both private and public health facilities to provide services under NHIS coverage, such as medicines. The NHIS also regulates reimbursement prices for medicines dispensed by pharmacies (Ashigbie et al. 2016). Like that observed in other low- and middle-income countries (LMICs), although the number of pharmacies to a population is regulated by the Pharmacy Council (which stipulates that new retail pharmacies should not be located less than 400m close to an existing pharmacy/chemical seller), there is no regulation to ensure the even distribution of pharmacies across Ghana, especially between rural and urban areas (Ghana Pharmacy Council 2021). The Pharmacy Council is charged with primary responsibility for ensuring the highest standards in the practice of pharmacy in Ghana. This is done by assuring competence of service providers and prescribing standards of practice for them. In addition, the Council ensures a reliable medicine supply and distribution system and promotes the rational use of drugs (Ministry of Health 2010). As a way of assuring the quality of services provided, only licensed and NHIA-accredited private pharmacies may dispense medicines under NHIS coverage and apply for reimbursement. All new pharmacy applicants must have operated for at least six months; have a good record of service provision; accept the quality assurance standards, utilization review, and payment mechanism; have a formal quality assurance program in place; and must permit inspection of facility premises (NHIS 2022).

Ghana's NHIS periodically updates a reimbursement list of medicines (separate from the country's essential medicines list [EML]) that are covered by the scheme. As of 2015, the list included 549 formulations, which cover more than 80% of the medicines required to treat diseases of common occurrence in Ghana, such as malaria, upper respiratory tract infections, and diarrheal diseases, and medical emergency care (World Health Organization [WHO] Regional Office for Africa 2016; Alhassan

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et al. 2016). HIV and antiretroviral drugs, gynecological hormone replacement therapy, cancer drugs, and program drugs are excluded from this list. There are some program drugs exceptions, such as sulfasoxine + pyrimethamine, which are maintained on the public facilities list (and are provided for free) to the unavailability at some facilities across the country, prevent malaria during pregnancy, and aid the country's attainment of Millennium Development Goal 5 (improve maternal health) (Opoku 2015). The private sector is not necessarily obliged to comply with standard treatment guidelines and the EML, but providers and dispensing pharmacies under the NHIS are compelled to do so through the scheme's pharmaceutical reimbursement system. In fact, by creating and implementing its own list of medicines, the NHIS has been able to influence prescribing and dispensing practices in the private sector (WHO Regional Office for Africa 2016).

Reimbursement prices for medicines by the NHIS are the same for public and private providers, including private pharmacies, and are expected to be set annually based on medicines prices found in the local market (WHO Regional Office for Africa 2016). From 2003 to 2007, medicines were paid on a fee-for-service (FFS) basis, separately from other services, which were reimbursed under the Ghana diagnosis-related group model. On the one hand, the FFS reimbursement model enabled standalone drug outlets to dispense medicines under coverage of the NHIS (Ashigbie et al. 2016). On the other hand, this payment method incentivized supply-induced demand, which led to huge claims cost to the NHIS. In 2008, the NHIA introduced the Ghana diagnosis-related group system to pay healthcare providers to contain escalating costs that were observed under the FFS payment system; however, medicines are still reimbursed under FFS. What was initially introduced as an attempt to improve the reimbursement system has only increased claim costs and a put financial burden on the NHIA (Nsiah-Boateng et al. 2016). According to NHIS regulation, claims are reimbursed after 90 days. In reality, it takes more than 180 days to reimburse claims (WHO Regional Office for Africa 2016). Ghana's case illustrates the importance of considering reimbursement mechanisms and timeliness for efficient contracting.

The NHIA is responsible for monitoring and auditing services provided by participating pharmacies. NHIA accredits both private and public health facilities to provide services covered by the NHIS (Ashigbie et al. 2016).

Effects of the Information Technology Management Systems on Access to Services

Ghana's existing information and communication technology (ICT) infrastructure is rudimentary and has not been fully integrated in a manner that will support healthcare services locally or across facilities, including at private pharmacies. The latest e-health strategy for the country from which this information is drawn was drafted for the 2010-2020 period. The NHIA has deployed an ICT infrastructure for the automation of health insurance services, where all accredited providers, including pharmacies, operate a common platform with common protocols for patient authentication and claims management (Ministry of Health 2010). Electronic versions of prescription history are not available, and there is no electronic logistics and supply chain management system in place for medicines and non-consumables. There is a data management platform, DHIS2, which is used by the government. However, because many service delivery points in Ghana do not have access to electricity, routine data are collected using paper-based

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registries, and incongruities exist between data reported to the DHIS2 and the paper-based reporting systems. In addition, data on quality are often lacking altogether (Rowan et al. 2019).

The lack of data integration and the separate data reporting structures increase the workload of pharmacy and health facility staff, and the duplicative bookkeeping is a burden at all levels. The health sector in Ghana suffers a shortage of ICT skills required to deliver large-scale e-health programs. The underlying health information technology infrastructure is weak due to consistent under-investment. In addition, the market is crowded with information technology vendors who are only capable of providing basic ICT services (Ministry of Health 2010).

Given the complexity of workplace and technological challenges involved in the rollout of e-health solutions, building the human resource capacity to meet the challenge will be an uphill task. The need to nurture such skills and ensure that they are ready for effective implementation of the strategy can create significant delays in the system. Many LMIC have leapfrogged the rollout of information technology systems in pharmacies by using instant messaging systems like WhatsApp.

Effects of Contracting and Reimbursement on Access to Services

Any licensed private pharmacy accredited by the NHIA can dispense medicines on the NHIS list under coverage and apply for reimbursement. The contract management system in Ghana with a public insurance (NHIS) uses district offices of the NHIS to manage the contracts with and payments to healthcare providers, including pharmacies (Honda & Obse 2020). Private accredited facilities often drop out after an initial period due to delayed reimbursement and unfavorable reimbursement prices, which in turn affects delays in paying suppliers. Reimbursement prices being the same for private and public facilities is unfair because private providers incur additional expenses, including payment of salaries, utilities, and taxes, which are paid by the government for the public sector. In fact, key informant interviewees have reported that prices set by the NHIS are below market prices. These reimbursement challenges pose affordability issues. Schemes not paying claims regularly to accredited hospitals and pharmacy shops make it difficult for those private providers to generate the requisite revenue to replenish drugs and other medical supplies needed to enhance quality service delivery, thus leading to their dropping out of the schemes or imposing a co-payment (to make up for the lower reimbursement), although they are technically not allowed by the NHIS (Ashigbie et al. 2016).

Geographical Accessibility

All Ghanaian regions have Private Retail Community Pharmacies (PRCP) participation in government schemes. However, like in Brazil, an imbalance in the geographic distribution of those pharmacies exists, with implications for access to essential medicines and pharmaceutical care, especially by the poor and rural dwellers.

With one PRCP per 9,390 insured persons, Nigeria's coverage is considered to be inadequate. In the same 2019 analysis, it was found that Ghana had an even lower participation of PRCPs relative to NHIS coverage: one PRCP services 33,000 insured persons.

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Ghana's PRCP participation to ensure effective implementation of a scheme that will guarantee improved access to medicines is inadequate. As discussed above, this stems from the issue where reimbursement prices are the same for private and public providers and leads private pharmacies to incur additional expenses, thus decreasing incentives for their participation (Okoro 2019).

Poor accessibility has repercussions for affordability to the patient and for quality of care (Bertoldi et al. 2012). Not only can poor accessibility lead to patients filling prescriptions at pricier pharmacies that are not part of the contracting scheme, but poor accessibility can cause prescriptions to go unfilled, thus leading to the inappropriate use of medicines. Therefore, geographical access to pharmacies is important to ensure access to essential medicines and related services (Okoro 2019).

Accessibility of Private Pharmacies Related to Insurance Coverage

Every Ghanaian is eligible to enroll in the health insurance scheme; however, this is not effectively implemented because of the relatively large informal sector and weak administrative capability of the NHIA. For example, according to a SEND-Ghana report in 2010, some registered NHIS members did not have access to healthcare services in the Upper West, Northern, Upper East, and Greater Accra regions because of delayed issuance of membership cards by the NHIS district offices. Overall, 17% of the poorest households are insured compared with 44% of the richest households. In turn, greater coverage has been reported among those with tertiary/higher education, and among women (Okoro 2019).

