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Frontier Health Markets (FHM) Engage

GUIDE TO RULES, REGULATIONS, AND NORMS ANALYSIS

For Private-Sector Participation in Markets for Family Planning and Maternal, Newborn, and Child Health Products and Services

July 2023

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Authors:
Barbara O'Hanlon, Sarah Alphs, Xaher Gul

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c/o Chemonics International, 1275 New Jersey Ave. SE, Ste 200,
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Acronyms

BEmONC	Basic Emergency Obstetric And Newborn Care
FP	Family Planning
IUD	Intrauterine Device
MDA	Market Development Approach
MNCH	Maternal, Newborn, And Child Health
MOH	Ministry of Health
NGO	Nongovernmental Organization
NHIA	National Health Insurance Agency
PPMV	Patent and Proprietary Medical Vendor
UHC	Universal Health Coverage
USAID	United States Agency for International Development
WBG	World Bank Group
WHO	World Health Organization

Introduction

In low- and middle-income countries, the private sector operates alongside the public sector to deliver key health products and services, including for family planning (FP) and maternal, newborn, and child health (MNCH). Governments have an important role to play in engaging the private sector to ensure more equitable access to such products and services, by creating an enabling policy environment through an effective regulatory framework.

Frontier Health Markets (FHM) Engage is a United States Agency for International Development (USAID) project that supports developing country governments, donors, and their implementing partners in strengthening local health markets to ensure more equitable provision of and access to FP and MNCH products and services. It uses a market development approach (MDA) that focuses on identifying and addressing the root causes of underperformance in core market functions in order to achieve sustainable changes to supply and demand.

Building on more than 30 years of USAID efforts in this area, FHM Engage works to 1) improve the market environment for greater private-sector participation in delivering health products and services and 2) ensure more equitable access to and uptake of high-quality, consumer-driven health products, services, and information.

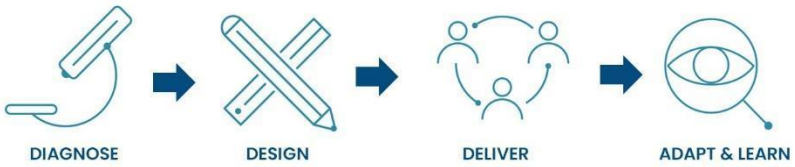
Over the years, USAID projects have gained extensive knowledge of and experience in regulatory reforms, and evidence is available on the rules, regulations, and norms that support or hinder private-sector provision of FP products and services (Feeley, R, 2009; Callahan, S, 2019). For example, much is known about the following elements of regulatory reforms: 1) health professional licensing requirements, 2) facility requirements for public and private providers, 3) licensing of pharmacists and professionals, 4) facility requirements for pharmaceuticals, 5) licensing requirements for supply chain actors, 6) consumer and patient protection, and 7) enforcement mechanisms and regulatory capacity. But until now, guidance has been lacking on how to apply this information through an MDA to strengthen market performance.

This document from FHM Engage provides updated information on rules, regulations, and norms in the context of an MDA and offers guidance on legal and regulatory analysis. It also explores new areas of the regulatory domain that have not received enough attention in terms of how they contribute to market performance or underperformance. These include regulations linked to market operations (e.g., market entry, competition, and data transparency), norms that create barriers to consumer demand, and provider bias in supplying FP and MNCH products and services.

FHM Engage created this document to clarify the complex configurations of rules and regulations, procedures, and enforcement mechanisms that are currently in use or are needed in these market systems to strengthen market performance and help achieve global health goals. It is intended to help governments, donors, and implementing partners (including FHM Engage) assess how existing rules, regulations, and norms enable or constrain FP and MNCH market development. It offers 1) a simple approach to understanding the myriad policies, laws, and regulations that directly affect FP and MNCH markets, 2) guidance on the types of information to collect and how and where to assess the impact of rules, regulations, and norms, and 3) insight into trends in regulatory barriers.

FHM Engage has also developed a companion document – *Guide to Rules and Regulations Reform* – that explains how to apply the knowledge gained from the in-depth analysis described in this document. Both documents are based on the Pathway to Impact process (Diagnose, Design, Deliver, and Adapt and Learn; see Figure 1) for effectively implementing interventions for market development.[1]

FIGURE 1. PATHWAY TO IMPACT



This document introduces key concepts in rules and regulations analysis, explains a process for conducting a rules and regulations review, and provides case study examples to illustrate the process. The annexes provide checklists for examining regulatory areas, common barriers, and strategies to overcome those barriers.

Background

According to a recent analysis of care-seeking patterns in 36 low- and middle-income countries, more than one in three women using modern contraception obtains her method from a private-sector source (Bradley, S, 2022). In addition, more than one in five births in these countries occurs in a private-sector setting (Benova, L, 2015). Pharmacies and drug shops are becoming increasingly important as locations for obtaining FP and MNCH supplies and treatment (Wafula, F, 2010), while financial barriers and inequalities in the use of secondary-level clinical facilities are increasing (MacIntosh, M, 2016). Private providers are often conveniently located for care-seekers and can offer products and services at relatively low cost, but the quality varies, posing risks to patient safety and the efficacy of care. In this context, achieving key global health goals – such as ensuring equitable access to and use of high-quality FP and MNCH products and services – will require accurate analysis of, and well-targeted interventions in, the market systems in which these products and services are provided.

In many low- and middle-income countries, the growth of private-sector markets for FP and MNCH products and services has happened organically and often in the absence of clear rules and regulations. Organic growth has its pros and cons. On the one hand, it is a response to consumer demand and needs. On the other hand, elements that ensure population health (e.g., clinical quality) may be absent. Organic growth in the absence of a clear understanding of demand and supply can also lead to missed opportunities to engage the private sector. For example, if the rules governing market entry are too stringent or the cost of entering certain markets is high, the private sector may stay away, thereby hindering the optimal use of private-sector resources in areas of economic and societal need. Conversely, clear rules and regulations can send market signals that greatly improve market performance.

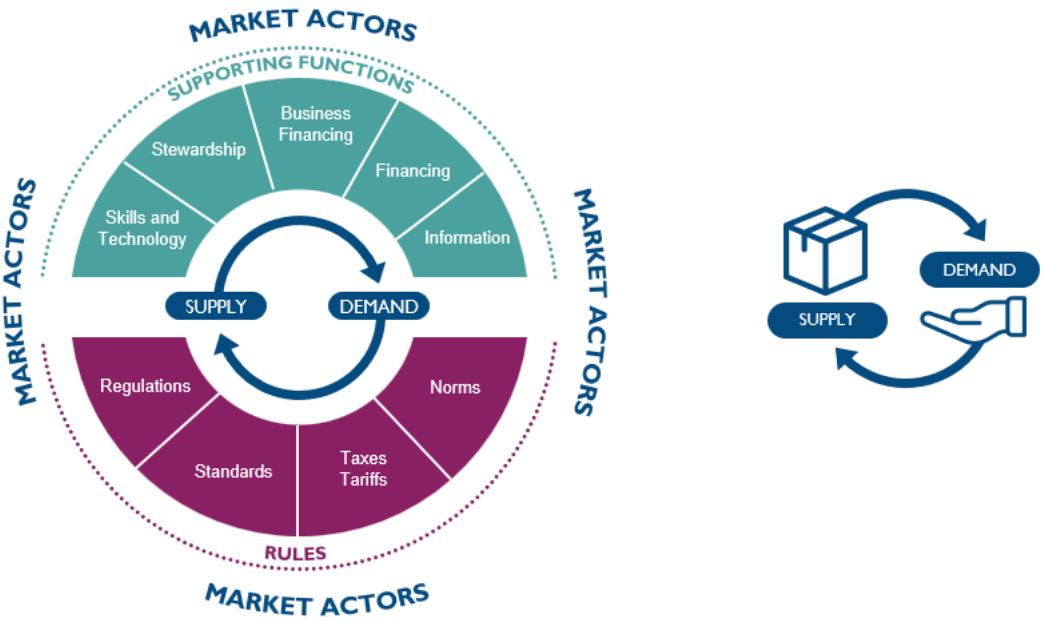
[1] For more information on the Pathway to Impact, see FHM Engage "Course Notes: Implementing a Markert Development Approach (MDA) in the Health Sector, Session 2 of 4: Design," August 2023.

MDA programs focus on changing the operation of market systems in health (see Figure 2). This can improve access to health-related goods and services and eventually lead to improved health outcomes. But what exactly is a market system? What does a review of rules and regulations involve? And can the findings from this type of analysis change the core operations of health markets?

As Figure 2 illustrates, a health market system comprises:

- A network of buyers, sellers, and other market actors that come together to conduct transactions for particular health products or services (outer ring)
- A set of functions, rules, and norms that collectively determine the operating environment (second ring) for all market actors (inner ring)

FIGURE 2: FRAMEWORK FOR UNDERSTANDING ELEMENTS OF A HEALTH MARKET SYSTEM



Transactions between market actors are at the core of a health market system. In a transaction, one party offers something (the supply), and another party receives it (the demand). In FP and MNCH health markets, a transaction can occur between providers of products and services and consumers. Note that a transaction between market actors can occur with or without an exchange of money. For example, a woman obtaining free contraceptives at a public or private pharmacy would fall under this definition of a transaction.

Understanding the core operations of a specific health market – e.g., the nature of the transactions between supply and demand – requires closely examining the supporting functions, regulations, rules, and norms that shape and influence that market.

- **Supporting functions:** Attributes of a market system – such as stewardship, financing, market intelligence and information, and access to finance – that influence incentives for consumers and suppliers and their ability to perform their respective roles in that system.
- **Rules:** Formal mechanisms that govern the behavior of market actors. Rules include policies, laws, and regulations issued by public authorities, as well as rules and standards (not to be confused with clinical standards) issued by professional associations and industry bodies, such as codes of conduct.
- **Norms:** Informal rules that govern the behavior of individuals, groups, and societies and are products of local culture, religious traditions, value systems, cultural practices, and other factors. Norms influence the extent to which formal rules are accepted.

Analyzing rules, regulations, and norms is critical to understanding the transactions within a specific health market and diagnosing the root causes of why a specific health market is underperforming. The findings from this analysis enable market actors to design interventions that target those root causes – not the symptoms – and can, over time, improve market operations in terms of availability, quality, and affordability of health products and services that address high-priority health problems.

Methodology

This document examines the configurations of rules and regulations, procedures, and enforcement mechanisms that are currently in use or are needed in FP and MNCH market systems to enable market development. It is not a theoretical description of the rules and regulations that are needed but rather an elaboration of what exists across country contexts to promote market development in FP and MNCH.

The document is based on a desk review of relevant data, focusing on peer-reviewed and grey literature (including USAID and World Bank websites) and all relevant documents from previous and current USAID-funded programs, including regulatory reviews and technical briefs from the past 10 years. The literature review also included an analysis of private-sector assessments in several countries to develop checklists of common legal and regulatory barriers across country contexts.

Key Concepts in Rules and Regulations Analysis

One key government stewardship function is to create a supportive and effective environment for collaboration between the public health sector and the private health sector. Under ideal circumstances, governments can use regulations to make the best use of both sectors and foster confidence and trust for mutual collaboration. Ineffective or outdated regulations, on the other hand, can perpetuate mistrust or create roadblocks that impede the overall performance of the health system and key health markets in FP and MNCH.

Before addressing the problems that arise from absent, excessive, inadequate, or ineffective regulations, it is important to know what the private health sector consists of and what legal instruments may need to be modified, replaced, or enforced to help it develop. Note that the term *regulations* is often applied loosely to a spectrum of governmental powers and functions that are designed to maintain control over private-sector activities.

The Private Health Sector

Key elements of the private health sector include:

- **Private for-profit entities:** Commercial entities that deliver health services (e.g., hospitals, clinics, and single practitioners) or health products (e.g., manufacturers, distributors, pharmacies, and drug shops).
- **Private not-for-profit entities:** Nongovernment organizations (NGOs), faith-based organizations, social enterprises, and other organizations that deliver health services and products.
- **Formal entities:** Entities in the private sector that comply with regulatory requirements.
- **Informal entities:** Entities in the private sector that practice illegally.

Regulatory Levels and Instruments

Assessing the rules, regulations, and norms of a specific market system requires understanding the layers of the legal and regulatory environment and the range of instruments used to set the rules of the health system and how the government engages private market actors.

Regulatory instruments governing the health system include:

- **Policies:** Statements of government intent, including those with constitutional backing and the force of law and those that may be an unenforceable vision for the future. Many low- and middle-income countries have a constitutional commitment to deliver health care to their population for free thus governments set formal charges for public clinics but may also establish policies that disincentivize private provision of care.
- **Legislation, statutes, or laws:** Instruments that put a policy into effect and give authority to specific government agencies to establish rules governing the health system. For example, laws may authorize a ministry of health (MOH) to establish and enforce rules governing the operation of health providers and facilities in the public and private sectors.

- **Regulations:** Generally, detailed standards that are adopted by the government within the framework of a particular statute. A designated government agency defines the regulations and elaborates on the standards set in legislation. This same agency inspects, reviews, and enforces sanctions. For example, in East Africa, medical councils are responsible for setting standards for facility licensing and professional certifications.
- **Guidelines:** Instructions that clarify regulations and standards (often referred to as *clinical* or *operational guidelines*). In particular, guidelines can facilitate the work of inspectors, who receive authority from the regulatory agency to enforce the regulations (or terms of contract). For example, a pharmacy regulation may require that pharmacists keep a copy of every prescription signed by a physician who is authorized to prescribe a certain controlled class of drugs. The guidelines would generally reflect the latest clinical best practices and/or technologies that pharmacists should use to comply with the regulation.

This document also discusses regulatory areas that are not commonly examined – specifically, economic regulations that govern the market conditions under which private providers and suppliers operate. These include regulations governing market entry, price and profit margins, taxes, competition, and incentives (mostly economic and financial) to grow and/or limit private health care businesses.

