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NAVIGATING UNCHARTED WATERS: A GUIDE TO THE LEGAL AND REGULATORY ENVIRONMENT FOR FAMILY PLANNING SERVICES IN THE PRIVATE SECTOR

September 2006

This publication was produced for review by the United States Agency for International Development. It was prepared by Betty Ravenholt, Rich Feeley, Denise Averbug, and Barbara O'Hanlon for the Private Sector Partnerships-*One* project.

PSP-*One*
PRIVATE SECTOR PARTNERSHIPS FOR BETTER HEALTH

Technical Report No. 5

Technical Report Series: PSP-*One* Technical Report Series addresses important issues relating to the private sector's role in reproductive health and family planning. Papers in the series may discuss lessons learned and best practices, highlighting PSP-*One* technical areas.

Recommended Citation: Ravenholt, Betty, Feeley, Rich, Averbug, Denise, O'Hanlon, Barbara. September 2006. Navigating Unchartered Waters: A Guide to the Legal and Regulatory Environment for Family Planning Services in the Private Sector. Bethesda, MD: Private Sector Partnerships-One project, Abt Associates Inc.

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Contract/Project No.: GPO-I-00-04-00007-00

Submitted to: Susan Wright, CTO
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Global Health/Population and Reproductive Health/Service Delivery Improvement
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Bureau for Global Programs, Field Support and Research
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Family Health International ■ Forum One Communications
■ IntraHealth International ■ O'Hanlon Consulting ■ Population Services International ■ Tulane University's School of Public Health and Tropical Medicine

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ABSTRACT

The legal and regulatory environment can have a profound affect on the feasibility of reproductive health/family planning (RH/FP) programs. Despite numerous experiences demonstrating their importance, however, most programs still fail to consider this context prior to program design, resulting in constraints to implementation—or even complete failure. This guide helps RH/FP program designers and implementers conduct a legal and regulatory assessment to prevent barriers to programs and address constraints encountered during implementation. The manual focuses on issues relevant to the private health sector, because of its increasing involvement in the provision of RH/FP services. Issues related to the private-sector provision of RH/FP services to youth are included, as many countries have laws and regulations for serving this group.

The manual begins with an overview of the potential legal and regulatory issues related to different programmatic areas, followed by a practical guide on how to conduct an assessment. The last part provides strategies to address the legal and regulatory issues identified in the assessment. This guide should help program designers and implementers assess the legal and regulatory environment for their RH/FP programs and, therefore, improve the chances for their projects' success.

ACRONYMS

ARV	Antiretrovirals
CMS	Commercial Market Strategies
FP	Family planning
HAART	Highly active antiretroviral therapy
HMO	Health maintenance organization
IEC	Information, education, and communication
IMF	International Monetary Fund
ISO	International Organization for Standardization
IUD	Intrauterine devices
MOH	Ministry of Health
NGO	Nongovernmental organization
PROFIT	Promoting Financial Investments and Transfers
PSP	Private Sector Program
PSP-*One*	Private Sector Partnerships-*One* Project
RH	Reproductive health
USAID	United States Agency for International Development
WHO	World Health Organization

ACKNOWLEDGMENTS

The authors are grateful to the following staff from the YouthNet project, who provided useful input and added valuable information to this document regarding its relevance to youth: Shawn Aldridge, Ed Scholl, Haguerenesh Woldeyohannes, and Sharifa Tahir. A number of internal reviewers also contributed valuable insights and suggestions, and their input is very much appreciated: Françoise Armand, Jeff Barnes, Ruth Berg, Susan Mitchell, Mary Segall, and Barbara Seligman. The PSP-*One* Project is ably guided by Maggie Farrell, Shyami DeSilva and Susan Wright at the US Agency for International Development. Their technical direction in support of this paper is also very much appreciated.

1. INTRODUCTION

1.1 BACKGROUND

Many diverse yet interrelated factors affect the provision of reproductive health and family planning services in the private sector. Program planners, health-policy makers, and commercial marketers frequently evaluate the feasibility of planned service delivery or product sales by analyzing market demographics, consumer preferences, distribution- and service-outlet infrastructure, media penetration, latent demand, and provider biases. Often overlooked, however, is the legal and regulatory environment for delivering services and selling reproductive health and family planning products. Without knowledge of the laws, regulations, and policies, neither program planners nor private-sector managers can design effective strategies for service and product delivery.

When programs and marketing efforts are undertaken without knowledge of the legal and regulatory environment in which they will be implemented, delays and even program failure may occur. For example, a project for distributing antiretrovirals (ARVs) that was to be implemented through a donor-funded contract recently was halted when it was learned after the contract was awarded that ARVs in the target country cannot be distributed legally in the private sector.

An assessment of the legal and regulatory environment should be part of all private-sector reproductive health and family planning service delivery project planning and design. Through the knowledge gained from this assessment, strategies can be developed for working successfully within the environment, overcoming barriers existing regulations create, taking advantage of opportunities created by current policies, and fostering a more-favorable legal and regulatory environment for reproductive health and family planning service delivery. Attempting legal and regulatory reform will consume significant time, money, and effort. An assessment of the legal and regulatory environment, therefore, may be especially cost-efficient to help inform strategies for working around constraints or working within the existing legal infrastructure to achieve effective service delivery in the private sector.

Removing legal and regulatory barriers, however, may not prevent or resolve an identified constraint from impeding access to reproductive health and family planning products and services. For example, to decrease contraceptive prices and increase their affordability, program implementers may persuade government authorities to exempt contraceptives from tariffs. Importers, however, may take advantage of this change to increase their profit margins rather than pass the savings on to the consumer in a reduced product price. Indeed, some of the greatest barriers to increased family planning service delivery in the private sector typically arise from governing factors that are not based in laws and regulations. Such factors may include provider biases, cultural mores, religious beliefs, political concerns, and profitability priorities, all of which may constrain the private sector's provision of reproductive health and family planning services and products. For example, the largest nongovernmental organization (NGO) in a country discovered that many of its physicians undermined its youth programs—based on their religious views, some physicians believed that youths and unmarried young adults should not be allowed to receive family planning counseling and services. To be comprehensive, an assessment of the legal and regulatory environment also should identify potential, non-law-based regulating factors.