Quality of Pharmaceutical Services

The introduction of the NHIS lowered the barriers required for provision of pharmaceutical services. The fact that Ghana only requires private providers to be accredited by the NHIA to provide services under coverage, coupled with private pharmacies being some of the facilities that are most commonly accredited, has a positive effect of allowing for more widespread access to better quality of care (Lamprey, Nsiah-Boateng, Agyemang, et al. 2017). However, there is an unintended consequence of health insurance, which is linked to the patient having to mandatorily go to an accredited health facility like a hospital, clinic, or maternity home to obtain services or products under coverage. Therefore, although quality of care may improve, this kind of arrangement may result in fewer products dispensed at other private pharmacies, such as community pharmacies, thus leading to job losses and depriving society of the benefits of pharmaceutical services in the immediate communities, especially in some rural areas where a smaller volume of NHIS-accredited pharmacies may be present (Adjei 2012; Opoku 2015; Alhassan et al. 2015).

Payment arrangements are another factor that can affect the efficiency, equity, and affordability of public-private contract agreements. In fact, the combination of payment methods and payment rates can shape the behavior of healthcare providers. Specifically, late or irregular payments can make it difficult for providers to generate the requisite revenue to replenish drugs and other medical supplies needed to enhance quality service delivery (Opoku 2015). Please refer to the section on Effects of Contracting and Reimbursement on Access to Services above for more information on this topic.

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As previously mentioned in the contracting and reimbursement section of this case study, sub-optimal participation of private pharmacies in contracting schemes is prevalent in LMICs like Ghana, challenging access to quality care, one of the central ideas of contracting private providers for public sector clients. One study focusing on Ghana reported negative attitudes toward the NHIS and the lack of enforcement of separation of services of prescriber and dispenser as plausible reasons for this observation (Okoro 2019).

Regulating the quality of pharmaceutical services in Ghana is challenging due to the scarcity of resources at the Food and Drugs Authority and weak self-regulatory capacity of the private sector (WHO Regional Office for Africa 2016). Human resource capacity is a bottleneck to the rapid expansion of pharmaceutical services in Ghana. The WHO conducted an extensive assessment of human resources for pharmaceutical services in Ghana; however, the most recent data are from 2009 (Pharmacy Council 2010).

Choice of Family Planning Methods

The revised national policy of 1994 states that the aims of the family planning (FP) component in the reproductive health policy in Ghana are the “provision of information to individuals” and “making available a full range of safe and effective contraceptive methods” (Adjei et al. 2015).

The NHIS initially excluded FP services because other programs existed for FP that were implemented by the Ghana Health Service under the Ministry of Health and by international partners. Despite these efforts, barriers to access remained and so in 2012, legislation addressing NHIS reform requiring inclusion of a FP package was passed (Naik et al 2014).

In 2017, Ghana made a Family Planning 2020 pledge to revise the national health insurance benefits package to include free FP services and supplies. Where the government used to procure directly about one-quarter of all FP commodities, they committed to increase this percentage to one-third. This includes making FP free in the public sector and supporting the private sector to provide services (Family Planning 2020 2020).

In May 2018, the NHIA began a pilot program to evaluate the effectiveness of providing FP under the NHIS. As of 2019, the Ghanaian government had approved a budget for the financing of essential health commodities, including contraceptives, and began a process of including access to a wide range of modern contraceptives in the NHIS package. Ghana is also taking steps to ensure that complementary strategies are in place to support an expanded NHIS FP benefits package. The complementary strategies include increasing the share of domestic financing of FP commodities from 25% to 33% to be assured through funding from the dedicated health commodities budget line. In addition, pilots are underway to ensure that [Ghana's Community-Based Health Planning Services](#) can provide a range of modern FP methods to communities around them (Oyatoye 2019). Little to no information is available about the current status of FP products provision under NHIS coverage, possibly due to the COVID-19 pandemic.

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A 2015 study found that 84% of private facilities (including pharmacies) and 65% of public facilities had modern methods of contraception, the most common method being oral contraceptives. Male condoms were found to be mostly available at pharmacies (95%). Overall, there is higher availability of methods, such as emergency contraceptives and spermicides, at private facilities, including pharmacies compared with public facilities (Adjei, Laar, Narh, et al. 2015).

Most pill and condom users in Ghana (75% and 54%, respectively) receive their contraceptives from such shops; however, the country's most popular method—the three-month injectable contraceptive, depot medroxyprogesterone acetate or DMPA—is a prescription drug and is available only from a qualified medical provider or for purchase, but not injection, from a pharmacy. Pharmacists usually refer clients to hospitals or health facilities for injection, even though these facilities often experience stockouts of the method. Compared with public health facilities, licensed chemical seller shops keep longer hours, have shorter wait times, have staff whom clients perceive as friendlier, and are less likely to suffer from stockouts. Overall, private pharmacies and drug shops offer convenience and accessibility. Allowing them to sell the injectable could increase access to and use of the method (Lebetkin, Orr, Dzasi, et al. 2014).

Affordability

Ghana has a single NHIS benefit package that covers 95% of disease conditions afflicting Ghanaians. In theory, there are few limits placed on NHIS members' consumption of benefits, including medicine benefits. There is no cost-sharing beyond premiums and no annual or lifetime limits. In addition, people over the age of 70, children under 18 whose parents both enroll, the “core poor” and, since July 2008, all pregnant women, are exempt from paying premiums (Blanchet et al 2012).

A Ghanaian study that surveyed a sample of public and private providers (which includes private pharmacies), found that the introduction of the NHIS has led to increased use of medicines by removing cost barriers to patients. Patients who could not afford to purchase medicines before the introduction of the NHIS now have free access to them. In this way, the NHIA has not only improved affordability, but has also enabled patients to stop purchasing incomplete doses of medicines, especially antibiotics, thus improving adherence and quality of care (Ashigbie et al. 2016).

The fee-for-service payment method used in Ghana has been cited by the WHO as a common reason for healthcare systems inefficiency. When the rates are above the marginal cost of service, there is a risk of over-provision of services. When the rates are below the marginal cost of service, the risk is shifted to patients. Payment arrangements have a strong incentive power; therefore, it is important for public purchasers to design the payment arrangements with providers in a way that the incentive for the private pharmacies contracted to act in their own self-interest is removed (Honda & Obse 2020).

Strategies adopted by private providers (including private pharmacies) to circumvent low reimbursement rates has consequences on patient affordability. A study focused on Ghana revealed that because private providers incur additional expenses, including payment of salaries, utilities, and taxes—which are paid by the government for the public sector—this may result in their dispensing medicines at a higher price than what is reimbursed by the NHIS and asking the patient to pay the difference (Ashigbie et al. 2016).

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Another strategy used by providers for specific medicines with low reimbursement rates is dispensing a therapeutically equivalent alternative that has a higher markup. For example, the NHIS reimbursement price for amoxicillin capsules in Ghana is below the supplier price, and private pharmacies, which are free to set their own fee schedules (Honda & Obse 2020) were found to be using markups of between 30% and 50 % for the same category of medicines to make up for the difference in reimbursement, depending on the location of the facility (Okoroh et al. 2018). Moreover, findings from a 2020 Ghana commodity supply chain assessment suggest that private pharmacy prices for tracer drugs are consistently above NHIS prices, except for some retail pharmacies that sell insulin at or below the NHIS reimbursement price, with metformin representing the highest range of price markups (PATH 2020).

Where the payment rates for public and private providers are the same and the payment rates are too low and/or are considered “low” by private providers, private providers either decide not to take part in the NHIS, thus treating patients covered by the NHIS differently, or balance the bill by applying additional charges to patients where it is allowed (Honda & Obse 2020).