Norms

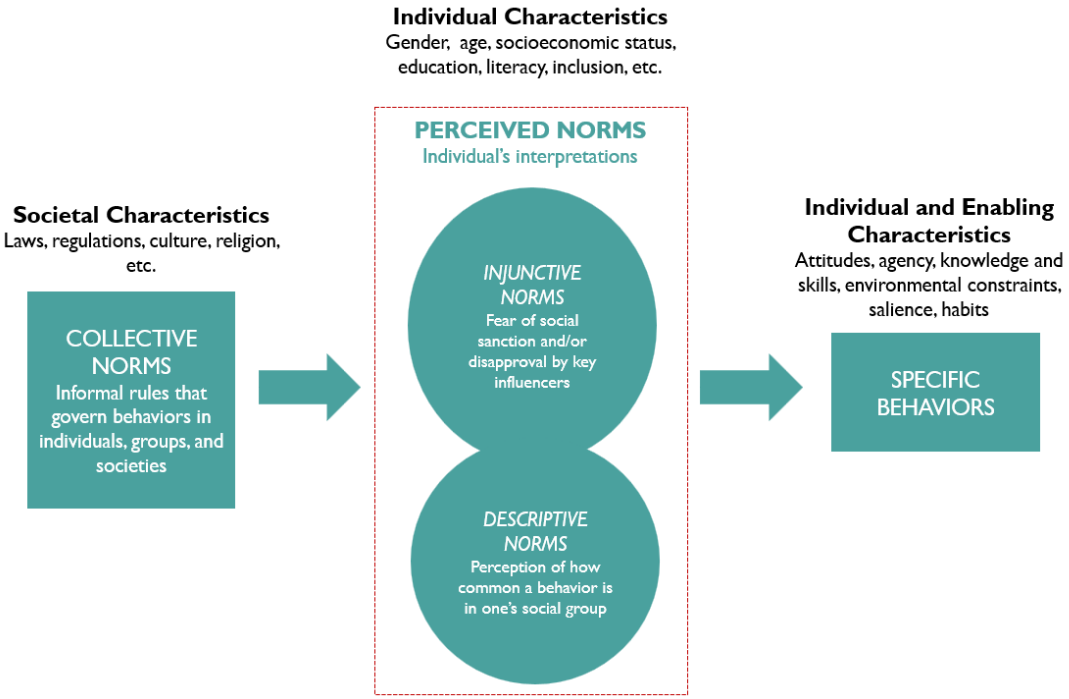
Norms are an underappreciated factor that affects market performance. It is important to note the differences as well as the linkages between norms and laws. Norms are socially negotiated and contextually dependent. Laws and regulations, on the other hand, are explicitly codified in the instruments described earlier, and violations are linked to corresponding punitive measures and/or sanctions. Laws are not socially negotiated – although their enforcement may be – whereas norms and their violation, by definition, are negotiated through social interaction (Rimal, RN, 2015). This is an important distinction because it explains why a certain practice (e.g., home delivery rather than in a facility, to reduce maternal mortality) might be acceptable in one social context but not in another.

Laws and norms can and do reinforce one another. For example, a smoker may choose to refrain from lighting up in a public place for any number of reasons, including legal (fear of being penalized) or normative (fear of reproach from others). However, an individual's judgement and perceptions are also at play, such as when a physician smokes despite clear evidence of the negative health impact of smoking and clinical guidelines that identify smoking as a high-risk behavior. To understand (and empirically assess) the influence of norms on the behaviors of key market actors, it is essential to understand how norms are perceived at the individual, psychological level (Lapinski, M et al., 2005; Rimal, RN, 2015; Chung, A, 2015).

Perceived norms can be divided into two types (see Figure 3):

- **Injunctive norms:** Individuals' perceptions regarding what they ought to do, based on whether they believe a certain behavior will result in social sanction and/or disapproval from key influencers.
- **Descriptive norms:** Individuals' perceptions regarding what they ought to do, based on what they believe most others in their social group do.

FIGURE 3: TYPES OF NORMS AND THEIR INFLUENCE ON BEHAVIOR



The Review Process

As discussed in the previous section, a review should encompass a wide range of laws, policies, regulations, and guidelines, which can be overwhelming. So where to start? As with the Diagnosis process – the first step in the Pathway to Impact – the starting point is working with local market actors, both public and private, to identify the scope of the problems in the given area of health care, such as FP and MNCH, and the markets that offer an opportunity. Often the markets are related to a specific health product or service or both. Having a shared understanding of the problem and agreement on the health markets to consider can greatly facilitate the review process.

This section presents a five-step process for reviewing the myriad rules and regulations affecting market performance for FP or MNCH (see Figure 4). Each step presents strategic questions to consider; offers guidance on the sources of information needed; outlines key rules, regulations, and norms to examine and their potential positive and negative effects on market performance; and identifies possible strategies to address market underperformance caused by rules and regulatory barriers.

FIGURE 4. PROCESS FOR REVIEWING RULES AND REGULATIONS

Although a desk review for steps 1 through 4 can easily reveal many of the regulatory barriers to a specific market's performance, engaging public and private market actors early in the process can greatly improve the analysis. Moreover, this engagement can lead to a common understanding of how these barriers affect market operations and performance and can start a dialogue on developing feasible solutions.

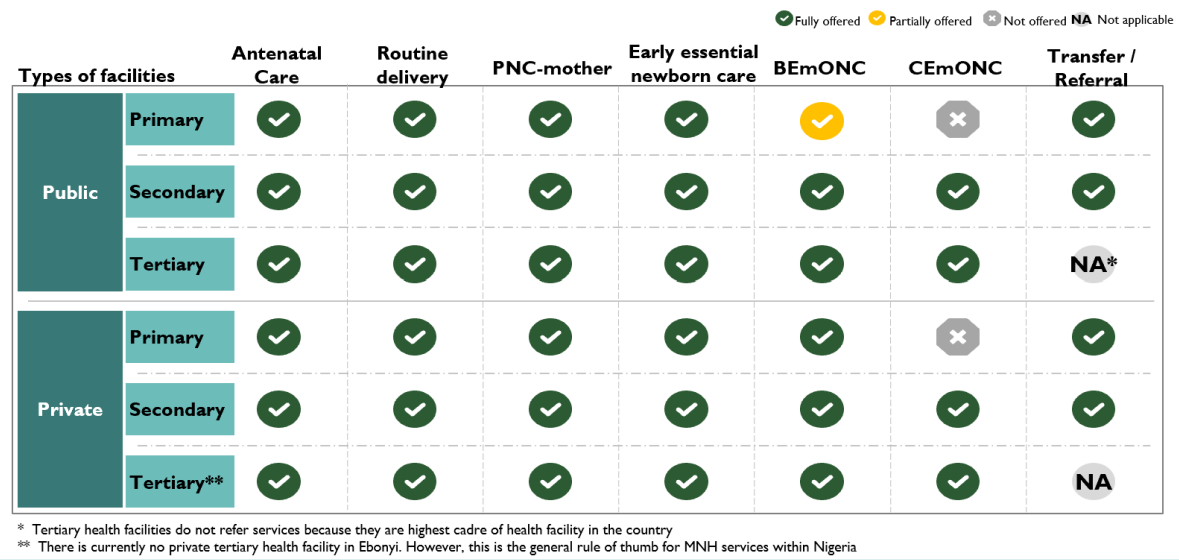
Case Studies

The first task is to define the health market. This helps narrow the focus of the review. Several of the upcoming boxes illustrate the process using two case studies. The first case study is based on efforts in Nigeria to increase access to basic emergency obstetric and newborn care (BEmONC). The second one is based on efforts in Tanzania to ensure adequate supplies of a key pneumonia treatment, Amox DT.

BOX 1: THE BEMONC MARKET IN NIGERIA

The World Health Organization clearly defines the life-saving interventions needed to treat causes of major obstetric and newborn morbidity and mortality (WHO, 2009). A facility, whether public or private, must be able to provide seven key services in the last three months of pregnancy to be classified as a BEmONC facility: 1) administration of parenteral antibiotics to prevent puerperal infection or treat abortion complications, 2) administration of parenteral anticonvulsants for treatment of eclampsia and preeclampsia, 3) administration of parenteral uterotonic drugs for postpartum hemorrhage, 4) manual removal of the placenta, 5) assisted vaginal delivery (vacuum extraction), 6) removal of retained products of conception, and 7) neonatal resuscitation.

In Ebonyi State, secondary and tertiary facilities run by the state MOH are BEmONC facilities. Private facilities at any level can be BEmONC facilities, but there are no private tertiary facilities in Ebonyi. The private BEmONC facilities in the state range from nurse/midwife clinics and maternity homes to private clinics and general hospitals owned and operated by specialists, doctors, and medical officers.



Types of facilities		Antenatal Care	Routine delivery	PNC-mother	Early essential newborn care	BEmONC	CEmONC	Transfer / Referral
Public	Primary	✓	✓	✓	✓	✓	✗	✓
	Secondary	✓	✓	✓	✓	✓	✓	✓
	Tertiary	✓	✓	✓	✓	✓	✓	NA*
Private	Primary	✓	✓	✓	✓	✓	✗	✓
	Secondary	✓	✓	✓	✓	✓	✓	✓
	Tertiary**	✓	✓	✓	✓	✓	✓	NA

* Tertiary health facilities do not refer services because they are highest cadre of health facility in the country
** There is currently no private tertiary health facility in Ebonyi. However, this is the general rule of thumb for MNH services within Nigeria

Step 1. Map the Institutional Arrangements

Tasks

Step 1 involves identifying the key actors involved in establishing the rules, regulations, and practices in the health market under consideration. The mapping has three levels.

Level 1: Identifying the laws, policies, and strategies that define the private sector's role in the general economy and specifically in health care. In addition to multiple departments in the MOH that can set policy on private-sector development in health generally or in specific health areas, some ministries and government offices outside the health sector are also crucial to private-sector development.

Level 2: Identifying the regulatory agencies that set the rules on how healthcare is delivered. Depending on the market focus, the review will concentrate on the regulatory agencies responsible for overseeing health services, health products, or both. For example, the Nigeria case study focuses on agencies that regulate health services, while the Tanzania case study looks at agencies that regulate the supply of health products as well as those overseeing delivery of child health services.

Level 3: Mapping regulatory agencies within and outside the health sector that set the rules that lead to favorable or unfavorable market conditions. Many fundamental health regulations have market impact, such as those governing health licensing and product registration. Regulatory agencies outside the health sector establish economic regulations that directly influence private investment in the sector and the profitability and sustainability of private health care businesses.

All of this mapping supports analysis of the rules and regulations themselves *and* helps identify a subset of market actors to focus on in a market diagnosis.

The first task is to create a table that lists the government ministries and regulatory agencies in the country that are related to the specific health market. Table 1 provides an overview of the regulatory agencies commonly found in low- and middle-income countries; their names will vary by country and region.

TABLE 1. OVERVIEW OF REGULATORY AGENCIES COMMONLY FOUND IN LOW- AND MIDDLE-INCOME COUNTRIES

PRIVATE-SECTOR DEVELOPMENT	
Regulatory Function	Regulatory Agency
Private-sector role in economic development	Office of the prime minister or president Ministry of finance and/or ministry of economic development
Private-sector role in health	MOH, office of the health minister MOH, department of policy and planning MOH, FP, MNCH departments Subnational government
SERVICES	
Regulatory function	Regulatory agency

Facility licensing	Medical council, medical bureaus Often organized by type of facility and/or profession
Professional certification	Medical council, medical bureaus Often organized by type of profession (e.g., doctor / dentist, nurse/midwife, pharmacist / pharmacy technician, allied professionals)
Clinical guidelines	MOH, department of quality MOH, MNCH and sexual and reproductive health departments
Quality accreditation	MOH, department of health services National health insurance authority and/or contracting agency
Information	MOH, department of policy and planning MOH, department of information and statistics National health insurance authority, government contracting agency
PRODUCTS	
Regulatory function	Regulatory agency
Facility licensing	Pharmacy council
Professional certification	Pharmacy council, allied professionals
Product registration	National drug regulatory authorities
Information	MOH, central medical stores
MARKET CONDITIONS	
Regulatory function	Regulatory agency
Business license	Corporate authority / business licensing and registration authority
Taxes	Varies depending on type of taxes (e.g., income taxes, sales taxes)
Tariffs	Import tax authority
Competition	Facility licensing agency control market entry/exit
Prices	MOH
Information	MOH, department of policy and planning MOH, department of information and statistics National health insurance authority, government contracting agency

Strategic Questions

Areas to explore when mapping the institutional arrangements include:

- What are the key agencies related to the health market under consideration, in order of importance?
- What are their main responsibilities?
- Do the responsibilities and mandates of these key agencies overlap?
- Is there competition and/or conflict between agencies?
- Do the agencies operate in silos, or do they coordinate and collaborate?

- Are there gaps in the regulatory functions in the health market?
- Do the key agencies have sufficient capacity (including budget, staff, expertise, and technology) to perform their roles?
- Do the agencies have the will (including authority, incentives, desire) to perform their roles?
- Are accountability mechanisms in place to ensure that the agencies and key individuals perform their roles?
- What barriers do they face in enforcing the regulations?

The answers to the strategic questions will reveal many of the factors contributing to weak enforcement. Below are the main reasons for lack of enforcement of regulations common across low- and middle-income countries (Source: Feely et al., 2009).

- **Competition.** In many low- and middle-income countries, "turf battles" between regulatory agencies can lead to inaction.
- **Costs.** Licensing fees are insufficient to cover regulatory agency costs. The agencies thus lack sufficient budget to hire and train staff and inspectors and cover vehicle and travel expenses. They also do not have the budget to hire or contract with lawyers to conduct disciplinary hearings.
- **Enforcement is a low priority.** The MOH may be focused on running its own facilities, not on enforcing standards and guidelines across the public and private health sectors. This often results in low budget allocations for enforcement.
- **Corruption.** Limited budget and weak controls create incentives for corruption among inspectors.
- **Complaints are ignored or inadequately investigated.** Patients often complain to the MOH about dangerous or negligent practices, particularly on the part of unscrupulous private providers, health businesses, and informal providers (such as "quacks" and "suitcase drug suppliers"). But the agency responsible for investigating these claims may ignore them due to lack of funds, the low priority given to enforcement at the MOH, or corruption.
- **Cumbersome processes.** When many complicated steps are required to revoke the license of a health facility or professional, disciplinary action may never be completed.
- **Lack of accountability mechanisms.** Without sufficient accountability mechanisms, both government agencies and private-sector providers can operate with impunity.

Data Sources

The three primary sources of information for mapping institutional arrangements are regulatory agency websites, the statues establishing each agency, and key informant interviews. There are interviews guides tailored for these key informants in the annex.

BOX 2: INSTITUTIONS THAT REGULATE MATERNAL AND NEWBORN HEALTH IN NIGERIA

Multiple institutions are responsible for regulations and guidelines governing maternal and newborn services in Nigeria's Ebonyi State. (Note that the market definition does not include products.) Many of these are federal institutions with state-level offices in Ebonyi. They include:

- → Corporation Authority—issues business licenses to health care facilities
- → State MOH Inspectorate Unit—inspects health facilities and issues and renews health facility licenses
- → State MOH Medical Services and/or Maternal Health Department—responsible for clinical guidelines for maternal and newborn care
- → Medical and Dental Council of Nigeria—issues and renews health professional licenses and approves continuing medical education hours (a requirement for license renewal)
- → Nursing and Midwifery Council of Nigeria—issues and renews health professional licenses and approves continuing medical education hours
- → Association of General and Private Medical Practitioners of Nigeria and the National Association of Nigeria Nurses and Midwives—the key representatives of maternal and newborn health providers in discussions on policy, regulations, and industry professional codes of ethics and codes of conduct

These institutions have clear scopes of responsibility that do not overlap, thereby avoiding conflicts between them. Due to their limited number, regulatory functions appear to be concentrated rather than fragmented. However, the institutions face some common obstacles to fulfilling their respective regulatory roles and performing their functions, such as low budget allocations and insufficient staff to process licenses and enforce regulations.

Step 2. Review Laws and Policies Governing Private-Sector Engagement

Tasks

The first task is to understand the government's general position on the private sector. The office of the president or prime minister and/or the ministry of finance develops these policies and strategies and is responsible for monitoring their implementation. A quick review will uncover whether a government is "pro-business" and whether it plans to partner with the private sector in specific economic and social sectors. This is an important exercise because the government position on private-sector development can change with administrations.