Assessing the legal and regulatory environment for the private-sector provision of reproductive health and family planning services is daunting. To make it more manageable for the non-expert, the Private Sector Partnerships-*One* (PSP-*One*) project has developed this resource to guide and facilitate the implementation of such an analysis, *Navigating Uncharted Waters: A Guide to the Legal and Regulatory Environment for Family Planning Services in the Private Sector.* The guide is intended for program designers, health-policy makers, donor-agency staff, contractor personnel, and private-sector project managers. It builds on the foundation created by several documents, including *Assessing Legal and Regulatory Reform in Family Planning* (Kenney 1993), *Practical Pointers for Conducting Commercial Sector Family Planning Regulatory Assessments* (Feeley 1997), and *Policy Issues in Expanding Private Sector Family Planning* (Cross 1993).

Since these documents were published, significant changes have occurred in the reproductive health and family planning field. There is a growing interest in stimulating a greater share of service provision by the private sector due at least in part to the need in many countries to shift some of the financial burden of service provision from the public sector into the marketplace and onto consumers. As national governments face increasing costs of providing health services, many policy makers look towards the local production of essential and basic drugs, including contraceptives, to help curb healthcare costs. Managed care and other types of provider- and service delivery networks are being developed to curb or redirect the burden of rising health-service costs. Other issues, such as intellectual property rights, good manufacturing practices, capital investment, insurance, credit, currency restrictions, and requirements for worker safety have gained significance. This guide updates and expands on the groundwork laid by previous documents to outline these and other emerging issues that must be considered in a comprehensive assessment of the legal and regulatory environment affecting the private provision of reproductive health and family planning services.

In this guide the private sector is defined as for-profit commercial entities. This group includes a range of providers, including medical providers (doctors, nurses, midwives, health assistance and outreach workers, and traditional healers), product retailers (pharmacies, dispensaries, and non-traditional retailers) and product manufacturers and distributors. The guide also considers legal and regulatory issues confronting the non-profit sector. There is increased pressure from donors on NGOs to become financially self-sustaining. Many NGOs must now make decisions like for-profit entities and, consequently, they face many of the same issues that are relevant to the commercial health care sector.

1.2 CONTENTS AND HOW TO USE THE LEGAL AND REGULATORY GUIDE

This guide consists of three components. The first component, chapters two through six, is the core of the guide and provides a comprehensive review of legal and regulatory issues related to reproductive health and family planning programs in the private sector. The guide is organized into five program areas:

- Product supply
- Contraceptive methods
- Service providers
- Service delivery outlets
- Awareness about products and services

By organizing the guide into program areas, readers can focus on the chapters relevant to their program. Each program area is organized in the same manner. First, each chapter presents an overview of the legal and regulatory issues critical to that program area, which is subdivided into operational areas. To illustrate the issues, the guide also provides country examples. Second, each chapter describes the legal and regulatory issues in a table. The tables are organized in columns as follows, from left to right:

- **Desired outcome:** the specific outcomes expected from each operational area in this program area
- **Issue or constraint:** the potential issues or constraints that can occur in each operational area impeding program implementation
- **Related legal and regulatory areas:** the legal and regulatory areas covering a group of issues or constraints
- **Responsible authority:** the government and other entities with decision-making authority related to that legal and regulatory area
- **Other influencing factors:** non-regulatory factors affecting achievement of the desired outcome

Third, following each table are questions that can be used during interviews with stakeholders to collect information for the legal and regulatory assessment. The questions are adapted from the *Private-Sector Assessment Tool Handbook* (LaVake 2003).