The takeaway from these payment rate challenges is that it is important to engage stakeholders in the process of determining fee levels. This helps make the basis for payment rates clearer and provides the opportunity for coordination between public purchasers and private healthcare providers (including private pharmacies), which can reduce their dissatisfaction with payment rates and thus mitigate unfavorable behavior (Honda & Obse 2020).

Procurement and Supply Chain Management Challenges

Ghana’s supply and distribution channel is fragmented, and multilaterals’ financing, donations, and procurement policies can have unintended consequences on the local private sector. Private retail pharmacies procure from distributors or directly from manufacturers, and usually select their suppliers based on quality, affordability, reputation, pricing, brand, and demand for the products. The method mix provided at private facilities is much more limited than that at public facilities, particularly for long-acting reversible methods. Less than one-quarter of private facilities offer intrauterine devices (IUDs) or implants, and less than one-third provide injectables. Lack of contraceptive choice in the private sector is due to a variety of factors. Many private facilities are pharmacies or drug shops, which are not authorized to insert or remove IUDs or implants. In addition, many private facilities must contract with private pharmaceutical importers to purchase commodities, and IUDs and implants do not provide a sufficient return on investment to be worth purchasing (Rowan et al. 2019).

In a 2020 report, AMPATH reported on a Access Accelerated and PATH collaboration with the Ministry of Health and Ghana Health Service (GHS). This work analyzed supply chain channels for NCD-related (diabetes, hypertension, and breast cancer) medicines and diagnostics, identified bottlenecks, and recommended interventions to strengthen NCD supply security. The assessment, which included 17 private pharmacies, found that 70%, 11%, 5%, and 5% of the pharmacies got 100%, 80%, 90%, and 70% of their orders, respectively. Reasons for incomplete orders were indicated as being either stockouts at the supplier end or the pharmacy’s own indebtedness to the supplier (PATH 2020).

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Despite its potential, the private sector has historically been excluded from procurement planning for national FP efforts, and so this is an area to be addressed to improve contraceptive security.

Vision for the Future of Pharmaceutical Services

In Ghana, there is enough scientific information available to policymakers to inform policy discussions on sustainability strategies for the NHIS. However, most of the research does not focus on the demand side (client-centered). Because there is growing recognition of the operational challenges confronting the NHIS in Ghana, adopting client-centered quality healthcare and health insurance services could enhance perceptions of the NHIS and increase client trust in the scheme (Alhassan et al. 2016).

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ANNEX 5. CASE STUDY OF NAMIBIA

Abbreviations

AFA	AID for AIDS Foundation
NAMAF	Namibia Association of Medical Aid Funds
NRP	Namibia reference price
OOP	out-of-pocket
PSEMAS	Public Servants Employees Medical Aid Scheme

Regulations, Contracted Services, Payments, and Monitoring of Pharmacies in Namibia

Namibia's pharmaceutical sector is highly regulated, mainly by the central government. The Namibia Medicines Regulatory Council is responsible for the prescribing and dispensing licensing processes, and licensed pharmacies need to be accredited by the Namibia Association of Medical Aid Funds (NAMAF) before they can provide services under the medical aid funds. NAMAF is also the authorized entity for negotiating and setting tariffs for all medical aid funds. The private sector is well organized. Medicines are supplied through four key wholesalers and are distributed to a network of 126 pharmacies (High-Impact Practices in Family Planning 2013). Pharmacies that have a NAMAF registration number are allowed to enter in yearly contracts with the medical aid funds. Some medical aid funds, such as the Public Servants Employees Medical Aid Scheme (PSEMAS), maintain separate agreements with pharmacies, whereas others are part of a group agreement or contracts with a pharmacy through the health scheme administrator. In the latter case, a pharmacy signs a contract with the health scheme administrator and is then automatically accredited to dispense medicines for medical aid schemes in that administrator's coverage (Eghan, et al. 2014). There are no laws or regulations restricting the types of medicines that can be covered by a Namibian benefits program or medical aid scheme, but each medical aid fund has its own list. All the medical funds use the Namibia reference price (NRP), which sets the maximum reimbursable price for a group of products that are generically equivalent. For pharmacies, the pricing and reimbursement model for medicines is $[\text{SEP} + 50\%(\text{margin}) + 15\%(\text{value added tax}[\text{vat}])]$. If a patient chooses a treatment option that costs more than the NRP, s/he must pay the difference out-of-pocket (OOP) (Eghan et al. 2014). Pharmacy providers must obtain approval for providing medicines to the beneficiaries. Authorizations are obtained for any product on the chronic diseases list and renewals are required every six months. The Nexus Administration System (which indirectly manages pharmacies under each scheme), automatically splits claims into chronic and acute medications for tracking adjudication purposes. Once entries are done, the System generates levies and fund rules. As for monitoring, the Namibia Financial Institutions Supervisory Authority requires each medical aid fund to set up an independent board of trustees. In addition, each medical aid fund, such as PSEMAS, is managed by a medical aid administrator, who handles operations, including claims, payments, and contracts with private pharmacies. The Pharmacy Provider Network in Namibia has access to three separate vendor-marketed dispensing applications, which are used to generate reports with the pharmacy provider dispensing system, which monitor medicines dispensed by health plan and therapeutic area, total medicines value per member, and daily financial performance (Eghan, Evans, Mazibuko, et al. 2014).

Effect of Regulations of Pharmacies on Access to Services and Medicines

For Namibia, inadequate or lack of inventory management has been explicitly reported. For instance, the absence of a standardized national coding system for medicines may require development (where absent) and standardization (where present, such as in the medical aid schemes) of existing coding for medicines nationwide for more efficient resource tracking (Eghan et al. 2014).

Effects of the Information Technology Management Systems on Access to Services

For a long time, Namibia's information technology infrastructure was driven by development partners, which resulted in uncoordinated information systems, in conflict with the primary healthcare goals of an integrated health information system. As a result, there are vertical programs, duplication of functionality, and many systems operating in silos. Integration of information technology with health programs is difficult because there is poor data quality, fragmentation, budgetary constraints, irreconcilable system architectures, and incompatible data. In the Namibian health environment, many systems, databases, and processes are fully manual, paper-based, or only partially electronic, and to a large extent, formats are either fragmented or non-standard. This adds significantly to work burdens and seriously undermines efficiency (Dlodlo & Hamunyela 2017).

Effects of Contracting and Reimbursement on Access to Services

The pharmaceutical distribution channels in the medical aid funds are that of an open model, where plans provide medicines and health services through contracts with a network of service providers, including private pharmacies (Eghan et al. 2014). All medical aid funds in Namibia use the NRP, which sets the maximum reimbursable price for a group of products that are generically equivalent or similar. One of the key issues reported by the Pharmaceutical Society and pharmacies about reimbursement mechanisms was the lack of transparency for Pharmacy Benefit Management organizations when setting prices and reimbursement amounts.

The Pharmaceutical Society of Namibia and NAMAF have separately suggested the need for a group like Management Sciences for Health or Abt Associates, which are in-country, to support a review of pricing models (Eghan et al. 2014).

Accessibility of Private Pharmacies Related to Insurance Coverage

One of the greatest challenges of the Namibian health system is its fragmentation and the differences in health coverage between those covered by PSEMAS (10% of the population), those who can afford private medical aid (8% of the population), and those who have neither (81% of the population). This means that nearly 1.8 million Namibians remain uncovered and are thus reliant on the public health system or on OOP payments for private healthcare (African Collaborative for Health Finance Solutions 2019.)

Quality of Pharmaceutical Services

Human resource capacity and training/curriculum at pharmacy schools and at pharmacy assistant schools have been identified as bottlenecks that need to be improved to achieve the efficient provision of pharmaceutical services in the private sector (Eghan et al. 2014). This challenge is magnified in the public sector because pharmacy staff are in short supply (McQuide et al 2013).

There is sparse information on Namibia's pharmaceutical quality control systems. Legal provisions exist to inspect the premises and to collect samples; however, samples are not tested for post-marketing surveillance. Legal provisions also exist for detecting and combating counterfeit medicines, and for the recall and disposal of defective products (Fourie 2009).