The second task is to understand the government's constitutional powers and ethical responsibility to protect citizens from harm caused by the actions of other citizens. This is often referred to as "police power," which gives the government authority to protect patients who may be unable to judge the qualifications or quality of a health care provider or the efficacy or safety of a drug or medical device. Governments also have the power to structure markets and the economy to protect patient safety and facilitate broader access for the poor. This enables the government to impose conditions on medical providers, services, or prices for medical care or drugs. The review of laws and policies will also determine whether the government encourages or discourages private provision of medical care.

Strategic Questions

- Is there a guaranteed right to free health care? Does this prevent the private sector from charging for it?
- What agencies have the legal power to draft and adopt health regulations?
- Do the same agencies have the power to enforce the rules?
- What is the government policy regarding private-sector engagement? In general? In health care?
- What mechanisms has the national government put in place to engage the private health sector?

Data Sources

The necessary information can be easily obtained through a quick review of key articles in the constitution and the national health policy (sometimes called the Health Act or the Health Code). Interviews with public health officials can reveal this information as well. Box 3 exemplifies an important finding from reviewing current policies and regulations.

BOX 3: PRIVATE-SECTOR ENGAGEMENT IN NIGERIA

While Nigeria has several policy frameworks for private-sector engagement at both the national and state levels, implementation of these policies in Ebonyi State has been limited. The 2005 National Policy on Public Private Partnership for Health in Nigeria recognizes the importance of engaging the private sector, but Ebonyi has no active unit within the state MOH to lead private-sector engagement or public-private partnerships. Public-private interaction is only ad hoc and informal.

Step 3. Review the Core Regulatory Areas Affecting Private-Sector Engagement

Tasks

Step 3 is the central part of the regulatory assessment. Five core regulatory areas directly influence private-sector capacity to deliver essential health services such as FP, reproductive health, and MNCH. These areas are summarized in Table 2. This step involves systematically examining each of the five areas and highlighting the most frequent barriers to private-sector engagement and/or market performance in each one. Lack of enforcement can also be the root cause of a regulatory barrier and should be part of this review.

TABLE 2: CORE REGULATORY AREAS AFFECTING PRIVATE-SECTOR ENGAGEMENT

1.	Rules and regulations governing health facility and pharmacy licensing
2.	Rules and regulations governing health professional licensing
3.	Rules and regulations governing the supply of pharmaceuticals
4.	Regulations governing market conditions and shaping provider incentives
5.	Regulations and norms governing private-sector data and reporting

Data Sources

Many of the relevant statutes, regulations, and guidelines can be found on the MOH and/or regulatory agency's website. If not, it will be necessary to visit the regulatory agency to obtain a copy of these regulations. Legal language can be daunting and tedious to review. Focusing on the five core regulatory will help narrow the scope of the review. The checklists in Annexes 1 through 5 can also help.

Stakeholder interviews can also help identify the main regulatory barriers, and they can help identify the gap between what the regulations say and what happens in practice. Annex 6 contains the interview guide used in the Nigeria BEmONC case study, which can serve as a template for exploring the strategic areas in each of the five core regulatory areas.

Area 1. Rules and Regulations Governing Health Facility and Pharmacy Licensing

Facility licensing requirements fall into three categories: staffing, equipment, and the physical facility. Licensing for pharmacies and drug shops focuses on the same three categories but with different specifications. Below are common problems created by facility licensing regulations and processes. (See Annex 1 for a checklist that can help identify these constraints.)

Excessive regulation. Highly detailed, prescriptive regulations raise the cost of medical care without providing benefit to patients. But regulations that are silent on truly critical elements also create risks. When examining facility licensing regulations, look to see if the regulatory agency has created multiple license classes and/or has matched physical facility and equipment requirements to the types of services provided by the facility. In most low- and middle-income countries, public facilities are not subject to facility licensing requirements. But in some cases, the facility and equipment requirements are more stringent for private providers than for public ones providing the same services.

Overly detailed facility requirements can discourage private providers from entering the market, thereby limiting access to essential services. A typical consulting room used by a nurse, doctor, or clinical officer in a practice that performs basic diagnosis and prescribes simple treatments should be subject to minimum facility requirements because the provider does not perform invasive procedures or have extensive diagnostic equipment. But if a physician is to perform invasive procedures such as examinations or insertions of intrauterine devices (IUDs), additional equipment and sanitation and sterilization requirements may be called for, but not more than would be included in the design of typical public facilities performing the same procedures (Feeley, R, 2009).

To address quality concerns, facility licensing regulations in low- and middle-income countries often require specific health professionals who are in short supply to be on site at all times and/or supervise

lower-level staff. This can lead to unintended consequences. Sometimes public nurses are barred from opening a private practice, even in underserved areas (Feeley, R, 2009). In Zambia, public nurses provide most primary care and perform a wide range of procedures and prescribe a list of medicines. But regulations require that facilities have a managing physician to supervise private nurses in order to receive a facility license. The assessment in Nigeria identified a supervisory requirement for nurses and midwives in the private sector as a regulatory barrier. Lack of clarity on how much physician supervision is required has also created cost uncertainty, and there is no guidance on terms of payment. This puts nurse/midwife business owners in a difficult negotiating position with physicians because they need a supervising physician in order to obtain a license (Barnes, J, 2008).

This same barrier exists with pharmacies. Most low- and middle-income countries allow only fully licensed pharmacies with an onsite pharmacist to dispense certain essential drugs (such as antibiotics or painkillers). However, most pharmacists are employed in big hospitals or urban pharmacies, so this regulation limits access to essential medicines in rural and remote areas. Despite regulatory reforms in Nigeria to expand access through patent and proprietary medicine vendors (PPMVs), other factors have created barriers: Many PPMVs do not recognize the value of facility registration, registration and renewal fees present a financial burden, and tensions exist between the Pharmacy Council and associations representing PPMVs (Child Health Task Force, 2021).

Cumbersome licensing processes. In many low- and middle-income countries, the MOH and its regulatory agencies still rely on paper-based systems for licensing facilities and professionals. The application process often requires private health facility and pharmacy owners to present their application in person, which can mean closing their business and traveling a long distance to reach the capital city. For example, the 2016 private-sector assessment in Uganda found that private providers in the north spent about three days traveling to Kampala to submit their paperwork. They would then have to wait four to six months for an inspection appointment. The assessment found that the entities that license pharmacies are spread across multiple agencies, creating confusion, and adding additional costs to submit duplicate license applications (O'Hanlon, B, 2016).

Inconsistent or conflicting licensing regulations. In Nigeria, a nurse needs five years of experience in the public sector before opening a private nursing home, and a midwife needs five years of experience before opening a private maternity home. The National Nurse Midwife Council establishes the regulations, and the state health department issues the license for the private facility. The council does not require a supervising physician, but various states have standards beyond those established by the council, leading to discrepancies between states. This creates additional costs and burden for private nurses and midwives in some states (Barnes, J, 2008).

BOX 4: HEALTH FACILITY LICENSING REGULATIONS AND PROCESSES IN NIGERIA

Facility licensing is cumbersome and costly in Ebonyi but does not pose a serious barrier to private health care businesses. A private health facility must first obtain a business license from the Corporation Authority before seeking a health facility license with the state MOH. According to key informant interviews, the facility scopes (e.g., staffing, equipment, and physical facility) are commensurate with the level of care by facility type. Notably, public facilities are required to obtain a facility license, but few do. Facility regulations are the same for public and private facilities. The licensing process mostly affects private providers, and it is cumbersome (in terms of paperwork) and costly (in terms of fees and time lost waiting for an inspection). Also, the regulations require annual renewal of the facility license—less as a strategy to ensure quality and more as a way to raise revenues through fees. Finally, facility licensing requirements include data reporting by both public and private facilities, but this is not enforced—one of many factors contributing to low rates of private-sector reporting.

The annual renewal requirement has created a huge backlog in applications, and many private facilities operate without a current license as they wait for an inspection, potentially endangering patient safety. During this period, some private facilities operate outside of facility scope—for example, if they have been classified as a secondary facility and still perform some of these functions but have lost key staff or key equipment, the inspection process cannot keep up with the changes and reclassify the facility appropriately.

Ownership restrictions are a barrier to private provision of BEmONC. The regulations require nurses and midwives to have at least five years of experience in the public sector before opening a private practice. Moreover, they need to demonstrate "access" to a licensed obstetrician/gynecologist, which increases operating costs for the private facility.

Effective facility regulations can create positive behaviors and changes in the marketplace:

- Quality guarantees can encourage wealthier people to use the private sector, expanding public-sector access for the poor.
- Statutes can create pressure to improve the quality of public services, increase patient access and consumer responsiveness, and reduce unnecessary investments in equipment and infrastructure (e.g., MRI and ultrasound machines, office labs) or staffing that are not relevant to patient needs.
- Flexible requirements can motivate private providers to open facilities in underserved areas and allow for optimizing staffing levels in the face of shortages of health professionals.
- Regional and local inspection offices and a national register of professionals/facilities can lead to faster and more responsive inspections.
- Agencies that license facilities can have a clearer understanding of the scope of their oversight responsibilities (e.g., professional vs. facility).
- Inspection staff that are skilled and have enough resources can reduce the risk of corruption (e.g., bribery).
- Transparent record keeping can build trust between the private sector and regulatory authorities.

Area 2. Rules and Regulations Governing Health Professional Licensing

Professional licensing (also referred to as certification) encompasses licensing/relicensing, continuing medical education, scopes of practice, and private practice. Unlike facility licensing, health professional licensing applies to all health professionals, whether they work in the public sector or private sector or both (dual practice), as is the case in many low- and middle-income countries. Below are common problems in licensing regulations for health professionals and enforcement of those regulations. (See Annex 2 for a checklist that can help identify these constraints.)

Out-of-date scopes of practice. Scopes of practice should be linked to health professional skills and training. In general, the scopes of practice for service providers are well thought out and do not constitute a barrier to private-sector development. For example, Nigeria's MOH thoroughly defines reproductive health responsibilities in the booklet *National FP Reproductive Health: Guidelines and Standards of Practice*. For FP, the guidelines specify that patent medicine vendors and traditional birth attendants can sell condoms and refills of oral contraceptives (first-time users must see a qualified provider for a consultation); licensed pharmacies can sell emergency contraception and oral contraceptives without a prescription; nurses can counsel patients about FP, initiate and resupply oral contraceptives, and administer injectables; midwives can perform all of the aforementioned functions plus insert IUDs and implants (if they have been trained in the procedures); and physicians can perform all of these functions (Barnes, J, 2008).

But many scopes of practice are not based on evidence-based models that enable this kind of "task shifting." Although the World Health Organization (WHO) recognizes that operators of retail outlets such as pharmacies and drug shops can safely and effectively provide FP products and services commensurate with their clinical qualifications, many low- and middle-income countries still restrict them from offering these products, thereby limiting access, primarily in remote and rural areas (WHO, 2017). The restrictions stem from concerns that drug shops and less qualified vendors might not have training in FP counseling and might not give appropriate advice to clients (Rutta, E, 2015).

Although some low- and middle-income countries are liberalizing scopes of practice to allow task shifting, other barriers limit the positive impact of these reforms. In the Philippines, the scopes of practice match the facility levels and skill levels of each professional cadre. Private providers are allowed to offer the same types of FP products as public ones, and regulations specify which commodities can be offered by each cadre. However, other regulations restrict the ability of private providers to deliver a full range of commodities, underscoring the need to review inconsistencies across all types of regulations. Although private providers are not subject to a temporary restraining order that bans the use of contraceptive implants, the order itself has limited the supply of this product in the market, in effect restricting private providers' ability to offer the implants. Midwives are allowed to offer injectables and IUDs, but lack of access to training and certifications in these methods has created additional barriers (Callahan, S, 2019).

Lack of licensing renewal or continuing medical education requirements. Low- and middle-income countries face strong resistance from professional associations that are concerned that the government will not propose a fair process to "grandfather in" other health professionals. When a continuing medical education requirement is in place, professional license renewal should be required at least every five years to demonstrate technical/clinical competency. The requirement should also be

clearly defined for each cadre, linked to current clinical guidelines, and be a condition of licensing renewal.

But even practical regulations on continuing medical education cannot achieve their intended effect without support to help health professionals comply with them. In Nigeria, 24 hours of continuing education is required for renewing a professional license every two years. The Medical and Dental Council of Nigeria approves the institutions that are qualified to provide such education. The MOH (often with donor funds) and NGOs perform most clinical update training, especially in essential health areas such as FP and MNCH. These programs are nominally open to for-profit providers, but no mechanism exists to identify and recruit private providers to attend this training. Invitations to private-sector providers are ad hoc and depend on personal connections. This lack of access to required training creates an undue burden on private providers to comply with quality requirements (Barnes, J, 2008).

Lack of regulations governing dual practice. Dual practice is common in many low- and middle-income countries but not often regulated. It is important to check whether dual practice is allowed, if there are clear terms under which public health employees can engage in dual practice (e.g., hours, conflicts of interest, fees). St. Lucia has no guidelines on possible areas of conflict between an employee's public duties and private practice; this results in individual interpretations. Although Victoria Hospital – the sole public hospital – has contracts with its employees outlining terms for dual practice, these contracts have little binding authority, leaving room for potential abuse such as consultants not completing their full shifts at the public hospital before leaving for their private practice (Rodriguez, M, 2012). Other countries that have clear regulations on dual practice have fared better. In the Philippines, dual practice is proscribed under the Code of Conduct and Ethical Standards, which prohibits public employees from engaging in private practice unless authorized by law. But dual practice is permitted, common, and endorsed by the Department of Health as a retention incentive (Callahan, S, 2019).

Lack of enforcement of quality standards. Private-sector assessments in the Democratic Republic of the Congo (DRC), Ivory Coast, Ghana, Nigeria, Tanzania, and Uganda have found that although regulatory agencies have established regulations, in reality few have the necessary resources to conduct quality control or monitoring activities (Feely, R, 2009). The fees received for licensing are insufficient, and health ministries do not allocate sufficient budget. The Pharmacy Council is funded only by fees, which are not enough to support staff and logistics for inspections, given the explosive growth in PPMVs (Barnes, J, 2008). Institutional arrangements are also fragmented. In Uganda, the 2016 assessment found that institutional arrangements governing the private sector were highly fragmented and spread across five entities, two of which had duplicate responsibilities, creating uncertainty about which was the lead authority and allowing many unscrupulous practices to occur (O'Hanlon, B, 2016). The divided regulatory system has created cumbersome licensing and reporting requirements. All private health providers interviewed agreed that everyone should be made to comply with these obligations. But current licensing processes are confusing, time consuming, and costly for private providers. Moreover, MOH reporting requirements are burdensome, with no perceived benefits because private providers never receive feedback.

BOX 5: HEALTH PROFESSIONAL LICENSING IN NIGERIA

Nigeria uses two mechanisms to ensure the quality of health services: licensing to ensure the technical competency of health care professionals and quality accreditation of facilities. As noted earlier, multiple agencies issue professional licenses related to BEmONC. Guidelines are clear on licensing requirements, renewal, and continuing medical education. There is no apparent overlap in or duplication of scopes of practice among the levels of health cadres offering maternal and newborn services, and it is clear who can perform BEmONC (e.g., nurses, midwives, and medical officers in primary health centers and secondary facilities as well as OB/GYNs in secondary and tertiary facilities). The scopes of practice are the same for public and private health cadres.