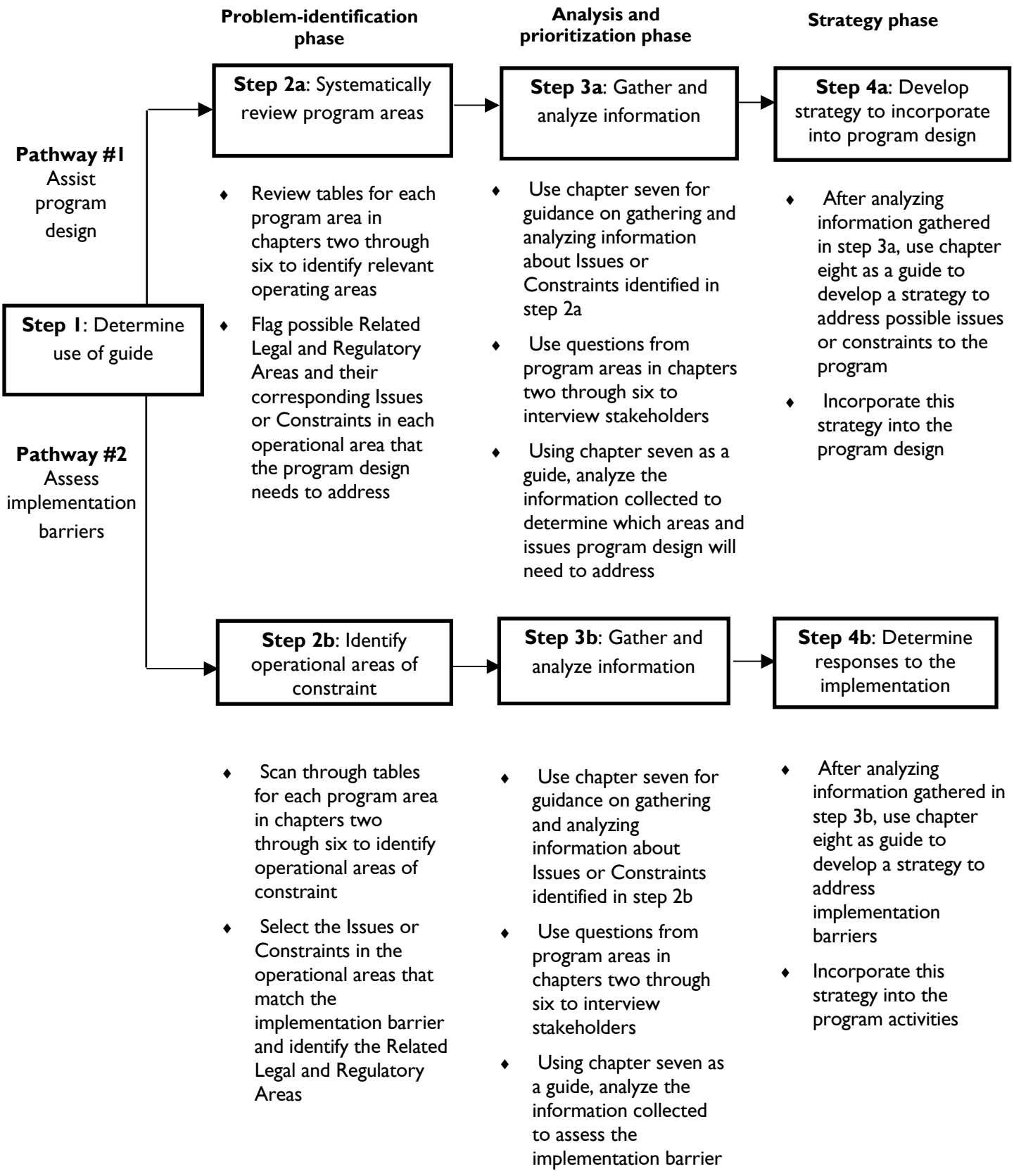
The second component of this guide, chapter seven, outlines the essential steps of a legal and regulatory assessment, including identifying sources where relevant laws and regulations are likely to be found, model protocols for conducting interviews, and guidelines for analyzing collected information. This chapter is adapted from *Practical Pointers for Conducting Commercial Sector Family Planning Regulatory Assessments* (Feeley 1997). The final and third component of this guide, chapter eight, includes guidance about overcoming legal and regulatory barriers and is also adapted from *Practical Pointers for Conducting Commercial Sector Family Planning Regulatory Assessments* (Feeley 1997).

The best way to use this guide depends on the purpose of the reader, as it was designed with two main uses in mind:

- to identify potential legal and regulatory barriers prior to program design and implementation
- to assess existing implementation barriers in ongoing programs and provide guidance on addressing them

Figure 1 illustrates how readers with different objectives might apply the guide. People using this guide to identify potential barriers prior to program design should follow the path outlined in steps 2a through 4a, while those using it to assess existing implementation barriers should follow steps 2b through 4b.

FIGURE 1: HOW TO USE GUIDE



2. PRODUCT SUPPLY

Program Goal: Timely and consistent supply of quality family planning products in the marketplace

Without a consistent supply of a range of affordable, high-quality contraceptive and other reproductive health products, reproductive health and family planning services cannot be delivered effectively. When a variety of brands, prices, and product types is not available within a market, consumers may not find a contraceptive product suitable for them and may discontinue use or fail to begin use. Reliable availability of products in the marketplace, therefore, can have a direct impact on contraceptive prevalence rates, continuation rates, and unplanned pregnancies.

The sustainable supply of contraceptive and reproductive health-related products in the private-sector marketplace depends largely on their profitability to the manufacturers, importers, distributors, and retailers. Profitability is determined not only by market size and product price, but also by the time, money, and effort of bringing those products to market. Unwarranted regulation or inefficient implementation of regulations can increase the costs to the private sector of supplying products and, consequently, can lower the private sector's willingness and ability to maintain a consistent supply of a range of affordable, high-quality contraceptive and other reproductive health-related products.

There are five major operational areas that affect the availability and accessibility of contraceptive and reproductive health-related products in any marketplace:

- product registration
- pricing
- local manufacture
- importation
- distribution

A variety of sometimes inter-related legal, regulatory, and policy issues impact each of these areas.

2.1 REGISTRATION OF PRODUCTS

Registration of pharmaceutical products with the relevant governmental agency is required in virtually every market in the world before the products can be sold legally. Designed to protect the public's health, unnecessary delays in the registration process may limit contraceptive options for consumers. Limited contraceptive choice is associated with lower contraceptive prevalence rates (Panini et al. 1991).

Example: Regional comparison

Registration for an oral contraceptive in Nigeria can be accomplished in two to three weeks, compared to the average of one year in most Latin American countries. This hold-up can create significant delays in launching a new product.

2.2 PRICING STRATEGIES

The pricing of contraceptive products impacts not only their accessibility to various segments of the consumer population, but also the ability and willingness of manufacturers, importers, and distributors to ensure that those products are available. In some countries, the government controls pharmaceutical prices and sets them as part of the product-registration process. In almost all countries, national policies relating to import tariffs, other taxes, and fees affect product prices. Governmental and donor subsidy policies also may affect pharmaceutical pricing. Pharmaceutical manufacturers, however, may have corporate strategies related to product profitability or other marketing needs that affect their pricing decisions.

Example: Egypt

While governmental price controls in Egypt have kept some brands of oral contraceptives affordable for even the lowest-income consumers, the enforced prices have not allowed manufacturers and distributors a sufficient profit to ensure a consistent supply of those brands in the commercial marketplace.