Choice of Family Planning Methods

All medical aid funds use a restricted formulary system. They cover a subset of all products registered by the Namibia Medicines Regulatory Council. This subset serves as a preferred medicines list, which consists of generic medications that cost less than preferred brands. There are limits to oral and long-acting reversible contraceptives (Eghan et al. 2014). In 2015, the main specialized services offered by pharmacies included blood pressure monitoring, glucose screening, and interestingly, family planning counselling (present at 63% of Namibian pharmacies). Female condoms were available at 44% of the facilities. Male condoms, pills, injectable contraceptives, and emergency contraceptive pills were available at more than 80% of the pharmacies (High-Impact Practices in Family Planning 2013).

In 2019, Namibia added subcutaneous depot medroxyprogesterone acetate (DMPA-SC, injectable contraceptive) to its national list of contraceptives. It is now available at public facilities, private clinics, and private drug stores, including for self-injection (UNFPA 2019).

Affordability

Each medical aid scheme has its own benefits package and associated rules, and the AID for AIDS Foundation (AFA) is currently in talks with the medical aid schemes to assess options for increased access to more affordable antiretrovirals and HIV and AIDS services. AFA is a complete HIV and AIDS disease management program that offers both members and registered dependents medication to treat HIV, treatment to prevent opportunistic infections, and regular monitoring of disease progression and response to therapy. Although the AFA program is available, currently only four medical aid schemes cover HIV and AIDS. Members with chronic diseases are required to register for a chronic disease management package, which determines a preferred medicines list for each condition. A lower copay levy is applied when members choose preferred medicines, whereas a higher levy is applicable when they choose the non-preferred medicines. The one medicine that is paid for by all funds is the immunization against the human papillomavirus virus, if certain conditions are met. As for oral and long-acting reversible contraceptives, the funds pay up to a limit of Namibian Dollar 160 per claim (Eghan et al. 2014).

Longer eligibility or wait times are required for members who, at the point of registration, have chronic diseases, such as hypertension and diabetes. Many respondents to a 2014 medicine benefit assessment

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conducted in Namibia indicated that the overall impact of longer eligibility and wait times reduced access in terms of affordability and increased OOP spending (Eghan et al. 2014).

Another inefficiency that may lead to higher healthcare costs and, thus, have affordability ramifications for patients, is the way that private providers are paid. For instance, PSEMAS uses a fee-for-service mechanism to pay providers, including pharmacies, for the services rendered and the medicines dispensed. This payment mechanism may result in over-servicing because providers have an incentive to deliver more services than what is medically necessary, leading to higher healthcare costs. This has been confirmed in a review of PSEMAS expenditures, where insured patients are referred through the system, including for care that is not covered by PSEMAS or other medical aid funds. In turn, this leads to increased expenditures, often with OOP costs, for the patients (World Bank 2019).

Procurement and Supply Chain Management Challenges

In the private sector in Namibia, medicines and medical supplies are procured through four key wholesalers (NewMed, NamPharm, Erongo, and Geka) (Eghan et al. 2014) and are distributed to a network of 126 pharmacies (High-Impact Practices in Family Planning 2013).

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ANNEX 6. CASE STUDY OF SPAIN

Abbreviations

CP	community pharmacy
EC	emergency contraception
LNG EC	levonorgestrel-only emergency contraception
MOH	Ministry of Health
UPA EC	ulipristal acetate emergency contraception

Regulations, Contracted Services, Payments/Reimbursements, and Monitoring of Pharmacies in Spain

Spain has decentralized regulatory functions, except in the case of medicine authorization and pricing, both of which are the full responsibility of the central government. The remaining roles are regulated by the Autonomous Communities, taking into consideration the national regulatory frameworks. Community pharmacies (CPs) are subject to healthcare planning established by the Autonomous Regions (Global-Regulation. Law 14/1986, General Healthcare Law, 25th April, and the Law 25/1990, 20th December, on Medicines). These regulations deal with supply and dispensing of medicines and various services, including medical appointments (e.g., nutrition), consultations, measurement of biological and biochemical parameters, pharmaceutical care programs, smoking cessation, needle exchange, medication review, drug waste management, as well as rules regarding provision of written standardized information (Martins et al 2015).

There are geographic and demographic criteria to open a pharmacy. These regulations have an impact on the distribution of pharmacies, and have consequences on access, equity, and price competition (see below) (Lluch & Kanavos 2010). Retailers directly collect user fees from patients at the time of purchase, and the regional health service is invoiced monthly for the rest of the cost. In the case of drugs eligible for public reimbursement, the reimbursement of retail pharmacists and wholesalers relies on fixed and price-proportional markups of the consumer price before tax.

CPs are reimbursed by government at a margin of about 28% of the pharmacy fixed retail price. In reality, there are so many exceptions that this cannot be taken as the overall margin. For example, there are lists of drugs that fall into different margin categories of 4%, 7.5% and 15%. Pharmacies are subject to a different tax regime linked to the sales volume (10 brackets that go from 0% to 20% of the revenue) and this impacts their margins. We have no information on federal or state activities regarding monitoring and evaluating Spanish CPs.

Effect of Regulation of Pharmacies on Access to Services and Medicines

In Spain, the differences in regulation of pharmacies by region have an impact on the distribution of pharmacies, and have consequences on access, equity, and price competition (see below) (Lluch & Kanavos 2010).

Effects of the Information Technology Management Systems on Access to Services

Spain has information technology management and eHealth adoption systems but electronic records are not being used systematically to monitor the effect of interventions and policies. CPs are scattered across the country, largely as independent businesses, with some working in small rural communities. Therefore, there is a need to allow scattered CPs to take advantage of electronic patient records, billing systems, and other technology (Digital Health Europe 2020). Nonetheless, almost all Spanish pharmacies are digitized. During COVID, the system has worked well, allowing the tracking of which patients should receive COVID-related medication. But this seems to be managed by the government administration and not by the actual CPs.

Effects of Contracting and Reimbursement on Access to Services

The Spanish Ministry of Health (MOH) is responsible for approving the reimbursement of medicinal products. All Spanish CPs have an agreement with each state health administration for the supply and dispensing of medicines and a very limited number of services. This generates a complex situation because the MOH makes decisions on pricing and reimbursement, but the Autonomous Regions are responsible for financing the medicines.

Fragmentation of healthcare delivery has led to the development of 17 separate and different Autonomous Regional health services. Critically, there is lack of payment for certain essential services and there appears to be a lack of advocacy from most of the leadership for changes to the current remuneration system. This continues to be a critical factor delaying the implementation of services (Lluch & Kanavos 2010; Gastelurrutia, Faus, Martínez-Martínez 2020; Barbarisi, Bruno, Diglio, et al. 2019). As one example, only pharmacies in some regions of Spain are allowed to perform COVID antigen tests. In general, there is some criticism about the limited number of services that the pharmacies are allowed to provide. (HIV tests is one of the few exceptions.)

Geographical Accessibility

Although the percentage of the population within a maximum distance of 200 m of a pharmacy has significantly increased, accessibility for users in the least densely populated areas did not substantially change. If entrance into the pharmacy marketplace is left just to the free choice of private sector entrepreneurs, improvements in accessibility are actually poor, especially for those living away from urban centers. Equity and access seem to be better achieved by establishing geographic, 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). Among 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).

There is a limited effect on users’ accessibility to new drugstores because they tend to be positioned in the areas of a city with an already high density of existing retailers, thus producing just a moderate average reduction in the distance of most disadvantaged consumers from the closest store. The closer the pharmacy is to the population, the less use of primary care (doctor) in subjects under 65 years of

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age (Lluch & Kanavos 2010; Carrasco-Aguello, et al. 2013; Barbarisi et al. 2019). Given the fragmented nature of the Spanish system, each region defines this aspect.

For the government, it appears to be more profitable to have only a few big pharmacies (due to the taxation mentioned above; the bigger the pharmacy, the higher the tax rate). An increased competition due to an increase in the number of pharmacies may eventually even lead to the closure of pharmacies. This happened in the Spanish Autonomous Community of Navare, which had liberalized establishment rules (Vogler 2014).