Health professional licensing requirements do not create any serious barriers to private delivery of BEmNOC. Dual practice is unregulated and widely practiced, but informal rules are observed by public health professionals on the number hours and days of work in a public facility before they can work in their own private clinic.

The license renewal process is cumbersome but does not create a barrier. Health professionals are required to renew their license every year. Once again, the annual renewal requirement is a strategy to boost revenues. Health professionals face excessive paperwork, high costs, and time delays. Although the renewal process is digitized, delays are still significant due to lack of staff for reviewing the documentation and verifying continuing medical education hours.

Responsibility for quality assurance is divided between the state MOH's Quality Department and the National Health Insurance Agency (NHIA). The Quality Department establishes the clinical guidelines, while the NHIA accredits facilities. As an interim measure, the NHIA also certifies facilities that are on the path to accreditation. These two agencies also have insufficient budgets and staff for quality assurance in private facilities. The Quality Department visits only public facilities, while the NHIA struggles to certify both public and private facilities.

Effective regulations on health professional licensing can lead to many improvements in the marketplace for FP and MNCH products and services, including:

- The licensing board can maintain a list of practicing health care professionals and maintain quality oversight over all licensed health professionals.
- The licensing board can be independent of the MOH and medical (professional) societies.
- The public interest can be protected over the self-interest of professional groups.
- Terms for professional licensing can be clearly defined so professionals can plan for market entry.
- Skills updates for all health care providers in both the public and private sectors can be facilitated.
- Conflicts between health care professionals and between inspectors and facilities can be reduced.
- Adoption of new health care services and medicines and pharmaceutical innovations can be encouraged through continuing medical education.
- Access to low-risk, high-benefit drugs can be expanded through task shifting to licensed and trained professionals.

- Flexible terms for dual practice can be adopted to increase staff retention and reward public health service.

Area 3. Rules and Regulations Governing the Supply of Pharmaceuticals

Pharmaceutical laws and regulations are designed to ensure that safe, efficacious, high-quality medicines are available to users and that the public has access to accurate information about these medicines (MSH, 2012). Laws and regulations govern safety and quality along the drug's life cycle, from product innovation to manufacture, adoption and registration, procurement, distribution, sales, and use. While the aim of pharmaceutical regulations is to protect patients, regulatory bodies face the challenge of balancing the interest in safety and efficacy with the interest in access (Olson, MK, 2014). These tradeoffs, as well as inefficiencies in implementing pharmaceutical regulations, can lead to decreased competition in the market (e.g., high barriers to market entry or product withdrawals), parallel trade (e.g., proliferation of substandard or counterfeit products), price increases for users, delays in access to innovative and novel medicines, and other unintended and undesirable impacts. The key types of legislation and regulations that affect pharmaceutical supply are described below.[2]

Production regulations. These are designed to ensure consistent quality, safety, and efficacy of pharmaceutical products and cover all of the operations involved in preparing and manufacturing finished pharmaceutical products (WHO, 2020). All of these regulations are also associated with higher costs of production. They include regulations and policies governing 1) intellectual property rights (which may prohibit the manufacture of medicines with on-patent status), 2) taxes, tariffs, and duties (e.g., for raw materials and packaging), 3) labeling and packaging, 4) environmental impact, and 5) quality (e.g., good manufacturing practices or stringent requirements for regulatory approvals by entities such as the U.S. Food and Drug Administration or the European Medicines Agency or WHO prequalification). Onerous regulations can discourage high-quality entrants into a market, while overly lax regulations may increase the availability of substandard products. Producing high-quality medicines and health products has a cost, so it is important that other policies and regulations (e.g., procurement policies) acknowledge the quality and price tradeoffs and do not completely advantage those offering the lowest price.

Pricing policies. As defined by WHO, these are "written principles or requirements for managing the prices of pharmaceutical products, agreed or adopted by a public institution, a group of purchasing organizations or individual health service." Pricing regulations aim to ensure that high-quality medicines are equitably accessible and affordable. WHO recommends considering the following types of policies on setting, managing, and influencing pharmaceutical prices:

- **External referencing pricing**—deriving benchmarks based on pharmaceutical product prices in one or more countries or regions or across organized purchasing authorities, for the purpose of negotiating prices or reimbursement rates
- **Internal reference pricing**—deriving benchmarks based on products that are therapeutically comparable or interchangeable, for the purpose of negotiating the price or reimbursement rate
- **Value-based pricing**—setting prices based on a measured or quantified "value" for the purpose of fostering innovation to produce medicines valued by society

[2] Excluding regulations on pre-market authorization activities (e.g., research and discovery, clinical trials) and controlled substances (e.g., narcotics), which are outside the scope of this discussion.

- **Markup regulations**—regulating wholesale and retail markups and pharmaceutical remuneration to reduce pricing variability along the supply and distribution chain
- **Price transparency policies**—sharing or disclosing pricing information to the public to ensure accountability
- **Tendering and negotiation policies**—encouraging competition to achieve price reductions
- **Generic and biosimilar medicines policies**—encouraging the use of quality-assured generic medicines and biosimilar medicines, which are priced lower than the originator/reference product, to enhance price competition
- **Pooled procurement policies**—formal arrangements in which financial and non-financial resources are combined to create a single entity that purchases medicines on behalf of individual purchasing authorities, for the purpose of creating greater purchasing power through economies of scale
- **Tax exemption or tax reduction policies for pharmaceutical products**—reducing taxes on medicines or exempting them from taxes (e.g., sales tax or value-added tax [VAT]) for the purpose of overcoming trade barriers and tax burdens that can fall on patients, leading to higher costs (WHO, 2020)

Import/export regulations. These specify requirements for importing and exporting pharmaceuticals, including eligibility of applicants, eligibility of products (e.g., shelf-life requirements, labeling and packaging requirements, import/export license requirements, and inspection and sampling requirements). These regulations, when inefficiently implemented, overly burdensome, and not transparent, lead to increased costs for the supplier (and ultimately the end user) as well as delays in access to the medicines.

Marketing authorization/registration regulations. WHO defines marketing authorization as "a procedure for approval of a medical product for marketing after it has undergone a process of evaluation to determine the safety, efficacy and quality of the product and the appropriateness of the product information." This regulatory function is meant to ensure that only medical products authorized by a national drug authority can be manufactured, imported, distributed, and sold or supplied to end users. When these processes are overly burdensome and expensive, it can lead to undesirable impacts such as decreased competition, parallel trade, and product withdrawals.

Distribution and storage policies. Good distribution and storage policies are designed to ensure the integrity and quality of pharmaceutical products through controls across the chain of distribution. Lack of such regulations can lead to product loss, contamination, pilferage, theft, and degradation in quality when proper environmental conditions (e.g., cold chain) are not maintained. "Track-and-trace" regulations, which may require barcodes, serialization, and other key information about the health product, can help authenticate and monitor products through the distribution chain.

Sale/prescription/dispensing regulations. See the previous section for information on scopes of practice and licensing for private providers.

Post-marketing surveillance/pharmacovigilance regulations. These regulations ensure the monitoring of medicine safety, use, and efficacy (MSH, 2012). The aim is to ensure that counterfeit and substandard medicines do not proliferate and that systems are in place for adverse event monitoring and reporting as well as product recalls. These regulations may require market authorization holders to

periodically submit safety updates and reports, benefit and risk evaluations, risk management plans, individual case safety reports, and so forth.

Promotion policies. Pharmaceutical promotion by providers should be objective and reliable because misleading statements can pose significant risks to patient health, including death. However, unclear regulations or overly prohibitive regulations can stifle awareness and knowledge among providers and patients.

- Do regulations/policies exist along the product life cycle axis?
- Are global and national policies aligned?
- Are key market actors aware of the regulations, policies, or guidelines?
- What is the relative ease of compliance with the regulations? (Are they overly cumbersome? Cost-prohibitive? Nontransparent?)
- Is there capacity to monitor and enforce compliance?

It is helpful to think about key pharmaceutical regulatory barriers along the product life cycle pathway from development to post-marketing surveillance (see Figure 5). Questions to ask when determining whether regulations are a barrier to access to pharmaceuticals include:

FIGURE 5: THE PRODUCT LIFE CYCLE PATHWAY

Effective regulations yield many positive benefits for the drug supply in a country:

- Dangerous and ineffective drugs kept off the market
- User/patient safety maintained
- Adequate supply of essential products such as FP methods
- Accessible/affordable pricing

See Annex 3 for a checklist that can help with examining pharmaceutical supply policies.

BOX 6: ACCESS TO A PNEUMONIA TREATMENT IN TANZANIA'S PRIVATE SECTOR

The private sector is an important source of care and treatment for children with pneumonia in Tanzania; however, information on key national regulations, polices, and guidelines is often not systematically shared with the private sector, leading to information asymmetries that can result in lack of access to critical medicines.

The updated Tanzania National Standard Treatment Guidelines recommend Amox DT as the first-line treatment for pneumonia. Key barriers to accessing Amox DT in the private sector include: 1) lack of awareness of key pharmaceutical regulations among high-quality international suppliers, 2) insufficient knowledge about the process of obtaining market authorization in Tanzania, 3) regulations prohibiting the promotion of specific medicines in Tanzania, which exacerbates the lack of awareness among private providers, and 4) weak enforcement mechanisms for ensuring compliance with the standard treatment guidelines, which allow private providers to prescribe other medicines for the treatment of pneumonia in children.

Area 4. Rules and Regulations Governing Market Conditions and Shaping Provider Incentives

Multiple private-sector assessments show the breadth and scope of economic barriers to private investment in all five regulatory areas. One reason that low- and middle-income countries may not address these regulatory areas is that they do not understand their effect on health markets, given that economic regulations are usually outside the MOH's purview. Moreover, few of the countries have learned how to creatively use economic regulations to "crowd in" the private sector. This situation calls for greater attention to economic regulations that shape market conditions and create incentives. (See Annex 4 for a checklist that can help identify the market effects of the five regulatory areas.)

Market entry/exit restrictions. Facility licensing regulations can establish a minimum level of quality and prevent unqualified owners and facilities from entering the market. Low barriers to entry can have unintended effects. Nigeria has minimal requirements to obtain a PPMV license (e.g., reading and writing ability, passing an interview) and a capital requirement. As a result, some nurses and midwives obtain a PPMV license and then exceed the scope of practice of a PPMV by performing functions and prescribing medicines that require a nurse or midwife license (Barnes, J, 2008). In Uganda, the ease of opening a retail pharmacy or drug shop makes this sector, especially at the retail level, a very competitive market, with low costs, high volume, and low margins. Markups for retail prices are set arbitrarily, ranging from 50% to 600%. The competitive market has artificially capped prices, but at high levels, which have remained stagnant in recent years (O'Hanlon, B, 2016).

Ownership restrictions also create a barrier to entry to health markets, dampening private-sector investment in health. Examples include 1) a government service requirement before opening a private practice, 2) limits on the number of clinics one person can own, and 3) restrictions on who can own a health/pharma facility (e.g., excluding non-clinicians). In Nigeria, a nurse can open a private nursing home and a midwife can open a private maternity home only after five years of being registered and serving in the public or private sector. This is a common practice in many African countries. In Madagascar, only a pharmacist can own a pharmacy, and with a limit of two, which creates a barrier to aggregating pharmacies into a network or chain (Brunner, B, 2018).

Zoning and equipment restrictions can further suppress private investment in health. In Madagascar, the zoning regulations state that the presence of a pharmacy precludes the opening of a dépôt (drug shop) within 10 kilometers, and if a pharmacy opens near a dépôt, the dépôt must close within three months (Brunner, B, 2018). In Nigeria, a private-sector assessment identified a supervisory requirement for nurses and midwives as a barrier. The lack of clarity of how much supervision is required has created cost uncertainties. The nurse/midwife owner must estimate physician time or allocate a portion of fees to the supervising physician (Barnes, J, 2008). Zoning regulations are meant to increase access and encourage expansion to underserved areas, but with weak enforcement they have the opposite effect. To promote expansion to rural areas, Ivory Coast has similar restrictions. But with weak enforcement, most private pharmacies are in urban areas (Armand, F, 2018).

Price controls and margin caps. As a rule, private health providers do not want any regulations that cap prices or profit margins. Price controls on consulting fees, diagnostics, and other health care services, as well as limits on retail markup over wholesale or manufacturer prices for specified FP and MNCH products, are common. However, these types of regulations can limit sustainable market competition in the private sector if they are overly restrictive. In Ivory Coast, regulations governing pharmacies limit where pharmacies can be established, who can sell products, and how much products can be sold for, and they restrict commercial advertising of all pharmaceutical products, including contraceptives. Both commercial companies and social marketers must petition the government if they want to change the price of a product. These regulations prevent companies and organizations from reacting in a timely manner to market forces (Armand, F, 2018). Regulations to limit excessive profit and thereby ensure more affordable prices should be balanced with the need of health care businesses to stay in business. The solution will ultimately be to include private pharmacies and drug shops within government-sponsored programs or insurance schemes, but this is comparatively rare in low- and middle-income countries (Callahan, S, 2017).

High taxes and tariffs. Private health providers and commercial health care businesses consider high taxes and tariffs to be a major constraint on investment. The impact of both is well documented in many private-sector assessments. These private businesses are subject to income taxes, like individuals and businesses in other sectors, but many trade and professional associations and individual health care business owners argue that if the government wants greater private investment in health and/or expansion to underserved areas, it should offer preferential tax treatment, as it does in sectors such as transport, information technology (IT), and mining.

As a Madagascar private-sector assessment revealed, import taxes on contraceptives and other essential medicines for MNCH mainly affect the private for-profit sector (Brunner, B, 2018). As a result, many Asian and African countries have reduced or abolished import restrictions on key medical equipment, supplies, or drugs, which has helped reduce private provider costs and thereby increase the quality and affordability of the products and services they offer. The most common type of tax relief is removing import taxes on active pharmaceutical ingredients and taxes on imported finished pharmaceutical products. But barriers persist. In Madagascar, no taxes are imposed on finished pharmaceutical products except hormonal products, which affects the supply of oral contraceptives and emergency contraception (Brunner, B, 2018). To further complicate the rules, the regulations allow international NGOs and donors to import certain formulations of hormonal FP products tax-free, but private wholesalers are not permitted to do so. The overall confusion about the tax rules and the exemption for FP has limited the availability of FP products. In countries that are highly dependent on imported pharmaceuticals, such

as the DRC, multiple import taxes increase costs and lower price competitiveness, discouraging local production (SHOPS Plus, 2019).

Unmanaged and unfair competition. Private health care businesses have to compete in both the domestic and international markets. Managing competition in the health sector is an underexplored regulatory area, primarily because it is governed by regulatory agencies outside the health sector. Moreover, a different skill set is required to understand how markets will respond to different rules for managing competition. An unlevel playing field has important consequences for the size of the private sector and market development. As revealed in several private-sector assessments (DRC, Madagascar, Nigeria, and Uganda), private health care businesses have two main competitors in the local market: the public sector and illegal, informal providers. Private health care businesses have to pay for all of their inputs – including labor, infrastructure, drugs, medical equipment, water, and power – while government health services are funded by the national budget and international donors. Private health care businesses recognize the role of the public sector, but they would like governments to explore mechanisms (e.g., donated products; tax relief; subsidized inputs like buildings, water, and electricity; and advance purchase commitments) for reducing their inputs and costs if they expand their products and services to underserved groups and/or remote or rural areas.