2.3 LOCAL MANUFACTURING

National health-policy makers sometimes see the local manufacture of contraceptives and other pharmaceutical products as a way to ensure a steady supply of affordable products for the local market. To safeguard the public from low-quality drugs, most governments require that local manufacturers fulfill certain requirements to be licensed to produce pharmaceuticals. Further regulations that establish standards for good manufacturing practices and product quality control ensure that manufactured products are safe and effective. If the local firm is collaborating with an international manufacturer, a licensing agreement must be negotiated between the two firms and the international firm likely will require its own regular inspections and testing of product samples to safeguard its reputation and protect itself from the legal liability associated with drug failure or product-related adverse reactions.

Government policies regulating investment by domestic and foreign entities, taxation, credit, and foreign exchange can impact the ability or willingness of entrepreneurs to initiate and operate the local manufacture of contraceptive and other reproductive health pharmaceutical products. Laws or policies governing the importation of raw materials, equipment, and spare parts also can make local production more or less feasible for interested businesses. Local contract law becomes important in the negotiation of manufacturers' agreements with suppliers and distributors. The regulations governing workers' rights, mandated benefits, and safety and work conditions not only affect the quality of life for employees but also the costs of doing business.

Government regulation of the public-sector tender process, conditions for exportation, and restrictions in local manufacturers' licensing agreements with international partners may affect opportunities for local manufacturers to increase cost efficiencies, profitability, and long-term sustainability prospects through market expansion.

2.4 IMPORTATION

Importing pharmaceutical products will always be important for introducing new or improved technologies and when local production is not feasible or able to satisfy demand.

Regulations from many sectors of government impact the costs, profitability, and sustainability of pharmaceutical importation. Most countries require that the local government license firms wishing to import pharmaceutical products. Initial licensing usually is supplemented by regulations aimed at protecting the public health through quality-control standards and spot testing of samples from every imported batch.

Laws and policies regarding tariffs and taxes, repatriation of profits, letters of credit, availability of hard currency and currency exchange, and establishing local offices all affect the costs of doing business as an importer of pharmaceuticals. Laws, regulations, or policies that protect domestic production from competition with international manufacturers or that give preferential consideration to local producers in the award of public-sector tenders also may affect the long-term sustainability of pharmaceutical importation.

2.5 DISTRIBUTION NETWORKS

Distributing contraceptives and other products to the retail, pharmacy, or clinic outlets where consumers can obtain them is the final step in ensuring that contraceptive and reproductive health products are available in the marketplace.

Laws and regulations affecting the distribution of pharmaceuticals fall into two categories: those that govern the establishment and extent of the distribution business and those that affect the profitability of distribution. Included in the first category are requirements for the licensing of firms to distribute pharmaceuticals, regulations that define the types of outlets or providers to whom pharmaceutical products may be distributed, and the regulations that set standards for the safe handling and storage of pharmaceutical products. Local contract law is important in setting the relationships between distributors, suppliers, and manufacturers.

Pharmaceutical pricing, price structure, and taxation policies and regulations can affect the profitability of the distribution business and of the distribution of given brands or types of products. These laws and regulations are in the second category. Sustainable and, therefore, long-term private-sector distribution of contraceptive and related products depend on the profitability of that distribution business.

The matrix in Table 1 details the legal and regulatory issues that reproductive health and family planning program planners and implementers may encounter as they work to ensure that contraceptive and related products are available in the marketplace. The table identifies desired outcomes for ensuring the availability of commercially provided products and services, the authorities with regulatory responsibility for each issue, constraints that may limit availability, and other factors that may affect the desired outcome. Following the matrix are questions that should be asked when interviewing stakeholders regarding the issues listed in the table.

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
1. Registration of products				
▲ Efficient and timely product registration	▲ Delayed availability or non-availability of products ▲ Increased costs of product introduction	Registration process: time, cost, special requirements, politicization	▲ Ministry of Health/Drug Board	▲ Pharmaceutical company priorities and strategies ▲ Politicization of registration process
	▲ Interruption of product availability ▲ Increased costs of product	Re-registration	▲ Ministry of Health/Drug Board	
2. Pricing strategies				
▲ Range of product prices that cover all segments of private-sector market ▲ Availability of a range of affordable products ▲ Attractive profitability (for producer, importer, distributor, and retailer) that sustains private-sector product provision	▲ Affordability to end user (especially low-income ones), including youths ▲ Profitability for producer, importer, distributor, and retailer	Governmental controls	▲ Ministry of Health/Drug Board ▲ Ministry of Finance	▲ Political needs and concerns of local government ▲ World Bank and International Monetary Fund (IMF) requirements ▲ Pharmaceutical company leverage, quid pro quos ▲ Generation of revenues for government ▲ Protection of local industry ▲ Profitability needs of commercial sector ▲ Donor-agency agendas and strategies ▲ Political agenda of local government
	▲ Increased prices to end users ▲ Costs to importer, distributor, and retailer	Tariffs, other taxes, and fees	▲ Ministry of Finance	
	▲ Affordability to end user, including youths ▲ Fair competition between public and private sector	Government and donor subsidies	▲ Ministry of Health ▲ Ministry of Finance ▲ Donor agencies	
	▲ Affordability to end user, including youths ▲ Increased costs of production, distribution, and promotion	Price changes	▲ Ministry of Health/Drug Board ▲ Ministry of Finance	