Quality of Pharmaceutical Services

Medicine use reviews in CPs have been recently assessed (Garcia-Agua Soler et al. 2021). Problems with such reviews (in Spain and in other countries) have been that they do not integrate well with the patients' Primary Care pathway, and that physicians are commonly not especially positive about this service. In addition, a lack of communication and collaboration between general practitioners and community pharmacists can have an impact on the relationship between the patients and their general practitioners (Jové, Fernández, Hughes, et al. 2014). In Catalonia, small pharmacies are more likely to dispense antibiotics without a medical prescription compared with large pharmacies. Smaller income may create incentives to generate more revenues by selling prescription-only medicines over the counter, without a medical prescription in small pharmacies, and the person behind the counter may be the owner, whereas in large pharmacies, the person behind the counter is more likely to have no direct benefit from selling more medicines (Llor et al, 2010; Perraudin et al, 2016). This practice happens more when there is more inter-pharmacy competition because the pharmacist perceives that if s/he does not do the dispensing, patients will simply get it from the nearby pharmacy. We note that over time, the practice of dispensing antibiotics without a prescription has almost been eradicated. A study was conducted to investigate the effects of the implementation of a quality management system (based on the international standard ISO 9001: 2008) in the CP. Improvements were demonstrated in 10 of the 16 indicators, including symptom improvement and patients who received health education (Alhusein & Watson 2019).

Choice of Family Planning Methods

Each of Spain's Autonomous Communities has its own regulations on contraceptive subsidization. However, both male and female condoms are generally available free of charge or at subsidized prices. Oral contraceptives can only be sold with a prescription. In 2009, Spain's government made emergency contraception (EC) available over the counter and with no age restrictions. Some Autonomous Communities provide EC for free at public health clinics. In March 2010, a new law on reproductive health led to the MOH for the first time subsidizing hormonal contraceptives as birth control. The law covers three types of hormonal contraceptives. As a result, all women covered by the National Health System are now able to obtain some contraceptives at reduced prices. In Spain, levonorgestrel-only (LNG) EC has been available behind the counter from pharmacies since September 2009; this means that EC is available without a prescription but is not on the shelves and needs to be requested in order to purchase it. But this is quite an unrealistic case because typically people will go to a doctor for LNG EC. Since April 2015, EC pills containing ulipristal acetate (UPA EC) can also be purchased without a prescription from pharmacies and are available behind the counter. Physicians are the sole healthcare professionals authorized to prescribe EC. In some Autonomous Communities, the cost of EC is partially

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or fully reimbursed to the patient when it is sold with a prescription at the pharmacy. It is also free to the user when it is accessed in the public sector (Grindlay et al, 2013).

Affordability

If protective policies are not in place, reforms that increase the use of services can increase people's out-of-pocket payments through, for example, co-payments (e.g., user charges). In such instances, reforms might improve access to healthcare but at the same time increase financial hardship.

Under Spain's national health system, almost all covered services are free at the point of use, except for outpatient medicines. Children and adults are required to pay co-payments for prescribed medicines, depending on household income and pension status. Mechanisms to protect people have been limited, especially for low-income people of working age (Puig-Junoy, et al. 2014; Puig-Junoy et al. 2016). An interesting study in the Canary Islands found that the impact of cost-sharing among low-income pensioners produced a risk of lack of adherence to treatments for specific chronic disease conditions. Reduction in medicine consumption was also a consequence of prior stockpiling, especially among the most "inelastic" chronic disease medicines. Last, some therapeutic groups of medicines had a higher sensitivity to co-payments among patients with chronic and comorbid conditions than among non-chronic disease patients. The authors suggested that the Spanish government set up a co-payment scheme that pays attention to both the nature of the disease being treated (e.g., applying co-payments according to the therapeutic group that each drug belongs to) and the existence of individuals with comorbidities (Hernandez-Izquierdo, et al. 2019). Perhaps in reaction, in 2021, the Government of Spain introduced new exemptions from co-payments for various patients (WHO Regional Office for Europe 2021). From January 1, 2021, low-income pensioners, moderately and severely disabled children, and households receiving child benefits no longer have to pay out of pocket for prescribed medicines. On average, these changes did not significantly change the propensity to consume prescription or over-the-counter medicines (Martinez-Jimenez, et al. 2021). For those groups who pay (higher income), the price is only 10% of the price of treatment, with a cap of around 8 Euros per month.

Procurement and Supply Chain Management Challenges

Spain's MOH encourages—but does not mandate—joint, centralized medicines procurement to enhance the efficiency of the National Health System, which has allowed regional governments and other public institutions taking part to reduce costs and simplify medicine tenders. The pharmaceutical company, Pfizer, attempted to distribute medicines on its own some years ago, but it faced a strong pushback from the industry (wholesalers and pharmacies). One reason is that, currently, wholesalers supply pharmacies normally five times per day, which is, needless to say, very convenient for pharmacies. If the wholesaler system disappears or reduces its reach, it will impact the small labs or rare drugs that depend on wholesalers for distribution. This will finally have an impact on access to medicines for the patient. Andalusia is one of the few (if not the only region) that has a regional centralized medicines procurement system through a tendering process. Last year it decided to go through a reform and stop it due to the challenges, mainly stock ruptures due to high demand from one wholesaler. Medicines in Spain can be distributed by wholesale distributors or directly by the holder of the marketing authorization. That is, pharmaceutical companies can, if they so decide, operate without the services of intermediary wholesalers and can directly supply pharmacies. Wholesalers can only accept returns from

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pharmacies and pharmaceutical services if they previously supplied the relevant medicines directly to the returning entity. This restriction has been imposed to tackle a rather widespread practice that hindered the traceability of medicines. Medicines can only be purchased from, and distributed to, entities that are legally authorized to acquire them (that is, pharmaceutical wholesalers, pharmacies, and hospitals) (Global-regulation.com 2013).

Vision for the Future of Pharmaceutical Services

In Spain, professional pharmacy organizational leaders are publicly promoting and defending a more clinical and patient-oriented practice through service implementation. This discourse, however, is not being followed by a change in usual practice by ordinary community pharmacists. There are political pressures from various stakeholders—for instance, the nurses “lobby”—to prevent pharmacies from stepping into their competencies. A clear current example is the strong pushback to allow COVID-19 testing or vaccinations at pharmacies. Allowing pharmacies to perform certain services also faces budgetary challenges from the government because the government will have to partially subsidize these services that are now performed in the health system.

Lack of resources has repeatedly been found as the main reason for the lack of provision of comprehensive pharmaceutical care in the CP setting (Gastelurrutia, et al. 2020; Perraudin, et al. 2016). In general, home delivery of medication is available for those who fall into one or more of the following categories: acute or chronic illness that is classified as high-risk for COVID19 infection, (e.g., diabetes, immunodeficiency, pulmonary conditions, cancer, cardiovascular conditions, pregnancy, and limited mobility). Most home delivery services are carried out by volunteers or charities on behalf of the pharmacy. This has been an exception, and only in rare cases, with the help of voluntary teams, and also with a considerable amount of bureaucracy. So, home delivery is available but is not a common practice (British Embassy in Madrid 2020).

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ANNEX 7. CASE STUDY OF SWEDEN

Abbreviations

CP	community pharmacy
Cu-IUD	copper intrauterine device
EC	emergency contraception
LNG EC	levonorgestrel-only emergency contraception
OTC	over the counter
TLV	Tandvårds- och läkemedelsförmånsverket (Dental and Pharmaceutical Benefits Agency)
UPA EC	emergency contraction pills containing ulipristal acetate

Regulations, Contracted Services, Payments/Reimbursements, and Monitoring of Pharmacies in Sweden

In Sweden, a centralized body, the Medical Products Agency, is in charge of issuing permits and supervision of pharmacies. The pharmacy market was reregulated in 2009. The reregulation of the Swedish pharmacy market had three parts, all of which were implemented in parallel: (1) Changing hospital pharmacy regulation to provide flexibility for caregivers to organize their drug supply as they see fit; (2) creation of an open market for community pharmacies (CPs) by breaking up Apoteket AB and its monopoly; and (3) opening up of most over the counter (OTC) drugs to be sold in general retail stores. Because there appear to be no CP contracts with the government (unlike in the United Kingdom), regulations provide that the pharmacies' jobs are, among others, to: make medicinal products available and supply them; offer to substitute a generic for the prescribed medicine; provide information and advice about medicines; receive defective medicines and report complaints to the pharmaceutical company; and receive pharmaceutical waste from households. Included are many primary healthcare services (e.g., pre-booked basic medication reviews and other patient counseling sessions in privacy; blood pressure measurements; blood analyses of blood sugar; hemoglobin A1C; lipids and C-reactive protein; vaccinations) although not all pharmacies have these services, and for those that offer them, additional training is needed for the pharmacists to take and analyze blood samples. There is no reimbursement for pharmacies to do this.