Large donor presence also creates unfair competition for the private health sector. In low- and middle-income countries, the public sector often receives FP, HIV/AIDS, and child health products from donors that purchase these products through vertical programs that control their procurement and supply, mostly in the public sector. It is important to note that few international donors provide large supplies of maternal health products like oxytocin and misoprostol. These donors can negotiate effectively (purchasing in bulk to get cheaper prices) and ensure the quality of the products. Commercial private providers, however, are expected to negotiate volume and price on their own. When combined with a lack of rules and regulations to incentivize the private sector, this can affect local private supply of affordable and quality FP and child health products. For example, widespread distribution and volume of free condoms donated to the Tanzanian MOH has displaced commercial condoms by priming consumers to expect artificially low prices for condoms, even those who have the ability to pay (SHOPS Plus, 2021). In Ivory Coast, 90 percent of the market share for condoms belongs to Confiance, a brand that is socially marketed and donor-subsidized. This near-monopoly stems from the extremely low cost and high availability of the product (Armand, F, 2018).

Lack of regulations in the pharma sector has resulted in proliferation of parallel markets, with unlicensed drug outlets that carry substandard, nonregistered products (Brunner, B, 2018; Armand, F, 2018) in countries such as Ivory Coast, Madagascar, and Uganda. These unregulated drug outlets directly compete with registered pharmacies that are, in most cases, operated by licensed qualified pharmacists. Competition from unregulated drug shops makes qualified pharmacists less likely to open and operate quality pharmacies (O'Hanlon, B, 2016). Poorly regulated competition does not create incentives to invest in the supply chain. The public and private supply chains in the DRC are highly fragmented and duplicated. An assessment showed that there were 99 distribution channels for the public and nonprofit sectors, in addition to donor partners, 85 percent of whom created and used their own procurement agencies, warehouses, and distribution systems, causing waste and duplication (SHOPS Plus, 2019). The Uganda private-sector assessment concluded that tough competition in the distribution market in the pharma system has created a race to the bottom on prices and margins. In the absence of MOH policies to consolidate distributors, there is no incentive to invest in establishing regional warehouses, a

nationwide distribution system (O'Hanlon, B, 2016), or specially equipped transport for heat-stable products such as vaccines and oxytocin.

As the Uganda example demonstrates, local health care businesses like pharma manufacturers also have to compete internationally. To produce antiretroviral drugs for the East African market, the local manufacturer had not only up-front capital costs to establish manufacturing capacity but also recurring costs (e.g., for imported pharmaceutical materials, water, power, infrastructure, and equipment), while competing with manufacturers in China and India that produced the same products but were heavily subsidized by their governments (O'Hanlon, B, 2016). The manufacturer would not have survived without the advance purchase of their first five years of production by the Ugandan government.

Lack of access to finance. All of the private-sector assessments concluded that lack of access to finance is a major barrier to private-sector development in key health markets. In Nigeria, all of the barriers to opening a small health care business also apply to pharmacies, particularly lack of access to credit. All of the pharmacists and PPMVs interviewed for the Nigerian assessment said they were obliged to start their businesses with savings and family support, and that lack of access to credit for working capital is an ongoing constraint on maintaining sufficient stocks, meeting demand, and staying profitable (Barnes, J, 2008). In Uganda, access to finance was a major constraint for the private health sector—including faith-based organizations, despite the fact that they received subsidies from the Ugandan MOH. The limited government subsidy covered less than 10 percent of their operating costs and was insufficient to help them afford upgrades to their aging infrastructure and purchase new equipment to maintain quality standards (O'Hanlon, B, 2016).

Marketing restrictions. Many low- and middle-income countries restrict marketing of health products and/or services, which can help promote health messages to generate demand for private products and services. For example, Madagascar restricts doctors, nurses, midwives, and pharmacists from advertising their services and limits advertising by facilities (Brunner, B, 2018). In Ivory Coast, regulations limit the ability of distributors to advertise contraceptive products, which could increase awareness of FP in general (Armand, F, 2017).

Creative application of economic regulations can stimulate positive changes in market conditions, prompting private-sector actors to consider delivering FP and MNCH products and services:

- Establishing minimum capital requirements for market entry, which can help consolidate markets and promote investment (e.g., force small distributors to drop out, thereby creating space for medium and large distributors to invest in expanding reach)
- Offering tax relief to expand to an underserved location and/or deliver a missing health care service until a health care business can earn a profit, to encourage them to relocate and/or expand services
- Issuing "certificates of need," which can help manage competition better than zoning requirements and can (with other incentives) encourage private health care businesses to locate in underserved areas
- Linking access to credit to quality requirements, to ensure that private health businesses invest in infrastructure renovation and equipment purchases that are medically indicated to improve quality

BOX 7: EFFECTS OF MARKET CONDITIONS ON THE PRIVATE SECTOR IN NIGERIA

Market-related regulations do not create insurmountable barriers to private provision of BEmONC in Ebonyi State, but they do create unintended consequences that hurt market performance. Regulations that govern market entry (e.g., facility licensing and business licensing) do not create a barrier to private practice, nor are they so lax that anyone can open a clinic to offer BEmONC. However, economic regulations such as the income tax, VAT on goods and services, and import taxes drive up the costs of doing business, which are passed on to the consumer, making BEmONC unaffordable to most pregnant women in Ebonyi. Moreover, competition is not regulated, and competition among private providers is high. Quality of care is the main factor distinguishing one private provider from another, which creates incentives to invest in medically unnecessary equipment that does not improve quality in BEmONC of other health care services.

The regulations are "silent" on pricing of health services, which may contribute to BEmONC services being unaffordable to many. The private sector uses fee-for-service payment for BEmONC. The only price regulation applies to the public sector – all maternity-related services must be free. There are no pricing guidelines to establish a minimum (floor) or maximum (ceiling) for specific health services, including BEmONC. As a result, prices differ greatly among private providers that offer the same services, with little rationale for the price variation. This further contributes to high-priced services in the private sector.

The state MOH does not use economic regulations to create incentives to crowd in new providers and/or encourage expansion to underserved geographic regions or population groups. It also does not use any common economic regulatory tools to incentivize the private sector to deliver essential services such BEmONC. Such tools include: 1) waivers on specific facility licensing requirements to open a clinic in rural areas, 2) certificates of need for underserved areas to prevent new (public or private) entrants into the same geographic area, to manage competition, 3) income tax holidays until a rural facility can become financially sustainable, 4) partially or wholly subsidized input costs for rural services (e.g., land taxes, water, electricity), and 5) removal of import taxes on key equipment and medicines.

Other market conditions outside of the regulatory sphere create more pressing barriers to expanding private-sector delivery of BEmONC. They include private provider capacity and training in BEmONC, access to capital to make investments to deliver quality BEmONC, weak demand, and a large consumer base that is unable to pay for BEmONC.

Area 5. Rules and Regulations Governing Private-Sector Data and Reporting[3]

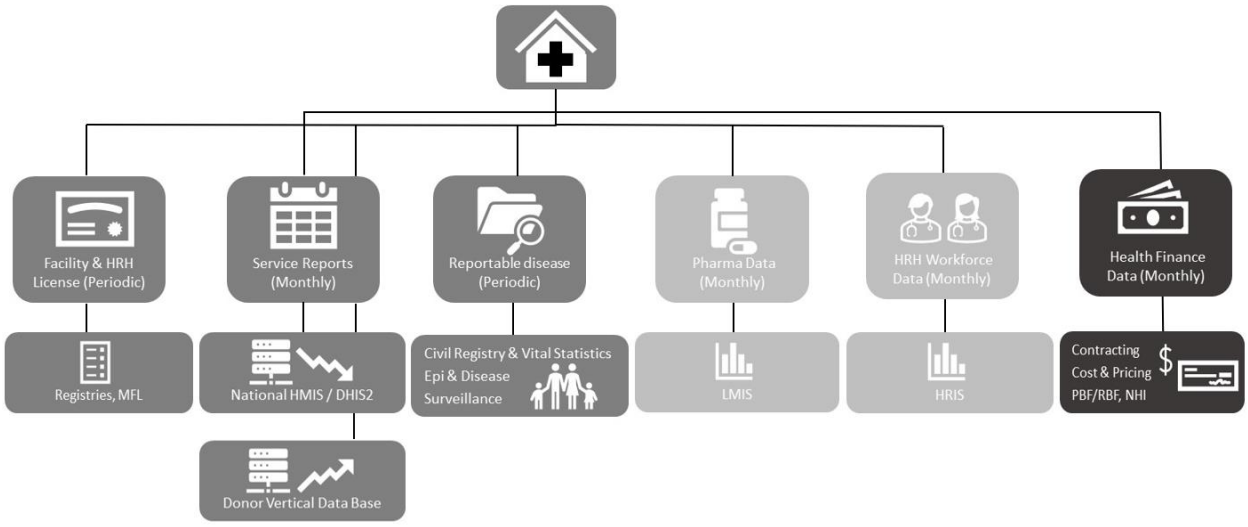
Accurate and reliable data on the private health sector is important for a range of market actors in health. Policymakers need good data to fulfill their stewardship and regulatory roles in the health sector. Such data can be used to inform dialogue with non-state actors, including the private health sector; strengthen policies and plans for a mixed health system; facilitate better coordination in implementing policies and plans; justify investments in the sector; and identify partnership opportunities. For private health care businesses, accurate data on the private sector and improved information sharing helps the government appreciate its contribution to health; sends market signals on government priorities and investment priorities; and provides important market information for health care businesses to invest and/or expand their activities to market areas such as FP and MNCH. Moreover, the information helps

[3] This section is based on a forthcoming WHO/WBG report on private-sector data and governance.

local and international investors – including donor agencies – identify priority areas for private and donor investment. (See Annex 5 for a checklist on market intelligence.)

Low- and middle-income countries collect a wide range of data from private providers and facilities (see Figure 6). A recent WHO / World Bank Group (WBG) report observes that this data can be grouped into three categories.

FIGURE 6: TYPES OF PRIVATE-SECTOR DATA COLLECTED



Level 1: Core data. All low- and middle-income countries collect a minimum set of data on the private health sector, whatever its size. This data includes: 1) health infrastructure and service availability data (from a master facility list), 2) facility and health professional licensure data (from agency registrars), 3) data on reportable diseases (from civil registration and vital statistics records), and 4) vertical program disease reporting. However, this core data set is often incomplete.

Level 2: Service delivery data. All countries aspire to collect service delivery data from private health facilities and pharma entities, but actual data collection is low. The private-sector facilities most able to report data are private hospitals, vertical donor program private facilities, and large pharmacies and pharmacy chains. Most data experts agree that few small- and medium-size private facilities report service delivery data. Data on pharmacy operations, pharmaceutical prescriptions, pricing, stockage, and sales in low- and middle-income countries is even weaker than service data. And the reported data is usually incomplete, inaccurate, and unreliable. Data on health outcomes following treatment is rarer still.

Level 3: Finance data. Only low- and middle-income countries with purchasing functions—contracting, results-based or performance-based financing, and/or health insurance—collect private-sector finance data. Data from the private sector on service pricing, costs, margins, payment rates, and related valuations for infrastructure, human resources, pharmaceuticals, and consumables is rare. Such data is commonly collected only in countries with a large national health insurance system and/or through strategic purchasing initiatives that use results-based financing and/or performance-based financing, contracting, or voucher initiatives.

Data challenges

Most private-sector providers agree that reporting is an important requirement, and in many cases they want to comply with reporting requirements outlined in health facility and other regulations. Yet the private-sector assessments and the WHO/WBG report confirm that collection and use of private-sector data in low- and middle-income countries remains a significant problem. Moreover, the report revealed that regulations are not sufficient to incentivize private providers to report data to the government and that other factors create barriers and act as disincentives to compliance with reporting requirements, as described below.

Lack of clarity on how the data will be shared and by whom. This is a major concern that frequently inhibits private provider reporting. Private providers are hesitant to share data because they are concerned that the MOH will use the data to regulate, audit, tax, or punish providers. Financial data is considered particularly sensitive. Private providers have also voiced concerns that competitors will gain access to their data and have a competitive advantage.

Lack of capacity to report data. As Figure 6 shows, governments require a wide range and quantity of data. Private-sector facility type and size affect the capacity to report data and the quality of the data reported. Larger hospitals have better data, more dedicated IT and reporting staff, and greater financial incentive to comply with reporting requirements.

Lack of data governance policies. Few low- and middle-income countries have 1) rules on how to share private-sector data across government agencies, 2) standard operating procedures for disseminating ministerial policies, plans, and regulations (much less formally and regularly sharing data on private-sector performance), or 3) a policy or commitment to use, analyze, and present "whole of system" data that reflects the private-sector contribution to health.

Lack of incentives to report data. The WHO/WBG report found that ministry leaders often do not prioritize creating and investing in data quality and data systems to inform evidence-based policymaking, including investing to facilitate private-sector reporting. Few incentives exist to motivate private-sector reporting besides those embedded in provider payment mechanisms. Regulations requiring reporting, when they exist, do not always lead to better data reporting, and are rarely enforced. There are also several deterrents to public-sector use of private-sector data: 1) MOH leaders not actively requesting or supporting collection of that data and its inclusion in ministry reports and plans, 2) reluctance among some ministry departments and agencies to share data (information is power), and 3) the MOH not understanding the value of private-sector data in governance functions, including regulations.

BOX 8: HEALTH FACILITY REPORTING REQUIREMENTS IN NIGERIA

In Ebonyi, regulations governing health facility licensing require all health facilities to report data to the state MOH. The regulatory agency responsible for facility licensing has accurate information on private facilities in terms of facility type, infrastructure, and staffing. But most private health facilities –particularly small and medium-size ones – do not regularly report service delivery data and disease data. Mostly large facilities, such as clinics and hospitals with adequate staffing (and, in some cases, IT systems and/or medical records) and those participating in donor-funded projects, report service statistics to the state MOH.

Large-scale coverage of a purchasing mechanism and private-sector accreditation can be "game changers" that incentivize the private sector to report data. Dialogue, transparency, reporting back, recognition, and other non-financial incentives – as well as clear and enforced penalties for noncompliance – can all make a difference. However, introducing national health insurance (with conditional and highly visible contracting accreditation and incentives for reimbursement) and/or strategic purchasing functions are the most significant factors associated with better-quality comprehensive service reporting by the private sector, and this can be transformative where large populations are covered.

Improved data collection, quality, and use can translate to positive changes in both the health system and selected health markets. These changes include:

- Improved performance of a mixed health system, which then facilitates progress toward UHC goals and the carrying out of key system functions (including assurance of quality, equity, access, and overall population health)
- Better health system functioning, driven by better-informed and more inclusive policies
- Better-targeted management initiatives to improve health system performance
- Public-private dialogue informed by data, thereby building trust between the public and private sectors

Step 4. Review the Norms and Practices Shaping Market Operations

MDA is, in essence, a process dedicated to change. After all, the main focus of market strategy is to stimulate sustainable changes in the systems that support a specific health market. A market strategy must therefore consider why market players are acting the way they are, what their motivations are, and the degree to which they can change.