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
3. Local manufacturing				
▲ Consistent and adequate supply of affordable safe and effective products that conform to international standards ▲ Internationally marketable products ▲ Public-sector tender-eligible products ▲ Profitable/sustainable operations ▲ Employee safety products ▲ Public-sector tender-eligible products ▲ Profitable/sustainable operations ▲ Employee safety	▲ Timeliness and cost of licensing process ▲ Manufacturing facility requirements ▲ Quality control, monitoring, and inspections	Licenses to manufacture	▲ Ministry of Commerce and Industry ▲ Ministry of Health/Drug Board	▲ Agenda and strategies of international pharmaceutical companies ▲ Profitability priorities of local manufacturers ▲ Stability or instability of financial sector ▲ Agenda and strategies of multilateral development banks ▲ World Bank and IMF requirements ▲ Donor agency economic agendas ▲ Local government privatization agendas ▲ Balance of payments and national indebtedness ▲ Political need to facilitate growth and profitability of local industry ▲ Ministry of Health budget and infrastructure for monitoring and enforcement
	▲ Unwillingness of international manufacturers to transfer technology or license local manufacture ▲ Quality control and supervision ▲ Access to raw materials, packaging, etc. ▲ Division of costs and profits ▲ Other contractual obligations, such as limitations on markets to which products may be supplied and products produced ▲ Existence of unwarranted requirements ▲ Weak or inconsistent monitoring of compliance with requirements (warranted and unwarranted)	Licensing agreements	▲ Management of international manufacturers ▲ Management of local manufacturers	

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Unwillingness of international manufacturers to transfer technology or license local manufacture ▲ Illegal and low or inconsistent quality products in the marketplace	Patents and intellectual property rights Compliance monitoring Evidence-based regulation	▲ International trade conventions ▲ Local law ▲ International manufacturers' policies	▲ Access to international markets for local products ▲ Liability concerns of international licensing agency ▲ Political leverage of industry owners ▲ Political power of labor unions ▲ Local government need for popular agenda ▲ Contracts (with suppliers and distributors) ▲ Transfer of technology (standards, quality control, business management skills) by international investors and partners ▲ Need to generate government revenues ▲ Protectionist policies ▲ Monetary policies ▲ Certification of goods for export ▲ Taxes and tariffs
	▲ Constraints on foreign investment (such as limits on percentage ownership) ▲ Government-provided investment incentives ▲ Constraints on repatriating profits ▲ Limited access to hard-currency ▲ Unfavorable exchange rate	Investment (domestic and foreign)	▲ Ministry of Finance	
	▲ Unfair competition ▲ Limited profitability for manufacturers and investors	Taxes Subsidies and incentives to locally owned firms	▲ Ministry of Finance	
	▲ Timeliness of access to cash and hard currency for equipment and raw materials	Credit and foreign exchange	▲ Ministry of Finance	

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Definition of standards (absent, poorly defined or overly stringent standards) ▲ Process for monitoring and supervision ▲ Quality control (absence, limited enforcement) ▲ Definition of safety standards and procedures ▲ Enforcement of safety standards and procedures	Manufacturing practices and quality control	▲ Ministry of Commerce and Industry ▲ Ministry of Health/Drug Board ▲ International Organization for Standardization (ISO) standards	▲ Restrictions under licensing agreements ▲ Local government's reputation for prompt and full payment
	▲ Costs of benefits and worker safety ▲ Staffing ▲ Institutional flexibility in responding to changing staffing needs	Workers' rights, mandated benefits, safety and work conditions	▲ Ministry of Labor ▲ Ministry of Health/Environmental Division	
	▲ Timeliness of supply ▲ Quality of supply ▲ Responsiveness to direction and services needed ▲ Measures for contractor performance ▲ Enforcement of contractual obligations	Contracts (with suppliers and distributors)	▲ Local manufacturer management ▲ Local contract law	
	▲ Restrictive tariffs ▲ Access to hard currency	Importation (of raw materials and equipment)	▲ Ministry of Finance ▲ Ministry of Commerce and Industry	

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Financial sustainability of local production	Exportation (of finished product)	▲ ISO standards ▲ Ministry of Commerce and Industry ▲ Ministry of Finance	
	▲ Requirements for product certification ▲ Requirements for financial certification ▲ Capacity to meet volume and time requirements	Tender process (including announcement of tenders)	▲ Ministry of Health	
4. Importation				
▲ Wide range of international safe and effective products available in the marketplace ▲ Competitive marketplace ▲ Sustainable multi-national manufacturers supplying local market ▲ International products affordable to local consumers ▲ Effective marketing and management of products	▲ Financial sustainability of local production	Importation (of finished product)	▲ ISO standards ▲ Ministry of Commerce and Industry ▲ Ministry of Finance	▲ Certification of goods for export ▲ Restrictions under licensing agreements ▲ Commercial interests of regulatory officials ▲ Need for government revenues ▲ World Bank and donor pressure to increase government revenues ▲ Trade negotiations (World Trade Organization) ▲ Political needs of governing parties ▲ Budget availability ▲ Staffing capacity
	▲ Process is difficult: time, costs, and special requirements	License to import	▲ Ministry of Commerce and Industry ▲ Ministry of Health/ Drug Board	
	▲ Burdensome types and rates of tariffs and taxes on imported pharmaceuticals	Tariffs and taxes	▲ Ministry of Finance ▲ Ministry of Health/ Drug Board	
	▲ Restrictions on currency exchange or transfer of funds out of country	Repatriation of profits	▲ Ministry of Finance	
	▲ Process is difficult: time, costs, and special requirements	Letters of credit	▲ Ministry of Finance	

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Limitations on hard currency availability	Hard currency and currency exchange	▲ Ministry of Finance	▲ Commercial interests of decision makers ▲ Time, expense, and politicization associated with product licensing, accessing credit and product or materials importation
	▲ Protectionist policies, tariffs, and taxes	Competition with domestic industry	▲ Ministry of Commerce and Industry ▲ Ministry of Finance	
	▲ Existence of protocols ▲ Adequate testing entities ▲ Enforcement of standards	Quality control	▲ Ministry of Health/Drug Board	
	▲ Requirements for product certifications ▲ Requirements for financial certifications ▲ Capacity to meet volume and time requirements	Tender process	▲ Ministry of Health	
	▲ Limitations on foreign personnel as staff or management ▲ Limitations on kinds of services that can be provided (includes sampling and product sales) ▲ Taxation	Establishment of local office (license, taxation, staffing)	▲ Ministry of Finance ▲ Ministry of Labor ▲ Ministry of Commerce and Industry	
	▲ Exclusivity stipulations ▲ Responsiveness to direction and services needed ▲ Measures for contractor performance ▲ Enforcement of contractual obligations	Contracts (with distributors)	▲ International manufacturer management ▲ Local representation of international manufacturer ▲ Local contract law	