Costs for most outpatient prescription drugs are, only partially, paid for through the Swedish pharmaceutical benefits scheme and designated state grants to the county councils, and then treated as a restriction on the county council's revenues. For a drug to be subsidized by the government, a pharmaceutical company must submit an application for a subsidy and the government then decides whether the drug should be included in the drug benefits and at what price (Tandvårds- och läkemedelsförmånsverket [TLV] 2020). Patients pay a maximum of 2300 SEK per year for outpatient pharmaceutical treatment; any other medical costs are covered by the government. Blood sampling, healthcare, and drug treatment of general dangerous and contagious diseases are free for all.

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Inclusion in the pharmaceutical benefits scheme is determined by a national body, Tandvårds-och läkemedelsförmånsverket (TLV; the Dental and Pharmaceutical Benefits Agency), which sets prices following a value-based pricing system. All children under the age of 18 are offered free prescription medicinal products and medical devices are included in the reimbursement scheme. In addition, prescribed contraceptive drugs included in the reimbursement scheme are free for all women under the age of 21.

The Medical Products Agency is responsible for inspecting pharmacies in Sweden. Supervision can be performed as inspections onsite and administrative supervision. By law, the 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.

For prescription medicines, the central government and the county councils negotiate agreements of defined periods on the levels of subsidy paid by the government to the councils. Tendering contracts may also be used as cost-control measures by county councils and municipalities. The financing of health services through global budgets, volume caps, capitation formulas, contracts, and salary-based pay for staff, also contribute to cost control. In addition, TLV uses value-based pricing for prescription medicines, whereby the level of reimbursement is based on an assessment of health needs and cost-effectiveness (Mossialos, Wenzl, Osborn, et al. [eds.] 2015).

Effect of Regulation of Pharmacies on Access to Services and Medicines

In Sweden, the last two changes (the creation of an open market for CPs and opening up most OTC drugs to be sold in general retail stores) have produced, in the view of many, a Swedish CP system that has become too commercialized and has developed into a retail marketplace (Wissel, et al. 2015; Kullberg, et al. 2018). This perceived over-commercialization can be an impediment to access for certain medicines and certain economic groups.

Effects of the Information Technology Management Systems on Access to Services

A system for the documentation of medication-related problems has been available in all CPs. Sweden is one of the leading countries when it comes to e-prescribing, (i.e., prescriptions transferred and stored electronically). Currently, 99% of prescriptions are electronic. Although e-prescribing is well accepted and appreciated by pharmacists and patients, one document noted issues in legal restrictions on information access, healthcare, and reliability (Hammar 2014). The Swedish e-health agency (eHälsomyndigheten) was formed in 2014 to strengthen the national e-health infrastructure. It manages electronic prescriptions. Its activities focus on promoting public involvement and providing support for professionals and decision makers. Generally, both the quality of information technology systems and their level of use are high (Mossialos, et al. (eds.) 2016).

Effects of Contracting and Reimbursement on Access to Services

A government commission by TLV has investigated a possible introduction of publicly-financed, patient-oriented CP services/primary healthcare services, and is expected to conduct a pilot study aimed at increasing adherence to prescribed drug treatment through further developed community pharmacist

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counseling. As of January 2021, the government had given TLV the task of developing pharmaceutical services in outpatient pharmacies in collaboration with the pharmacy sector and other stakeholders, in accordance with the feasibility study presented by the authority in 2019. The results will be reported in 2024. It is proposed that the development work should take place in so-called policy labs, (e.g., a trial operation to test and evaluate these services) (TLV 2019; Hedlund 2021).

Geographical Accessibility

Reregulation has resulted in higher availability and longer opening hours, especially in urban areas. There are challenges in rural areas and—to maintain access—the government—via the TLV—financially supports some pharmacies in rural areas. Reregulation (or perhaps more correctly, liberalization of the pharmacy sector) may undermine the goal of equity in access to healthcare, even in a publicly-financed healthcare system. Systems where public and private health providers coexist and compete for patients may also present difficulties for health provision in rural areas because this reduces the ability of public authorities to coordinate care activities and promote cooperation between different care providers (Håkonsen et al. 2016; Hackelsjö 2015; Kullberg et al. 2018). There has been a sharp growth in online pharmacies. In 2020, online pharmacies accounted for 12% of sales and 18% of total volume in the CP market. Year-on-year growth in the value of online sales was approximately 36%. This is a challenge for the physical CPs because their volumes are declining.

Although there are currently no specific regulations for the establishment of pharmacies in rural areas, safeguard regulations exist whereby those CPs sold from the state to private companies must be kept running for at least three years after purchase. This rule is especially important for rural pharmacies to ensure that adequate mechanisms are in place for accessing medicines (Vogler, et al, 2012).

There are no dispensing doctors or hospitals dispensing to outpatients in place of community pharmacists. In practice, several CPs (both private and the state- owned Apoteket) are also located in hospital premises.

Quality of Pharmaceutical Services

Some regions offer free contraceptive drugs for all women under the age of 25; however, according to Swedish legislation, all women under the age of 21 must be offered a free prescription for contraceptive medicines (1177 Vardguiden 2020).

Most women (65%) sampled in a survey reported that they would prefer to purchase emergency hormonal contraception from a pharmacy instead of visiting a clinic, with availability selected as the motive for this choice by the majority. Pharmacy staff frequently asked simulated patients about their previous use of a prescribed medicine but did not pay attention to their negative responses. Swedish pharmacists state that new health policies, such as the introduction of mandatory generic substitution, have resulted in an unwanted change in the content and focus of the dialogue, from health and medical information to finances and politics (Larsson, et al. 2004; Westerlund, et al. 2013; Eades, et al. 2011; Olsson, et al. 2014; Olsson, et al. 2017). A prospective randomized controlled trial in Stockholm concluded that the addition of a skilled pharmacist to the primary care team may contribute to

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reductions in the number of medicines and maintenance of self-rated health in elderly patients with polypharmacy (Lenander, et al. 2014).

Choice of Family Planning Methods

The following institutions can prescribe contraceptives: youth clinic, gynecological clinic, maternity care center, and general health center. Most contraceptive prescriptions are issued by nurse midwives and gynecologists and almost none by general practitioners. Recently, subsidies have been increased for women ≤ 21 years, who receive certain contraceptives free of charge. In most regions, women ≤ 25 years pay approximately €10 per year for contraception (Hellström, et al. 2019).

Emergency contraception (EC) is available in Sweden: levonorgestrel-only EC (LNG EC), EC pills containing ulipristal acetate (UPA EC), and the use of copper intrauterine devices (Cu-IUD) for EC are included in national policies for family planning. EC pills are only sold/distributed at pharmacies, hospitals, youth clinics, and family planning clinics. LNG EC and UPA EC are available free of charge from youth clinics, and Cu-IUDs may also be provided free of charge depending on the area. Physicians and midwives are also authorized to provide or prescribe EC (European Consortium for Emergency Contraception 2020).

Affordability Related to Copayments

There is a fairly comprehensive range of publicly financed health services available for adults, and free access to all covered health services for children and adolescents. Yet, outpatient medicines are the largest single driver of financial hardship for the poorest quintile. Data on unmet need due to cost show that socioeconomic inequality is greater for prescribed medicines than for other health services. There are no co-payment exemptions based on household income, and older people are not exempt from co-payments for outpatient prescriptions and medical devices. Although there is an annual cap on co-payments for outpatient prescriptions and medical devices, there are no exemptions from these co-payments based on income, which explains why outpatient medicines are the main driver of financial hardship for the poorest households (Anell, et al. 2012; Bergman, et al. 2016).