Many market strategies and interventions fail because they: 1) make assumptions about market players' motivations and do not explore the underlying causes of behavior (e.g., assuming that change processes only need a champion rather than recognizing the multiple factors that lead to change), 2) use methodologies for program design that focus on the symptoms rather than the underlying political economy of markets (political, legal, social, and cultural factors), and 3) don't take incentives into account in their vision of how market systems can operate in the future (Springfield Centre, 2015). Conversely, market strategies and interventions that are grounded in detailed knowledge of incentives can ensure that the incentives are aligned to unleash the power of market systems.

FHM Engage proposes building on political, legal, and regulatory factors that influence health markets by expanding the analysis to include the social and cultural factors that influence market actors' behavior. This step focuses on understanding the incentives and capacities of market actors in the public and private sectors – whether formal or informal, large or small, and local, national or international – to learn what the market actors value and why, how their values are shaped by prevailing norms and behaviors, and how these social factors encourage or inhibit change in the systems supporting a health market.

Facilitators of and barriers to behavior change can be categorized as follows (Pathfinder, 2013):

- Individual (e.g., personal beliefs, attitudes, abilities, or knowledge)
- Social (e.g., ways that family, friends, or neighbors help or discourage change by individuals)
- Environmental (e.g., lack of facilities, services, or laws that are necessary to make a change)

It is important to note that no one can change another person. People have to *want* to change, know *how* to change, and have *barriers to change removed* from their path. An individual or organization must recognize that the change is a good thing and that it is widely accepted by their key influencers or reference group (a group of people who significantly influence an individual's behavior). If the desire to change and ideas about how to change are not accepted by their key influencers or reference group, it will be hard to adopt new behaviors.

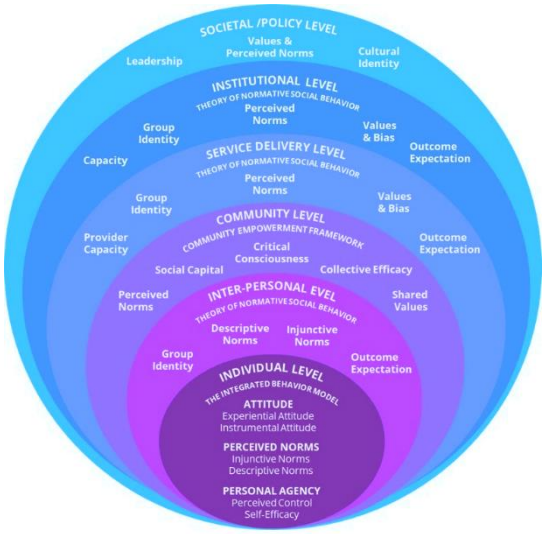
Tasks

The five tasks in this step take into account market actors' incentives and capacity. They are different from the approaches and tasks used in the rules and regulations review.

Task 1. Identify who needs to change. A market description/diagnosis can reveal a range of barriers that necessitate behavior change by multiple market actors. This task involves identifying which market actors have an interest in the outcome of the market system change. As Figure 7 shows, there is a wide range of individuals and institutions to consider – whether the change is to a regulatory agency's policy and regulations or to a consumer's attitude about accepting and seeking a health product or service (McLeroy, KR et al., 1988).

This task also includes identifying each market actor's key influencers or reference group, which might extend as far as their community and its leaders. The reference groups to which individuals and/or organizations belong provide professional standards or social norms by which they judge their attitudes and behavior.

FIGURE 7. SOCIAL-ECOLOGICAL MODEL



Task 2. Define the desired behavior change. The next task is to define the desired behavior change. For example, a regulatory agency might need to change a regulation to allow pharmacies to supply injectables. Or a pregnant mother might want to act on knowledge that delivering with a skilled

birth attendant will ensure a safer delivery. It is important to choose behaviors to focus on that will move the market most.

Task 3. Identify market actors' interests and why they behave the way that they do. Individuals and/or organizations may be sympathetic (supportive) or negative (opposed) toward a market system objective. But more likely they will have a more nuanced combination of both that is driven by several factors: ability, agency, attitude, beliefs, knowledge, motive, power, and practice. Beliefs and perceptions regarding the attributes of specific market innovations or interventions associated with the behavior also heavily influence their acceptance, adoption, and endorsement by key market actors. (See Table 3 for definitions of these terms.) Incentives can fall into the following categories (Springfield Centre, 2015):

- **Materially oriented**—based on a desire to get something or not lose it (e.g., food, money, market share, property, or freedom)
- **Socially oriented**—based on the need to belong to, or not be rejected by, a wider collective (e.g., a group of peers with shared values)
- **Purpose oriented**—based on a quest to achieve a goal, which can be individual (e.g., becoming a village head or running a marathon) or collective (e.g., supporting a political cause)

Various approaches can be used to learn a stakeholder's motivations for specific behaviors, what makes it hard to change those behaviors, and what would facilitate change. The aim should be to reinforce positive incentives in support of change and ways to overcome negative incentives (such as fear, vested interest, or tradition) that cause resistance to change.

TABLE 3: NORMS-RELATED TERMS AND DEFINITIONS

TERM	DEFINITION
Ability	What I can do
Agency	What capacity I have to act
Attitude	What I think; what I feel
Attributes of innovation	What I think about the new behavior/innovation/intervention
Behavior	What I do
Behavioral intention	What I plan to do
Belief	What (I believe) I know
Collective norms	What informal rules govern my behavior
Key influencers	People who influence me or others
Knowledge	What (I believe) I know
Motive	Why I do what I do
Normative	What is standard or most commonly done or believed in my society

Perceived norms	What I think people do or my community should or should not do (empirical expectations) What I think others expect me to do (normative expectations)
Power	My ability to do something or influence someone to do something
Practice	What I do habitually/routinely
Reference group	People whose behavior and beliefs shape my behavior and beliefs; What I think others expect me to do (normative expectations)
Self-efficacy	How easy I feel a behavior is
Social network	People I am connected to
Source: Georgetown University, 2021 Definition sources include Kasprzyk, D et al., 1998; Fishbein, M, 2000; and Rimal, R, 2008)	

Task 4. Prioritize market actors whose behaviors need changing. Figure 6 illustrates that there are too many market actors to feasibly attempt to change. It is therefore critical to prioritize the market actors that are most important and influential to any intervention to improve market performance. There are two criteria by which to prioritize market actors' behavior change:

- **What is a market actor's capacity for change?** Understanding the capacity of market players means assessing their ability to perform relevant functions in market systems. Capacity can be viewed at the individual, group, and organization level and call fall into the following categories (Springfield Centre, 2015):
    - Physical—the structures, assets, human resources, scope, or outreach (customer base, distribution system) to carry out actions
    - Strategic—the vision, governance, and networks to perform appropriate roles in the system
    - Personal or cultural—the ethos, attitudes, and leadership to shape effective performance
    - Technical—the knowledge and ability to carry out actions to a required standard
    - Financial—the money to carry out actions
- **What is the market actor's importance and influence?** It is important to be strategic and focus on actors who can directly affect the market system changes and/or intervention goals or indirectly influence and support key market actors to make the desired behavior change. These can include stakeholders from a market actor's reference group who may not be market actors themselves but can influence the market actor's behavior.

Task 5. Determine priority actions. The previous tasks lead to identifying the type of market interventions needed to affect the desired behavior change. The task itself is outside the scope of this document, but it is important to note that market interventions must strike a balance between ambitious behavior change goals and what has a realistic chance of success. This means that the

incentives of different players are central to any consideration of the roles they play now and might play in the future. Understanding these incentives is important so market interventions can be aligned with them to pursue a valid and realistic vision of the future.

Factors to consider when understanding norms include the importance of informal rules and the shifting influences on change. While all market players operate within sets of formal rules that are meant to guide actions, in practice informal rules are often more important. For example, guidelines require prescriptions for certain FP methods and MNCH products, but in many low- and middle-income countries pharmacists dispense these products without a prescription. Health ministries have policies to work with the private health sector, but in some countries, they resist and/or do not implement strategies to foster collaboration. Understanding informal incentives is critical to shaping behaviors.

The dynamic nature of market systems means that the relative importance of different influences also changes. Problems, crises, pressures, and other factors can change market actors' incentives, creating opportunities for interventions. For example, the COVID-19 pandemic highlighted the bottlenecks in the public health system and created opportunities for health ministries to engage the private health sector to address some of these constraints. There are, in reality, very few situations in which the confluence of factors creates the ideal scenario for market interventions, but new opportunities—bound by time and context—can arise to build on market actors' incentives. In this sense, successful interventions are always opportunistic.

Strategic Questions

Areas to explore include key market actors, behaviors to change, new behaviors to promote, and psychosocial drivers of behaviors:

- Who are the key market actors at different levels of the Social-Ecological Model depicted in Figure 6?
- What are the priority behaviors to change among key market actors?
- What are the behaviors that need to be promoted among key market actors to achieve the intended outcomes?
- What do key market actors intend or plan to do regarding the new behavior?
- Who are the key influencers of the key market actors?
- What is the attitude of key market actors regarding the new behavior? Specifically:
    - What do key market actors think are the outcomes or value of the new behavior?
    - How do key market actors feel about the new behavior?
    - What kinds of social approval or disapproval do market actors anticipate from their reference group for the given behavior?
    - What do key market actors believe regarding how common the new behavior is among other people in their reference group?
    - What barriers and/or facilitators do key market actors believe impede or support the new behavior?
    - How easy or difficult do key market actors believe the new behavior is?

- What are the perceived attributes of the new behavior/innovation/intervention in terms of observability, complexity, compatibility, trialability, and relative advantage of the new behavior (Dearing, JW, 2018)?
- What agencies have the power to draft and adopt health regulations under the law?
- What is the level of knowledge and skills of key market actors relating to successful adoption of the behavior?
- Are there any environmental constraints that objectively impede key market actors from engaging in the new behavior?

Data Sources

Data on the norms and related psychosocial concepts detailed in Table 3 can be obtained through secondary analysis of existing information or through primary data collection. Both require the application of behavior theory to organize and understand how collective norms are interpreted by individuals and how these perceived norms influence attitudes, agency, and/or intentions.

Secondary Data Sources

- **Peer-reviewed literature and program reports relating to the perceptions and beliefs of key market actors (e.g., provider bias, behaviors, and behavior change).** Organizations often undertake assessments as part of their programs; these reports are often not published but may be available upon request. Inquiring about such information from key market actors at the institutional level can be useful.
- **Population-based survey reports (e.g., demographic and health surveys).** These sources are often most relevant for consumers, but the data will need to be mined to extract and compute key indicators. The application of a behavior change theory (e.g., the Integrated Behavioral Model) will facilitate identification of key variables from the data set by providing key concepts to look for.

Primary Data Sources

Programs can undertake primary data collection to assess norms and concepts related to key behaviors. Depending on the time, resources, and technical expertise available, programs can choose to undertake a qualitative or mixed approach, with findings from the qualitative phase informing the measurement variable for the quantitative phase.

- **Qualitative data.** Focus group discussions and key informant interviews can be undertaken using the strategic questions presented earlier for exploring market actor perceptions and analyzing findings by applying behavior theory to organize results. Such data can provide a nuanced understanding of priority beliefs and perceptions regarding normative influences, attitudes, and agency, along with qualitative insight into perceived gaps in knowledge and skills as well as environmental constraints.
- **Quantitative data.** Quantitative data on norms and related concepts can be obtained using a structured survey for key market actors. The development of the questionnaire is a critical step and requires that different beliefs identified during the qualitative phase be converted to

statements with standard five-point agreement-disagreement scales. Reported agreement-disagreement scores can be reported as favorable/nonfavorable depending on the belief. High correlation between the scores for specific beliefs and the intention to engage in the behavior can help identify beliefs to focus on. With empirical data at hand, programs can also choose to run reliability and validity assessments for the metrics and use the validated metrics to undertake rapid evaluations to detect shifts in beliefs related to key behaviors.

BOX 9: HOW NORMS SHAPE INCENTIVES AND BEHAVIORS IN NIGERIA

Several cultural and economic norms directly shape whether and where a Nigerian woman decides to seek BEmONC and where (the public sector or private sector). Preliminary informant interviews reveal that the number-one barrier is access to funds to pay for the services, whether in public or private facilities. There are hidden costs in state MOH "free" maternity programs, and the private sector uses fee-for-service payment. The high cost of care is further compounded by pregnant women's lack of decision-making authority over whether funds can be spent for their care. There is also still a strong cultural expectation—particularly among husbands—that since the women in the family have always delivered at home, their wives can as well.

Although delivering BEmONC may not be a winning business model, many norms motivate private providers to enter and stay in maternal and newborn care despite the difficult market conditions. First and foremost, many private providers, particularly nurses and midwives, are motivated by a desire to improve women's health. Second, they are motivated by their standing in the community and consider delivering quality maternal and newborn care to be a way to respond to the community's needs. Finally, their professional reputation motivates them to continue to learn new skills and offer a wider range of services.

Step 5. Assess the Impact of Rules and Regulations on Market Performance

Tasks

After reviewing the rules, regulations, and norms related to the FP or MNCH market, it is time to examine how they shape market operations and market actors' incentives and behavior. Many will create barriers, and a bit more digging can reveal whether a rule, regulation, or norm is among the root causes of weak market performance. Annex 7 provides a worksheet, shown in Figure 8 below, that helps organize the assessment of rules and regulations on market performance.

Task 1. List the barriers. Use the worksheet to list the barriers according to their main characteristic (e.g., regulation, standard, or norm). The review will have uncovered other market constraints not directly related to rules and regulations. List those as well, by the relevant supporting function. Also include a brief description on how the rule, regulation, or norm is creating a barrier.

FIGURE 8: MARKET SYSTEM PERFORMANCE WORKSHEET

Market System Performance Worksheet							
Market characteristics			A	I	M	Observations	A = Absent I = Inadequate M = Mismatched
Core market	Supply						
	Demand						
Supporting functions	Stewardship						
	Financing	Demand					
		Supply					
		Subsidies					
		Business					
	Info	Demand					
		Supply					
	Skills and capacity						
Rules and regulations	Regulations						
	Tariffs, taxes						
	Standards						
	Norms	Supply					
		Demand					

Task 2. Assign each barrier a classification. These are described below.

- **Absent:** A rule, regulation, or norm is missing or exists but is not enforced, or a practice is different than the written rule. For example, Ivory Coast has not had health facility licensing regulations since the civil war 12 years ago.
- **Inadequate:** A rule or regulation is out-of-date, inconsistent, and/or duplicates other regulations, or a market actor does not have adequate capacity or incentive to improve performance. For example, a national drug administration may lack the capacity or power to adequately enforce standards that are designed to restrict the import of fake pharmaceuticals.
- **Mismatched:** A rule or regulation is overly restrictive, has no medical benefit, or creates a negative impact. For example, administration of injectables may be restricted to qualified nurses or clinical officers when there are too few of those professionals to meet the demand, or oral contraceptive regulations may require monthly refills, creating a disincentive to continue use.