Table 1: Product Supply **Program Goal:** Timely and consistent supply of quality family planning products in the marketplace				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
5. Distribution networks				
▲ Multiple, qualified firms available for effective product distribution ▲ Access to multiple outlet types ▲ Sustainable private-sector distribution network	▲ Time and cost of process for licensing ▲ Overly stringent infrastructure requirements	License to distribute drugs and other types of products	▲ Ministry of Health ▲ Ministry of Commerce and Industry	▲ Political pressure to protect low prices on essential drugs ▲ Budget priorities of distribution companies ▲ Ministry of Health budgets for enforcing standards
	▲ Limitations on products sampling and promotion	Outlets and provider types (allowed to service)	▲ Ministry of Health	
	▲ Government-imposed limitations on product profitability	Price structure	▲ Ministry of Health/Drug Board ▲ Ministry of Finance	
	▲ Difficult requirements for safe handling, storage, and good inventory control	Quality control	▲ Ministry of Health	
	▲ Exclusivity stipulations ▲ Timeliness of supply ▲ Marketing support and co-promotion ▲ Responsiveness to direction and services needed ▲ Measures for contractor performance ▲ Enforcement of contractual obligations	Contracts (with suppliers and manufacturers)	▲ Distribution-company management ▲ Local contract law	
	▲ Kinds and rates of taxes applied to or to be collected by distributors	Taxes	▲ Ministry of Finance	

2.6 KEY QUESTIONS FOR ASSESSING LEGAL AND REGULATORY ISSUES RELATED TO PRODUCT SUPPLY

This section contains a list of the stakeholders that should be interviewed to better understand the legal and regulatory context of supplying family planning and reproductive health products. Also included are questions, organized by stakeholder, to gather the information.

DRUG-REGISTRATION AUTHORITY

- How many contraceptive products (including devices, such as condoms) are currently approved? How many have been approved in the last year, the last two years, and the last five years? What applications are pending?

- What weight is given to drug registrations in other countries? What weight is given to safety and efficacy studies performed for other countries?

- How long does it normally take to approve a new drug?

- What are the costs of obtaining a license for a new drug?

- What are the rules for testing regular shipments of domestically manufactured or imported drugs? What laboratories are qualified to do the testing? What is the cost?

- (In countries where contraceptives are manufactured) What are the rules for production facilities? (If written, obtain a copy and compare them with good manufacturing practices.) How frequent are inspections of manufacturing facilities? How are inspectors trained?

- If possible, try to follow the approval process for a contraceptive product licensed in the last two years. Compare the regulators' story with the manufacturer's or importer's account.

- What labeling and package insert requirements apply to contraceptives? Are there regulations governing content that targets specific groups (for example, youth)?

- Describe the process for obtaining registration for a drug. Is the process for medical devices, such as intrauterine devices (IUDs), different?

- Are prices set as part of the registration process?

- What approvals are necessary to sell non-ethical pharmaceutical products, such as spermicides and condoms, etc?

REGULATORY AGENCY RESPONSIBLE FOR LICENSING PHARMACIES

- What are the regulations governing establishing a pharmacy? Who can establish one? Is there any determination of need for a facility in a particular area? Is there a minimum standard (for example, x pharmacies per 10,000 people) of need used to determine whether a pharmacy may be established?

- What are the requirements for the physical facility? For record keeping? For the training and experience of the owner? For the training and experience of the staff? Is specific training required for providing youth-friendly services?

- Are there different regulations for different classes of drugs? If so, in what categories do various contraceptives fall? In which category are contraceptive devices? Are contraceptives subject to the same record keeping requirements as narcotics?

- What classes of contraceptives require a prescription? What classes of contraceptives have other access restrictions (for example, consumer age, parental or spousal consent)? What classes may be distributed over-the-counter?

- Are contraceptives usually stocked openly or behind the counter? Does this vary by method?

- Are there regulations governing the display of information concerning contraceptives? Are there any regulations that govern pharmacy staff counseling consumers about contraceptives (for example, staff allowed to counsel, consumers allowed to receive counseling, or the content of counseling)?

- What price-control regulations apply to retail pharmacies? If such regulations are in place, determine the price-control formula that applies at the retail level.

DRUG MANUFACTURERS AND IMPORTERS

- Describe the process by which a new product becomes licensed from the manufacturer's or importer's point of view (that is, as it actually happens).

- What good manufacturing practices apply to domestic production? How does the inspection process work for manufacturing? How well trained are the inspectors? Is there bribery or corruption?

- What is the process for monitoring the safety and efficacy of imported products? What are the sampling requirements? Is the cost of testing significant? Who performs the tests and how competent is the testing agency?

- Do foreign-exchange controls inhibit the import of contraceptives or manufacturing inputs? How hard is it to obtain the necessary foreign exchange? Is it as difficult as for other drugs?

- What quotas or tariffs apply to contraceptive products (compare them to international norms)? Do different quotas or tariffs apply depending on the type of institution receiving the products (for example, are contraceptive products free of duty for the government or nonprofits, but not for commercial sale)?

- Are there delays or leakages in the import process? Do official quality or customs inspections ever cause them?

- Are there special requirements that a firm must fulfill before it can import pharmaceutical products?