Procurement and Supply Chain Management Challenges

Sweden formerly had a one channel distribution, which meant that there were only two wholesalers or distributors in the market that supplied the market with all pharmaceutical products and all consumer products that were sold in pharmacies. Two of the biggest pharmacy chains, Apoteket AB and Apoteket Hjärtat, have also started their own distribution to take control of the distribution to pharmacies of OTC medicines. A single channel system is used for all prescribed medicines. In the Swedish pharmaceutical market, certain medicines can be exchanged for cheaper alternatives (Chivi 2020). That is, products competing for the selection are medicines that can be exchanged with each other, (i.e., generic substitutes are available to end customers). Prices are set based on “reversed auction.” This system has its advantages and disadvantages. From the perspective of the end-customer, the system provides lower prices and more affordable medications. However, this comes at a cost upstream in the supply chain because there is a lot of 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

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to be exchanged. Managing all this is considered time consuming, inefficient, and negative because more transports are needed to cover several deliveries of potentially new products each month (Chivi 2020).

Vision for the Future of Pharmaceutical Services

A major challenge in Sweden is that primary healthcare inquiries, strategic plans, and national policy documents usually do not include CP as a partner. Several different, promising primary care services are being offered, but they are usually delivered on a small scale due to a lack of remuneration and the philosophy of providers. Priority is given to sales and fast dispensing of prescriptions, often with a minimum amount of counseling. The development of a nationally-implemented, patient-oriented service/primary healthcare services in CPs is slow, probably due in part to a lack of collaboration among the different pharmacy chains since the reregulation of the pharmacy market in 2009. Nor has the issue of public reimbursement been addressed until recently, by the previously mentioned TLV Government Commission. Another factor is the rapid growth of pharmacy e-commerce in Sweden, resulting in a need for CPs and their pharmacists to find new ways to integrate this, (e.g., to develop new roles) (Westerlund & Marklund 2020). However, the newly started work, led by the TLV, to try out pharmacy service and systems for reimbursement is a positive step toward pharmaceutical services in CPs.

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ANNEX 8. CASE STUDY OF UK

Abbreviations

CP	community pharmacy
GP	general practitioner
MUR	Medicines Use Review
NHS	National Health Service
NHSBSA	NHS Business Services Authority
OTC	over the counter
PSNC	Pharmaceutical Services Negotiating Committee
UK	United Kingdom

Regulations, Contracted Services, Payments/Reimbursements, and Monitoring of Pharmacies in the United Kingdom

Centralized regulatory functions exist in the United Kingdom (UK) and the overall regulatory structure is similar in England, Scotland, and Wales (i.e., Great Britain), and in Northern Ireland. Scotland, Wales, and Northern Ireland have pursued an approach emphasizing partnership between purchasers and providers in the health system, whereas market forces play a greater role in the English health system, although specifically in the community pharmacy (CP) context, National Health Service (NHS) dispensing turnover, private sales, and net profits are strong drivers of what actually gets done.

The information contained here is primarily derived from England. National responsibility for CPs is shared with NHS England and the Department of Health and Social Care. The Pharmaceutical Services Negotiating Committee (PSNC) negotiates the contract on behalf of the profession in England. The system is governed by statutory arrangements, known as the Community Pharmacy Contractual Framework, which provides remuneration. The most recent contract considers the need for pharmacies to engage with local primary care networks (NHS 2021a). There are criteria for new pharmacies based on distance between pharmacies or number of people served. The Essential Small Pharmacy Scheme operating in Wales provides financial assistance to some pharmacies in addition their NHS payments when they are not economically viable because of their location but are considered vital to the provision of pharmaceutical services to the local community. Scotland has a similar Essential Small Pharmacy Scheme. There are no ownership restrictions in the UK, although the presence of a pharmacist at the point of dispensing is mandatory.

Pharmacy contractors are paid for NHS pharmaceutical services through a combination of (1) fees and allowances and (2) medicine margin. At its simplest, the medicine margin is the difference between the purchase price paid by the pharmacy contractor for a product and what they have been reimbursed by the NHS for the product. The amount of medicine margin being made by pharmacy contractors is assessed by a rolling annual medicine margin survey. The NHS Business Services Authority (NHSBSA) audits its own medicine pricing monthly by selecting and repricing a random sample of 50,000 items

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from all priced items in that month. In addition, there are independent checks to verify the accuracy of the pricing of prescriptions by the NHSBSA. These samples are selected on a random basis with the inclusion of set criteria to ensure that the sample is geographically representative and includes a mix of contractor size and types. All identified errors are notified to the NHSBSA and any resulting adjustment to the contractor's account (which can be an under or over payment) will appear on their next payment schedule (PSNC 2021b).

Under the 2019 general practitioners (GPs) contract framework, pharmacists will, in principle, be supported with an education/training program along with supervision by other pharmacists/ healthcare professionals (Wickware 2019). In the UK, the Pharmacy Quality Scheme forms part of the Community Pharmacy Contractual Framework. It supports the delivery of the NHS plan and rewards CP contractors that deliver quality criteria in three quality dimensions (clinical effectiveness, patient safety, and patient experience), but evidence is equivocal as to whether they are really helping to improve care and support.

Effects of the Information Technology Management Systems on Access to Services

Pharmacists are supportive of mobile apps in healthcare; however, several factors (i.e., risk, company policy, and lack of regulation) may currently preclude their wider use in pharmacy practice. There are many barriers to better information technology use. They include poor integration with other parts of the NHS due to the lack of interoperability of digital clinical systems; and issues around sometimes weak relationships between GPs and pharmacies, which, in turn, inhibit better integration and system design issues (Murray 2016; Davies, et al. 2014).

Effects of Contracting and Reimbursement on Access to Services

In the NHS England, under the 2019 NHS contract framework, by 2023/24, a typical network of 30,000–50,000 patients could choose to have its own team of approximately six fulltime equivalent pharmacists (NHS 2021b). Overall, there is flat funding until 2024, and no recognition of costs and inflation. Lack of workforce is one of the biggest risks to the entire plan. The plan makes little specific mention of CPs at all. There is mention of a plan to “substantially expand the number of clinical pharmacists.” It has been argued that CPs may be seen as having resisted or being unsuited to a clinical role. It is often argued by GPs and primary care planners/commissioners that clinical pharmacists are best placed in GP practices. But even there, pharmacists may play essentially administrative roles related to local budgetary control, rather than providing clinical care as defined from an informed patient interest perspective.

The existence of a medicine “margin” encourages pharmacy contractors to source products as cheaply as possible, which leads to competition putting downward pressure on selling prices, which in turn leads to lower NHS reimbursement prices. This fragmented medicine purchasing is a mechanism for keeping NHS drug costs down and would certainly be true for generic medicines. Others argue that drug cost control can be better achieved by central price and profit limitation mechanisms, together with large-scale purchasing.

However, for medicines not listed in the Drug Tariff (a monthly list of what will be paid to pharmacy contractors for NHS services provided either for reimbursement or for remuneration) and without a

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reimbursement price, this incentive mechanism is not very effective because pharmacy contractors are reimbursed based on the actual cost of the medicine that they endorse on the prescription. As a result, there is no incentive for pharmacy contractors to seek to source these products at the lowest possible cost.

There are other unintended consequences for the way that the NHS reimburses CPs; for example, excessive medicine margin on some products means that not all CPs have equitable access to the medicine margin-described in more detail here (Department of Health & Social Care, 2019).

Geographical Accessibility

In the UK, 84.8% of the population is estimated to live within a 20-minute walk of a GP premises: 81.2% in the most affluent areas; 98.2% in the most deprived areas; 94.2% in urban areas; and 19.4% in rural areas. This is consistently lower when compared with the population living within a 20-minute walk of a CP. It is not yet clear how patients perceive the differences in these providers, but results from qualitative studies suggest that for some services, due to the ease of access, CP is the preferred location. Clustering of CPs in England is common, although there is a positive trend between CP clustering and social deprivation, whereby clustering is more significant in areas of high deprivation (Todd, et al. 2015; Rushworth, et al. 2018). It is an interesting, but unanswered question, as to whether such clustering is helpful to the people living there or, rather, it represents a form of inadequate pharmacy service management.