Also important to consider are the various regulatory agencies' "skills" (e.g., resources, capacity, technology) and "will" (e.g., incentives, norms) to perform the necessary roles (e.g., implement and/or enforce).

Figure 9 shows the worksheet for the BEmONC case study. Several regulatory barriers related to facility licensing and economic regulations (or lack thereof) have led to poor market conditions for private-sector investment in BEmONC in Ebonyi. There are also capacity issues related to the government's ability to enforce existing regulations and to leverage (economic) regulations to create interest in this market. The regulatory review also detected other areas of underperformance that are not directly caused by regulation but are in other supporting functions (e.g., demand/supply financing, subsidies, business financing).

FIGURE 9. MARKET SYSTEM PERFORMANCE WORKSHEET FOR BEMONC IN EBONYI STATE

Worksheet : Analyze market system performance						
Market characters		A	I	M	Observations	A=Absent I =Inadequate M=Mismatch
Core Market	Supply					
	Demand		X		▪ HIGH OOP: Women cannot *access to funds* to pay for MN services in BOTH public and private – there are hidden costs for the SMOH's 'free' maternity program and fee-for-service in the private sector.	
Supporting Functions	Financing (D & S)		X		▪ WEAK DEMAND: Although Ntl Health Insurance benefits include MN services and does contract private sector, population coverage insufficient compensate for limited purchasing power	
	Subsidies			X	▪ COMPETITION/WEAK INVESTMENT: Govt and donor subsidies to SMOH create competition between public and private; also acts as disincentive to private sector to invest in BEoMONC	
	Information (S)		X		▪ WEAK ENFORCEMENT: Although health facility license require reporting, private sector under report. MOH lacks staff to enforce regulations nor have created 'incentives' to motivate private sector to increase reporting (see Norms)	
	Skills		X		▪ WEAK CAPACITY: Although have operating procedures and use IT to make processes more efficient, regulatory agencies are underfunded, understaffed to perform inspections and process licenses; SMOH priority and not motivated to fund regulatory functions	
	Business financing		X		▪ INTERCONNECTED: Market reg's not optimal but greatest barriers is lack of A2F (not a reg issues but market condition)	
Rules & Regs	Regulations		X		▪ FACILITY LICENSING: Slow processes result in many PS operating temporarily without licenses but does not pose a quality risk as eventually processes catches up to # of license applications	
				X	▪ FACILITY LICENSING: Ownership requirements create significant barrier to market entry, particularly for nurse/midwives who require access to a physician; supervision requirement also creates additional cost risking	
		X			▪ PRICING: Only price reg' applies to the public sector – all maternity related services must be free. But reg's are 'silent' on pricing for private health services (e.g. no pricing guidelines establishing a minimum or maximum) which may contribute the unaffordable fees for private BEmONC services . As a result, prices differ greatly between private providers offering same services	
		X			▪ ECONOMIC REGs: SMOH does not use economic regulations to create incentives to "crowd-in" new providers and/or encourage expansion to underserved geographic regions / population groups.	
	Norms (S)	X			▪ INFO (S) Private sector not motivated to report (e.g. reg's not enforced, do not trust how govt will use data, govt does not include private sector data in reports to reflect private sector contribution)	
				X	▪ POSITIVE PROVIDER INCENTIVES: Private providers (particularly N/M) are motivated to deliver BEmONC for (i) personal motives (improve women's health), (ii) community standing (offer service needed/wanted) and (iii) professional reputation (new skill, quality services) despite not 'winning' business model.	
	Norms (D)			X	▪ LACK OF AGENCY: Women lack decision-making authority in the household to decide if funds can be spent for her care. ▪ CULTURAL NORMS: Strong cultural expectation – particularly among husbands – that since all the women in the family delivered at home, their wives can delivery at home as well.	

The most effective way to conduct this analysis and then design appropriate interventions to overcome the barriers is to engage key market actors. This not only can build consensus on what the regulatory and normative barriers are, but it can also facilitate agreement on how the barriers are affecting market performance (absent, inadequate, mismatch). A venue for this engagement could be a half-day working meeting with representatives from the key regulatory agencies, relevant ministry departments, and private-sector groups to present and validate the analysis and prioritize the root causes of the barriers arising from rules, regulations, and norms.

Here are suggestions on how to prioritize the rules, regulations, and norms that create barriers, identify their root causes, and explore how to address them with key market actors:

- **Feasibility:** A review can take only a few months, but reforming a regulation or changing a law takes time. Understand procedures, timetables, and deadlines to determine the feasibility of changing a law, policy, or regulation.
- **Criticality:** Some barriers are more serious than others. Consider whether reforming the identified policy, regulation, or rule is absolutely necessary to improve market performance, and then weigh whether time and effort are available to pursue the reform.
- **Timing:** Recently adopted laws, policies, and regulations will be difficult to change. Ones that were adopted many years ago may be possible to revise with multiple changes at once.
- **Political will:** How open is the gatekeeper to changing this regulation, rule, or norm? Are one or more champions available to lead the reform initiative?

Applying the Legal and Regulatory Analysis to the Pathway to Impact

As noted earlier, the analysis generated through this process can serve as an input for the different stages of the Pathway to Impact process (Diagnose, Design, Deliver, Adapt & Learn). Legal and regulatory analysis is one area of inquiry in a market **diagnosis**. Current FHM Engage experience in both market description and diagnosis shows that constraints in rules and regulations as well as norms are key contributors to FP market underperformance and therefore merit a closer look. If sufficient resources are not available, this document can guide a review of regulatory and/or normative areas that affect FP market underperformance.

The companion *Guide to Rules and Regulations Reform* explains how to maximize the findings from a legal and regulatory analysis in other stages of the Pathway to Impact, such as **design**. It presents the most common regulatory barriers to designing a market intervention strategy as well as tactics to address them based on evidence from the literature review. It also offers tools to design interventions that can overcome regulatory barriers and strengthen enforcement capacity.

As a temporary, catalytic agent of change, FHM Engage works with and through local market actors to **deliver** market system change by bringing evidence and insight to support decision-making on rules and regulations. This involves co-creation of an action plan or roadmap in close collaboration with a government or other state actor (e.g., a provincial, regional, or district authority) to improve rules and regulations. The action plan should focus on who is best able to carry out important market functions related to rules and regulations – often based on their capacity, incentives, and credibility.

In the **adapt/learn** step, FHM Engage and its partners assess whether the market interventions have been effective in addressing the regulatory barriers and share lessons that can applied for further market development in a country market strategy. This can contribute to the growing body of evidence on strategies that are effective in addressing regulatory barriers that impede market performance.

Conclusion

The approach offered in this document fills gaps in MDA implementation by building on existing evidence to provide 1) a simple step-by-step process for rules and regulations review, 2) guidance on common legal, regulatory, and normative issues to consider when analyzing rules and regulations, and 3) an approach to analyzing how rules and regulations affect market operations. The checklists, interview guide, and analytical worksheets in the annexes can help those who want to understand how rules and regulations can negatively affect a health market and how reforms can enable or constrain market development.

This document will be updated and revised based on country experiences and will be tested in India, Nepal, and Pakistan to understand how rules and regulations affect the structure and performance of FP markets. The rules and regulations review will generate recommendations on changes and adaptations to address gaps in market development and on design interventions for implementing these reforms. Future versions of this document will be shared with both the FHM Engage staff and the global health community.

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Annex I. Health Facility Licensing Checklist

FACILITY LICENSING AND ENFORCEMENT	
Areas to examine for licensing health facilities	**Actions to facilitate private-sector role**
Staffing, equipment, and physical facility requirements	
▪ Staffing, equipment, and building levels are commensurate with risk and level of care and are harmonized between the public and private sectors ▪ Certificate of need issued for high-tech equipment/services ▪ Some authority to waive specific requirements in underserved rural areas	▪ Update/adjust facility requirements more often than required by the basic licensing law to stay abreast of new technologies, clinical practices, and patient demand for services ▪ Require facility relicensing at least every five years ▪ Require all facilities (public and private) to be subject to the same facility licensing requirements ▪ Waive specific requirements or allow more flexible arrangements for facilities in rural areas (e.g., allow networking or partnering as a mechanism to enable a rural or low-resource facility to meet licensing requirements) ▪ Adjust facility and staffing requirements to the service level
Inspections	
▪ Unannounced inspections are permitted and recorded ▪ Laboratories are required to undergo annual quality check ▪ Multiple inspection authorities are listed vs. one comprehensive authority ▪ Scheduled vs. actual frequency of routine inspections is similar ▪ Number and location of inspection staff are defined in the statute or in related regulations ▪ Enough inspectors with appropriate qualifications and training ▪ Maintenance of adequate facility inspection records ▪ Reports include the number of enforcement actions undertaken and concluded ▪ Procedures to control corruption ▪ Inspectors are able to review medical records	▪ Combine inspections (hygiene, medical) to reduce time and administrative barriers to licensing and renewal ▪ Decentralize inspections by the same agency at a decentralized level (even if facility accreditation is complete at the federal level) ▪ Inspections should inquire whether the facility classification is appropriate and adjust accordingly ▪ Require laboratories to do quality checks at random intervals, as a condition of facility licensing ▪ Facility inspectorate confirms license of required professionals and shares data on poor care with professional licensing agency ▪ Sufficient budget for inspection cadre and travel
Restrictions	

▪ Limits on number of clinics one person can own ▪ Limit on types of clinics private owner can operate ▪ Period of government service required prior to private practice	▪ Liberalize ownership restrictions ▪ Remove requirement for government services before opening a private practice
Areas to examine for licensing pharmacies and drug shops	**Actions to facilitate private-sector role**
Staffing, equipment, and physical facility requirements	
▪ Staffing levels are explicitly defined ▪ Physical facility requirements are clearly outlined and are responsive to drug storage and dispensing needs	▪ Allow managers to oversee administrative and financial aspects of running the pharmacy to free up pharmaceutical knowledge for relevant dispensing, patient assessment, and verification of appropriate storage mechanisms ▪ Permit technical supervision of facility by pharmacist without constant onsite presence ▪ Network of multiple sites overseen by a pharmacist, or franchises/network permitted ▪ Make exceptions to facility or staffing requirements for rural area; review exceptions periodically
Inspections	
▪ Unannounced inspections are permitted and recorded ▪ Scheduled vs. actual frequency of routine inspections is similar ▪ Number and location of inspection staff are articulated in the statute or in related regulations ▪ Enough inspectors with appropriate qualifications (e.g., pharmacy) and training ▪ Adequate pharmacy facility inspection records are maintained ▪ Reports include the number of enforcement actions undertaken and concluded ▪ Procedures to control corruption ▪ Inspectors are able to review dispensing records	▪ Decentralize inspections by the same agency (even if facility accreditation is done at the federal level) ▪ Inspections should determine whether the facility classification is appropriate and adjust accordingly ▪ Facility inspectorate confirms licensing of required professionals and shares data on poor care with professional licensing agency ▪ Sufficient budget for inspection cadre and travel
Owership restructions	
▪ Requirement of pharmacy ownership by pharmacist ▪ Limitations on ownership of multiple sites	▪ Relax ownership requirements, particularly for underserved areas

Record keeping	
▪ Requirements are explicit	▪ Ensure that reporting requirements are feasible given the type of facility (pharmacy or drug shop) and size
Drug requirements	
▪ Outdated and unregistered drugs are prohibited	▪ Use a tiered drug list according to the level of facility staffing/supervision
Areas to examine for enforcement of service and pharma facility licensing	**Actions to facilitate private-sector role**
▪ Sufficient number of inspectors with appropriate qualifications (e.g., pharmacists) and training ▪ Facility inspection records are maintained ▪ Procedures to avoid inspector corruption ▪ Inspectors are able to review medical records ▪ Duplicative inspections (e.g., one for hygiene, another for licensure) ▪ Clarity vs. confusion regarding licensure of individual professionals	▪ Facility inspectorate confirms licenses of required professionals and shares data on poor care with professional licensing agency ▪ Sufficient budget for inspection cadre and travel ▪ Combine inspections (hygiene, medical) to reduce time and administrative barriers to licensing and renewal

Annex 2. Health Professional Licensing Checklist

HEALTH PROFESSIONAL LICENSING	
Areas to examine for health care professionals	**Actions to facilitate private-sector role**
Professional licensing/relicensing	
▪ Clearly defined terms for professional licensing ▪ License renewal required at least every five years	▪ Streamline procedures (e.g., IT) for licensing and relicensing to encourage market entry and prevent bottlenecks ▪ Ensure that facility licensing laws and regulations on staffing mirror the professional scopes of practice
Continuing medical education	
▪ Continuing education requirements are clearly defined for each cadre	▪ Require proof of continuing education for license renewal ▪ Ensure that education requirements take into account realistic availability, and consider alternative measures to train professionals
Scopes of practice	
▪ Statutes permit special accreditation to enable professionals to achieve skill upgrades to offer certain services ▪ Scopes of practice are clearly defined for each health professional cadre ▪ Consistency between public and private sectors ▪ Prescribing privileges are clearly defined for the health cadres	▪ Require permit for supplemental accreditation of specified services ▪ Delegate authority to the appropriate professional licensing body to define scopes of practice to ensure that the scopes are consistent with training ▪ Establish a mechanism, such as an overarching council of allied medical professions or MOH, to resolve conflicts when more than one profession claims the sole right to conduct a particular activity or procedure ▪ Grant clear permission for an individual to be licensed for private practice within the agreed scope of practice
Areas to examine for health care professionals	**Actions to facilitate private-sector role**
Private practice	
▪ Determine whether dual practice is permitted ▪ Is there a waiting period to enter private practice? ▪ Is there clarity on the terms of dual practice or private practice after hours among health professionals employed by the public sector?	▪ Allow dual practice to incentivize retention ▪ Limit waiting period to enter private practice to no more than 2 to 3 years

Professional licensing/relicensing	
▪ License renewal required at least every five years	
Continuing education	
▪ Continuing education for pharmacists is clearly defined and appropriate to changes in technology and pharmaceutical innovations	▪ As technologies and improved diagnostic capacity evolve, allow prescribing and dispensing protocols to be flexible to enable task shifting ▪ Medical education and licensing guidelines should be flexible enough to adjust to changes in diagnostic capacity and available drugs
Scope of practice	
▪ Vague or restrictive scope of practice for pharmacists, pharmacist technicians, and drug sellers ▪ Requirement for prescribing based on the provider level ▪ Drug lists for different levels of facility and provider	▪ Establish drug lists for different levels of provider that are responsive to available staffing cadres ▪ Require prescriptions if the system can enforce the prescription but not where prescribers are unavailable or health risk is low ▪ Allow for franchises where a supervisory pharmacist can oversee a pool of pharmacy shops managed full-time by pharmacy technicians, particularly in rural areas where pharmacists may be scarce
Private practice	
▪ Clear and well-defined terms of dual practice or private practice after hours among health professionals employed by the public sector ▪ Clear and well-defined terms for health professional entry into private practice	
Restrictions	
▪ Limits on prescribing ▪ Limits on dispensing	
Enforcement	
▪ Specific regulatory agency is authorized to regulate and sanction medical professionals ▪ Law specifies who has authority to remove or limit the license or collect a fine ▪ Clearly defined penalties and sanctions for rules violatiions by licensed professionals and unlicensed nonprofessionals ▪ Transparent and clear process for sanctioning those who violate rules	▪ Vest authority in a professional registration council with government-appointed members ▪ Ensure adequate budget for inspectors and travel ▪ Ensure supervision of inspectors to reduce graft and abuse of authority ▪ Include fines, suspension, and corrective actions as well as delicensing among sanctions