DRUG WHOLESALERS AND DISTRIBUTORS

- Do price controls apply at the wholesale or retail level? Verify the method for determining allowable prices. What kind of profit margin does this leave at each level of the distribution chain?
- How does the price-control system respond to inflation in import or manufacturing prices? Does this deter import or production?
- What regulations apply to warehousing? Does this have any affect on product cost? How are these regulations enforced?
- Are there any restrictions affecting the marketing activities of the distributors?
- Are there limitations on where contraceptives can be distributed? Which products are non-pharmacies authorized to distribute?

RETAIL PHARMACISTS AND THEIR TRADE GROUP

- What is the process for establishing a new pharmacy?
- How difficult is it to establish a new pharmacy? What problems do prospective pharmacy operators encounter?
- How are pharmacy regulations enforced? How often is a facility inspected? What deficiencies are cited frequently? What happens when a deficiency is cited (for example, does the pharmacy pay a fine, is it given an opportunity to correct the problem, is a bribe paid to the inspector)?
- Are there overlapping regulatory requirements between health and municipal agencies? How do these affect the cost of running a pharmacy?
- Do price-control regulations apply to products retail pharmacists sell? How are these regulations enforced? What effect do price-control regulations have on profitability?
- Does the pharmacy have cash-flow problems? If so, why?
- What contraceptive products does national health insurance cover? What products are sold for cash?
- What classes of contraceptives require a prescription? What classes of contraceptives have other access restrictions (for example, consumer age, parental or spousal consent)? What classes may be distributed over-the-counter?
- Are contraceptives usually stocked openly or behind the counter? Does this vary by method?
- How much knowledge do pharmacists have about modern contraception? Do they feel comfortable counseling patients (including married and unmarried youths)? Do they have informational material to distribute to interested customers? Are these targeted to meet the needs of specific consumer groups (for example, youths)?

- What information or training do pharmacists receive about new contraceptive products?
- Does the pharmacy association have any input into regulations? What changes in regulations does it advocate?
- Does the pharmacy association advocate a limit on the number of licensed pharmacies? Does it advocate a crackdown on drug sellers not licensed as pharmacies?
- Which incentives do distributors offer you to purchase and stock contraceptive products?

SOCIAL-MARKETING ORGANIZATIONS

- Do import tariffs or exchange-rate controls affect the supply of contraceptive products or their cost? Please cite an example.
- Do maximum or minimum price regulations apply to the sale of the product? Do these create an economic problem for retailers?
- Are there limitations on where social-marketing programs may distribute contraceptive products? Can some methods be distributed beyond the pharmacy? If so, which methods?
- Does the social-marketing organization have any special exemptions from the government regarding regulations about importation, registration, branding, pricing, etc?

3. CONTRACEPTIVE METHODS

Program goal: Availability of a range of contraceptive methods

A range of contraceptive methods is essential to meeting the reproductive health needs of couples in any marketplace. Without contraceptive choices, couples may not be able to find a suitable method. Dissatisfied with limited choices, couples may discontinue or not begin contraceptive use.

The availability of contraceptive methods within the marketplace is also important to sustaining the interest of the private sector in providing reproductive health and family planning services. A diverse product line enhances the profitability of family planning service delivery and, thus, increases the long-term prospects for continuing private-sector participation. Evidence suggests that as the range of contraceptive choices is increased, the number of consumers adopting and using a method also increases (Jain 1989). Similarly, the larger the market for contraceptive methods becomes, the more commercially interesting it is to private-sector retailers and service providers.

There are three primary factors that affect the availability of contraceptive methods:

- approval of the method for use
- the conditions under which the method may be used
- the conditions under which the method may be provided

3.1 APPROVAL OF CONTRACEPTIVE METHODS

A governing entity's approval of contraceptive methods is necessary in every country with a functioning health bureaucracy. While approval is required to safeguard the public's health, constraints on the approval process (whether through inefficiencies in the system; inadequate knowledge and training of decision makers; or political, religious, and cultural concerns) can hurt the timely introduction of contraceptive methods and constrain the range of methods available.

Approval of a method for use as a contraceptive is a process separate from, but often related to, the registration of a pharmaceutical contraceptive product. A method like tubal ligation, for example, does not require a registered pharmaceutical product, but it does require approval for use as a contraceptive method. A pharmaceutical product, such as *Depo-Provera*, however, would not be granted registration as a contraceptive if the method (injectable) had not been approved already for use.

3.2 CONDITIONS FOR USE OF CONTRACEPTIVE METHODS

Approval of contraceptive methods often includes establishing the conditions in which the method may be used. Use of a particular method may be limited on the basis of the following factors:

- User age – Hormonal contraceptives, such as birth control pills, may not be provided legally in some countries to teens or girls in school. Though some countries restrict the use of some contraceptive

methods based on age, the World Health Organization's Medical Eligibility Criteria for Contraceptive Use does not rule out the use of any method based on age alone (WHO 2004).

- Parity – IUDs may not be provided in some countries to women who have not had at least one child. Tubal ligation, in other markets, may not be provided to a woman with fewer than three children.

- Medical conditions – When medical conditions are based on current medical knowledge, such as age and smoking status as conditions for oral contraceptive use, they are safeguards to consumers' health and appropriately limit the number of women to whom the method may be supplied. Outdated or unwarranted requirements, however, may unnecessarily constrain the number of women to whom methods may be safely provided. In countries where a method, such as tubal ligation, is not approved for general use as a contraceptive, the medical conditions under which the method may be delivered allows interpretation by physicians thereby limiting women's access to this method.

- Other party permissions – While requirements for acceptors' informed consent can increase user safety and satisfaction, permission for use from parents or spouses of the method acceptor also may be required.

Limitations on using a contraceptive method restricts individuals' access to contraceptive options and also constrains the size of the market for family planning and reproductive health products. Market size is a fundamental element affecting the profitability of a product and, therefore, the sustainability of private-sector service delivery. A compensating alternative to increased market size is increased prices for services or methods that can be delivered. Increased prices, however, also can limit potential users' access to contraceptive methods. While sexually active youths are an important market for private providers, they often have limited income, making the price of contraceptive services and products a potential barrier to access.