Quality of Pharmaceutical Services

The provision of pharmaceutical care by community pharmacists remains limited. Lack of time and resources have repeatedly been found to be the main reasons for the lack of provision of comprehensive pharmaceutical care in the CP setting. In Scotland, pharmacists were perceived principally to be suppliers of medicine, although there was some recognition of roles in dealing with minor ailments and providing advice. CP was seen to offer incomplete services, which did not coordinate well with other primary care services. The pharmacy environment and retail setting were not considered to be ideal for private healthcare consultations. Existing inspection and contract monitoring processes have little utility in providing evidence of the fitness to practice of individual community pharmacists in England. The current focus of assessments is on the CP premises and the pharmaceutical services provided, and not on the performance of the individual pharmacy professionals (Costa, et al. 2017; Gidman & Cowley 2013; Hindi, et al. 2018; Jacobs, et al. 2013; NSH 2020).

Choice of Family Planning Methods

Prescription drugs, including contraceptives, are completely subsidized in Wales, Northern Ireland, and Scotland. In England, there is a standard prescription charge per item. However, free prescriptions are available for certain groups, including adolescents and low-income women (Center for Reproductive Rights 2012).

Patients in possession of an NHS prescription for drugs and/or appliances used for contraceptive purposes have no prescription charges levied on certain categories of drugs, such as spermicidal gels, creams, films and aerosols, and some devices (Parsons, et al. 2012; PSNC 2021a; French, et al. 2018).

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Contraceptive services are free and confidential. This includes services for people under 16. There are strict guidelines for healthcare professionals who work with people under 16. One can get contraception for free from some GP surgeries; community contraception clinics; some genitourinary medicine clinics; sexual health clinics; some young people's services; and some pharmacies (NHS 2021c).

In addition, in most of the UK, women and girls 16 years or older have access to emergency contraception without a prescription. Emergency contraception can be obtained free of charge at contraception clinics and most sexual health clinics, which also provide free family planning consultations. It may also be purchased from private clinics and pharmacies, or free of charge for women of all ages if they have a prescription. In Wales, emergency contraception is available without a prescription and for free, including at pharmacies, for girls who are 13 years or older. In the UK, since 2001, emergency hormonal contraception has been available from CPs, and prescriptions for the following items are automatically exempt from prescription charges: spermicidal gels, creams, films, and aerosols. In England, some 87.0% of women and 73.8% of men accessed at least one source of contraceptive supplies in the previous year. Most women (59.1%) used general practice and most men (54.6%) used retail outlets. Although access to contraception has widened in the past decade, there remains yet more potential for expanding services in CPs. There is a limited effect on users' accessibility to new drugstores because they tend to position in the areas of the city with an already high density of existing retailers. The great majority of fertile women in the UK use GP surgeries and CPs. Yet few GPs offer a full range of contraceptive options, partly because the fees available may make it uneconomic for them to fit IUDs.

The ongoing development of information and health technologies, coupled with changing public expectations and self-care abilities, are creating new opportunities for community pharmacists to contribute to better individual and population-wide health outcomes. This is well illustrated in the field of contraception, but how fast developments will be achieved in Britain depends on factors ranging from the quality of health sector strategic direction to the speed at which pharmacists replace dispensing-oriented attitudes and communication habits with the more open, non-judgmental, and service-user needs and preference focus—consultation styles required to deliver good quality clinical care and support behavior change.

Affordability

NHS provides care mostly free at the point of access, but in some cases, patients do have to make co-payments and direct payments (for services not covered by the NHS or for private treatment) (Cooke O'Dowd, et al. 2018). Recourse to exemptions from co-payments varies across populations in the UK. Younger people and households with children are more likely than older people to experience excess health spending (Cooke O'Dowd, et al. 2018). This indicates that although children are protected against such user charges, they may still live in households at high risk of catastrophic health spending.

Catastrophic spending is mainly driven by out-of-pocket payments for medical products and dental care, despite income-based exemptions from prescription charges. This could reflect spending on over-the-counter (OTC) medicines, which may increase as the NHS has over the past few years begun to restrict the availability of prescriptions for OTC medicines. However, there is a big difference between a

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catastrophic health expense (one involving 100s or 1000s of dollars for access to life preserving treatment) and one involving \$5 or \$10 for accessing something like an OTC pediatric analgesic. A survey found that several groups felt that they would be adversely affected by such restrictions, including the disabled, elderly, persons with diabetes, and those with a low income or from a lower socioeconomic background (concerns that a lack of affordability could lead to adverse patient outcomes) (Cooke O'Dowd, et al. 2018). In particular, proposals to restrict access to insulin pen needles and blood glucose testing strips could increase adverse patient outcomes (NHS 2019), yet public health-relevant outcomes as measured by such variables as diabetes-related amputation and vision loss rates need to be analyzed to confirm this.

Procurement and Supply Chain Management Challenges

The health supply chain follows a similarly traditional model adopted by many countries globally. This is typically the sourcing of products from manufacturer to pharmacy (hospital and community) via a wholesaler or directly. A large proportion of activity in the healthcare supply chain is undertaken by pharmaceutical wholesalers. Key activities of a typical UK wholesaler are selection, licensing, procurement, importation, and repackaging of pharmaceutical preparations and the provision of competitively priced generics. CP teams (see reference to these teams elsewhere in this report) are directly impacted and can influence the supply chain due to their management of direct pharmacy inbound logistics. This requires a comprehensive operational/management skill set to complement their clinical skills to run what is effectively a small to medium size enterprise. Both the primary and secondary care sectors have been profoundly affected by regular medicines shortages in the medicines supply chain negatively effecting patient care (The Association of the British Pharmaceutical Industry 2022). From a public health perspective, robust evidence would be required to show how much these shortages have actually harmed patients as opposed to inconveniencing or stressing pharmacy teams.

Scotland recently implemented the Quality and Efficiency Payment, which involves registered pharmacists receiving a monthly payment of £150 to boost quality and efficiency in pharmacies across Scotland (Community Pharmacy Scotland 2022). In March 2016, the Welsh government announced that it would provide a £750,000 injection into the Efficiency Through Technology Fund aimed at fully integrating GPs and hospitals with CPs. In addition, the scope of CP services is to be increased under the Choose Pharmacy Scheme, where individuals can access advice and treatment for minor ailments on demand from their local CP (Welsh Government 2016).

Vision for the Future of Pharmaceutical Services

There is strong economic evidence to suggest that for people with or at risk of acute illness and medical emergencies, CP-based enhanced services are cost-effective. These interventions reflect the advanced services currently provided at CPs in England, which have been established for some time, and the accumulated evidence strongly supports the continuation of their provision. Nevertheless, in early 2021, the Medicines Use Review (MUR) and Prescription Intervention Service was decommissioned by NHS England as not offering "...good value for money." MURs will be replaced by structured medication reviews, which the NHS claims are "more clinically effective for patients." They will not be carried out by community pharmacists, rather by "clinical" pharmacists working in primary care networks (Cox 2019). The idea of removing MURs goes back to as early as 2016 (Sukkar 2016).

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There are specific challenges around dispensing efficiencies, freeing up pharmacists' time, wider use of clinical skills of community pharmacists, and CP viability and consolidations. Pharmacists will need to effectively record and use data to demonstrate value. Little has been done in the way of promoting pharmacy services or enhancing public understanding of pharmacists' knowledge and skills. Privacy and confidentiality of the pharmacy environment, or rather the lack thereof, was considered a major barrier for using advanced pharmacy services. Moreover, patients/the public have perceived pharmacists' limited authority to be a barrier to broadening roles (Houle, et al. 2014; Dawoud, et al. 2019; McNaughton, et al. 2011; Saramunee, et al. 2015).

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