▪ Sufficient and dedicated legal staff to pursue enforcement actions	▪ Permit fact-finding by administrative hearing officer or panel consisting of professionals and at least one consumer ▪ Allow delicensing to occur by administrative action and follow up with an option for appeal ▪ Acknowledge supplementary peer review or accreditation

Annex 3. Pharma Regulations Checklist

REGULATIONS ON PHARMACEUTICAL SUPPLY (checklist is not exhaustive)	
Areas to examine	**Actions to facilitate private-sector role**
Cross-cutting	
▪ National pharmaceutical laws and regulations exist to regulate the market ▪ National pharmaceutical laws and regulations are aligned with current global (WHO) and other best practices ▪ Key stakeholders (across the public and private sectors) are knowledgeable and aware of these laws and regulations and adhere to them ▪ Capacity exists to monitor and enforce laws and regulations	▪ Address gaps in regulations ▪ Involve private-sector stakeholders in regulatory reforms ▪ Widely disseminate laws and regulations ▪ Invest more funds in building regulatory agency capacity
Production	
▪ Regulations exist to ensure the production of safe and efficacious medicines ▪ Regulations are aligned with other global and national standards and best practices ▪ Costs to achieve production quality standards are not prohibitive ▪ Intellectual property rights do not prohibit the manufacture of key commodities ▪ Capacity exists to monitor and enforce regulations	▪ Follow international best practices in intellectual property ▪ Create incentives for international R&D to relax intellectual property laws ▪ Invest more funds in building regulatory agency capacity
Pricing	
▪ Regulations exist to ensure that high-quality products are affordable ▪ Capacity exists to adequately formulate/update pricing policies and monitor effectiveness on an ongoing basis	▪ Conduct regular market audits to understand pricing for key commodities such as FP methods ▪ Foster transparency and encourage alignment in pricing of key commodities by posting prices publicly
Import/export	
▪ Regulations governing import/export of pharmaceuticals exist ▪ Key market actors are aware of these regulations	▪ Relax/remove import taxes on essential medicines (e.g., FP methods) and medical equipment

▪ Regulations are straightforward, transparent, and not cost-prohibitive ▪ Capacity exists to monitor and enforce regulations	▪ Streamline customs processes and reduce customs fees on essential medicines and equipment
Market authorization/registration	
▪ Globally recommended (WHO) products and those listed within the country's standard treatment guidelines/essential medicines list ▪ A clear, transparent system exists for medicine registration and is streamlined and not cost-prohibitive	
Distribution and storage	
▪ Good distribution and storage practice policies exist and are adhered to ▪ Capacity exists to monitor and enforce regulations	▪ Ensure that costs for compliance are not prohibitive ▪ Invest in regulatory agency capacity
Sales/prescribing/dispensing	
▪ A schedule of medicines exists ▪ Capacity exists to monitor and enforce regulations	▪ Digitize the essential medicines list ▪ Widely disseminate best dispensing practices
Post-marketing surveillance/pharmacovigilance	
▪ A strong national regulatory authority exists to ensure the quality of generic and biosimilar medicines ▪ A system for product recalls exists ▪ A system for reporting adverse events exists ▪ Capacity exists to monitor and enforce corrective measures	
Promotion of pharmaceuticals	
▪ Clear and consistent regulations on pharmaceutical promotion exist ▪ Capacity exists to monitor and enforce regulations	▪ Key market actors are aware of these regulations

Annex 4. Market Conditions Checklist

This checklist presents an overview of the types of economic regulations to explore and possible strategies to address them. Note that some of these regulations are easier to reform than others. For example, establishing minimum capital requirements requires only a simple regulation change within the purview of the MOH whereas offering tax relief and/or removing a tariff is more complicated and is outside the purview of the MOH. Access to finance is outside the scope of this exercise but is addressed in other FHM Engage activities.

REGULATIONS ON MARKET CONDITIONS	
Areas to examine	**Actions to facilitate private-sector role**
Market entry/exit	
Determine whether facility licensing regulations have: ▪ Ownership restrictions ▪ Minimum capital requirements ▪ Zoning restrictions Determine whether facility licensing regulations: ▪ Are too lax, allowing anyone to enter ▪ Too stringent, preventing market entry ▪ Rational (e.g., do zoning requirements limit concentration and/or encourage location in underserved areas?)	▪ Remove ownership restrictions ▪ Examine benefits of requiring minimum capital requirements ▪ Rationalize zoning restrictions
Taxes, tariffs	
▪ Determine whether income taxes in health are more or less than in other sectors and whether there are provisions for tax relief ▪ Determine whether there are tariffs or taxes on essential products, equipment, and/or inputs (e.g., water, power, land)	▪ Explore whether other social sectors and/or state/local governments have used tax "holidays" ▪ Explore the difficulty (e.g., time, approval) of removing import taxes and/or granting relief on key inputs
Competition	
▪ Examine how donor subsidies are affecting the market	▪ Work with donors to remove and/or minimize impact of subsidies on the commercial market
Prices/margins	
▪ Are there guidelines that establish a minimum/maximum range for consultation fees and specific health services in the private sector? ▪ Are there regulations capping markups/margins on drugs and equipment?	▪ Establish pricing guidelines to rationalize pricing for similar health services/products but do not establish price controls ▪ Limit markups but do not remove them

▪ Are there restrictions on private-sector charges for specific health services (e.g., "free" maternity programs, "all health care is free")?	
Marketing approvals	
▪ Globally recommended (WHO) products and those listed within the country's standard treatment guidelines/essential medicines list	▪ Remove regulations

Annex 5. Market Intelligence Checklist

MARKET INTELLIGENCE	
Areas to examine	**Actions to facilitate private sector role**
Reporting requirements	
▪ Are there regulations requiring private-sector reporting? Do they specify what type of data? How often to report? Who to submit the data to? ▪ Do health facility licensing requirements include data reporting? What data? How often? ▪ Do health facility licensing requirements include maintenance of medical records? ▪ Do professional licensing requirements specify responsibilities for disease reporting? Other data reporting? How often?	▪ Engage the private sector in dialogue on appropriate regulations that require data reporting ▪ Incentivize private-sector reporting to DHIS2 ▪ Integrate facility census with DHIS2 ▪ Disaggregate public and private data for analysis ▪ Disaggregate annual service statistic reports
Data capacity	
▪ How often does the private sector report this data? ▪ What tools do they use to report data? ▪ What barriers does the private sector face in complying with reporting requirements?	▪ Build public and private capacity to report and collect data ▪ Use technology to facilitate private-sector reporting ▪ Merge databases of public and private facilities ▪ Disaggregate public and private data for analysis ▪ Facilitate private-sector reporting ▪ Build MOH capacity to analyze data
Data and information systems to regulate	
▪ What systems and infrastructure does the government have to collect, store, and share data (e.g., data on facility licensing, professional licensing, continuing medical education hours, drug registration)	▪ Invest in government infrastructure and capacity to digitize key regulatory functions ▪ Create policy and operating procedures on how data will be used and shared
Data governance policy	
▪ Is there a data governance policy? ▪ Does the government engage the private sector on data-related issues? ▪ Do the regulatory agencies share this data with other government agencies? With the private health sector?	▪ Partner with the private sector to agree on data needs ▪ Create incentives for private-sector reporting ▪ Integrate different data sets and make them accessible

	▪ Share data with the private sector to facilitate dialogue on policy barriers to private-sector involvement in the health sector ▪ Share data with the private sector to inform policy dialogue and planning

Annex 6. Interview Guide

SCOPE OF SERVICES
1. Outline the scope of services 2. Who delivers this scope of services and at what facility level?

INSTITUTIONAL ARRANGEMENTS		
Which institutions/agencies are responsible for regulating the particular service?	Facility licensing	□ Medical council, medical bureaus □ Professional associations
	Professional certification	□ Medical council, medical bureaus □ Professional associations (e.g., doctors/dentists, nurses/midwives, pharmacists/pharmacy technicians, allied professionals)
	Quality accreditation	□ MOH department of health services □ National health insurance agency and/or contracting agency
	Information	□ MOH department of policy and planning □ MOH department of information and statistics
	Other types of regulation	□ _____
Which institutions/agencies are responsible for regulating the particular product?	Facility licensing	□ Pharmacy council □ Professional associations (e.g., pharmacists/pharmacy technicians, allied professionals)
	Professional certification	□ Pharmacy council, allied professionals □ Professional associations (e.g. doctor/dentists, nurse/midwives, pharmacists/pharm technicians, allied professionals)
	Product registration/quality	□ National drug authority (FDA)
	Pharma entity quality	□ ????
	Other types of regulation	□ _____
Which institutions/agencies are responsible for setting the rules for market conditions?	Taxes	□ Varies depending on the type of taxes (e.g., income taxes: federal/state tax authority; sales (IVA/VAT) taxes: federal and state
	Tariffs	□

	Competition	□ Facility licensing (e.g., market entry/exit, zoning, certificate of need)
	Prices	□
	Information	□
	Other areas	□ _____

FACILITY LICENSING	
Who licenses health facilities for the particular service?	□ _____
Which facilities are allowed to deliver the service?	□ Primary □ Secondary □ Tertiary □ Other (e.g., nurse/midwife office, maternity home) _____
Are the facility scopes (e.g., staffing, equipment, and physical facility) commensurate with the risk and level of care at each type of facility?	□ Yes □ No If no, why not? _____ ___
Are licensing requirements the same for public and private facilities?	□ Yes □ No If no, how do they differ? _____
Is there flexibility to waive specific requirements in underserved rural areas?	□ Yes □ No
Is it difficult to obtain a facility license?	□ Yes □ No
If yes, why?	□ Cost to obtain facility license □ Lack of market information □ Lack of access to capital Other _____
How often does a private provider have to renew the health facility license?	□ _____
Is it difficult to renew the facility license?	□ Yes □ No
If yes, why?	□ Cost □ Excessive paperwork □ Time (days lost, waiting for inspection) Other _____

Is an inspection required to renew the health facility license?	□ Yes □ No
Are there ownership restrictions?	□ Yes □ Limit on who can own (e.g., must be a clinician) □ Limit on how many facilities one person can own □ Requirement for a physician/pharmacy supervisor □ Minimum # of years in public service before opening a private facility □ No
Do facility licensing regulations require data reporting?	□ Yes If, yes, what data? _____ How often? _____ □ No
What challenges does the particular agency face in performing its regulatory role?	□ Insufficient budget □ Insufficient inspectors □ Operating procedures and guidelines □ Overlapping scope with other agencies □ Other _____

HEALTH PROFESSIONAL LICENSING	
Which health professionals are allowed to deliver the particular service?	□ OB/GYN □ Nurse/midwife □ Others _____
Who licenses these health professionals?	□ Doctor/dentist council □ Nurse council □ Others _____
Are the scopes of practice clear between different health cadres that perform the service?	□ Yes □ No If no, why not? _____
Are the scopes of practice for health cadres the same between public and private?	□ Yes □ No If no, why not? _____

Are prescribing privileges clearly defined among the health cadres providing the service?	□ Yes □ No
Is it difficult to obtain a license as a health care professional?	□ Yes If yes, how is it difficult? _____ □ No
Does a professional license require a minimum number of years in the public sector before working in the private sector?	□ Yes □ No
Are health professionals required to renew their license?	□ Yes If yes, how often? _____ □ No
Do the renewal requirements differ between health cadres?	□ Yes If yes, what are the differences? _____ □ No
Is it difficult to renew a professional license?	□ Yes □ No
If yes, why?	□ Cost □ Excessive paperwork □ Time (days lost, waiting for inspection) □ Other _____
Are health professionals required to complete continuing medical educaton hours?	□ Yes If yes, how many hours? _____ □ No
Is dual practice allowed?	□ Yes If yes, under what circumstances? _____ □ No If no, is it still practiced? How? _____
What challenges does the particular agency face in performing its regulatory role?	□ Insufficient budget □ Insufficient inspectors □ Operating procedures and guidelines □ Overlapping scope with other agencies □ Other _____

MARKET CONDITIONS	
Are facility licensing requirements too lax, allowing anyone to deliver the particular service?	□ Yes If yes, who is offering the service that should not? _____ □ No
What economic regulations create barriers to private health facilities delivering the particular service?	□ High income taxes □ High taxes on key inputs □ High cost of necessary inputs (e.g., drugs, equipment) □ Import taxes on necessary inputs □ Others _____
Is competition tough for private providers delivering the particular service?	□ Yes If yes, with whom (e.g., public services, private services, informal practitioner services)? _____ □ No
Are there guidelines establishing a minimum/maximum range for consultation fees and specific health services in the private sector?	□ Yes □ No
Are there regulations capping markups/margins on drugs and equipment needed for the particular service?	□ Yes □ No
Are there restrictions on the private sector charging for given maternity services that are supposed to be free?	□ Yes □ No
Do regulations restrict advertising of services? Products?	□ Yes □ No
What other market conditions do private providers face in delivering the particular service?	

NORMS THAT AFFECT DEMAND AND SUPPLY	
What norms most affect access to and use of the particular service?	□ Sufficient information □ Awareness of benefits □ Ability to act (e.g., gender, household, community norms) □ Ability to act (e.g., distance) □ Ability to act (e.g. funds) □ Other

What norms affect provider behavior in delivering the particular service?	□ Sufficient information □ Provider bias □ Lack of skills □ Insufficient incentives □ Other

Annex 7. Market System Performance Worksheet

AIMS Worksheet : Market system performance analysis for INSERT COUNTRY & MARKET						
Market characters			A	I	M	Observations
Core Market	Supply					
	Demand					
Supporting Functions	Stewardship					
	Financing	Supply				
		Demand				
		Subsidies				
		Business				
	Info	Supply				
		Demand				
	Skills, Capacity					
Rules & Regs	Regulations					
	Tariffs, Taxes					
	Standards					
	Norms	Supply				
		Demand				

About FHM Engage

Frontier Health Markets (FHM) Engage is a five-year cooperative agreement (7200AA21CA00027) funded by the United States Agency for International Development. We work to improve the market environment for greater private sector participation in the delivery of health products and services and to improve equal access to and uptake of high-quality consumer driven health products, services, and information. FHM Engage is implemented by four core consortium partners: Chemonics International (prime and co-technical lead), Results for Development (co-technical lead), Pathfinder International, and Zenysis Technologies. FHM Engage Network Implementation Partners include ACCESS Health India, Africa Christian Health Association Platform, Africa Healthcare Federation, Amref Health Africa, Ariadne Labs, CERRHUD, Insight Health Advisors, Makerere University School of Public Health, Metrics for Management, Solina Group, Strategic Purchasing Africa Resource Center, Scope Impact, Stage Six, Strathmore University, Total Family Health Organization, and Ubora Institute.

FHMENGAGE

Healthy Markets for Healthy People

Learn more about FHM Engage and other USAID health market development projects at:

https://healthmarketlinks.org/