Example: Egypt

Women who are medically eligible for tubal ligation must have the written consent of their husbands to receive the procedure. As a result, tubal ligation accounts for less than 2 percent of total contraceptive prevalence in Egypt.

Example: Jamaica

Adolescent fertility is a significant factor in the population growth rate. The conservative Protestant religious beliefs of some healthcare providers that cause them to disapprove of pre-marital sex, however, have led them to discourage contraceptive counseling and service delivery to teenage girls.

3.3 STANDARDS OF PRACTICE FOR CONTRACEPTIVE METHODS

Agencies that govern the delivery of medical and health services often set requirements for the conditions in which contraceptive methods may be provided. These conditions, or standards of practice, can include requirements for medical screening of potential users, clinical procedures for method delivery, types of service outlets in which the method can be delivered, and types of providers who can

deliver the method. Prescription requirements for certain methods, especially hormonal contraceptives, are among the conditions for provision.

Regulations governing method provision are intended to protect the health of consumers. They may, however, be based on outdated information and, thus, introduce medically unwarranted constraints to the availability of methods. Regulations on method provision also can increase the cost to consumers of adopting a contraceptive method. Laboratory and other required diagnostic tests add to the price that the consumer must pay. Limitations restricting method provision to more expensive types of providers (for example, physicians rather than midwives or pharmacists and specialist physicians rather than family or general practitioners) can put methods out of the reach of lower-income private-sector consumers, including youths.

On one hand, costs of obtaining equipment and hiring the staff required for providing methods within regulated standards of practice can affect the profitability of service delivery for private-sector providers. On the other hand, private providers benefit financially from required tests, diagnostics, and follow-up visits. Most important to sustainable private-sector family planning service delivery, however, may be the legal ability of a variety of provider types to offer contraceptive methods. Midwives, for example, can play an important role with many women in promoting contraceptive use, providing counseling, and supporting continuing use. Provision of these important services only becomes financially sustainable for midwives when regulations allow them to provide a variety of contraceptive methods for which they can charge. Similarly, many youths prefer to obtain products, such as oral contraceptives and condoms, from pharmacies and similar outlets rather than traditional health facilities or school clinics because of the anonymity and convenience these outlets provide (Scholl 2004). These outlets also can serve an important role in promoting contraceptive products and information to a group that is often marginalized in its access to reproductive health and family planning services.

The matrix in Table 2 illustrates the legal and regulatory issues that family planning and reproductive health program planners and implementers may encounter in making a range of contraceptive methods available in the private-sector marketplace. The table identifies desired outcomes for ensuring the availability of commercially provided products and services, the authorities with regulatory responsibility for each issue, constraints that may limit availability, and other factors. Following the matrix are questions that should be asked when interviewing stakeholders regarding the issues in the table.

Example: Ukraine

A key factor restricting method choice is provider practice. Although it is not medically warranted, many physicians require excessive tests as part of the screening process before inserting an IUD.

Table 2: Contraceptive methods **Program goal:** Availability of a range of contraceptive methods				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
1. Approval of contraceptive methods				
▲ Availability of widest possible range of safe and effective methods	▲ Time and cost of process for approval or registration ▲ Criteria for approval ▲ Failure to update approval standards to reflect latest research ▲ Technical qualifications of decision makers	Registration or other formal approval	▲ Ministry of Health/reproductive health and family planning services delivery ▲ Ministry of Health/Drug Board	▲ Political agendas of decision makers ▲ Religious beliefs of decision makers ▲ Cultural norms of decision makers
2. Conditions for use of contraceptive methods				
▲ Safe and appropriate use of methods ▲ Informed choice ▲ Informed consent	▲ Appropriateness of criteria for legal use ▲ Medically unwarranted limitations on access to method ▲ Provider's capacity to provide information about selected contraceptive options to clients ▲ Provider practices regarding voluntary and informed choice (that is, providing clients with information about a range of options)	Legal user characteristics (age, parity, medical conditions, marital status, etc.)	▲ Ministry of Health/reproductive health and family planning services delivery ▲ World Health Organization (WHO) eligibility criteria	▲ Political agendas of decision makers ▲ Religious beliefs of decision makers ▲ Cultural norms of decision makers ▲ Long-held medical practices of decision makers ▲ Provider knowledge, attitudes, and biases (regarding youths, particularly for unmarried youths and young females)

Table 2: Contraceptive methods **Program goal:** Availability of a range of contraceptive methods				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Limitations on user privacy ▲ Service provision to minors ▲ Unnecessary limitations on access to method	Permissions required for method delivery (parental, spousal, etc.)	▲ Ministry of Health/reproductive health and family planning services delivery ▲ Medical school curricula	▲ Financial and other liability fears of providers
3. Standards of practice for contraceptive methods				
▲ Broad access to safe, voluntary, and affordable family planning services ▲ Wide range (price, location, type) of qualified providers of such services ▲ Sufficient access to youth-friendly services ▲ Criteria for method delivery and use determined by evidence-based medicine	▲ Failure to update screening requirements to reflect evidence ▲ Unwarranted screening requirements that increase costs to user (time, money, inconvenience, embarrassment, etc.) ▲ Provider knowledge, attitudes, and biases (regarding youths, particularly for unmarried youths and young females)	User-screening requirements (physical exams, diagnostics, means testing, etc.)	▲ Ministry of Health/reproductive health and family planning services delivery ▲ WHO eligibility criteria ▲ Medical school curricula	▲ Revenue needs of service provider and service delivery outlet ▲ Commercial interests of decision makers ▲ Long-held medical practices of decision makers ▲ Financial interests of providers ▲ Territorial jealousies of professional associations ▲ Medical prejudices of decision makers
	▲ Existence of protocols ▲ Lack of dissemination of protocols and training in their use ▲ Limited monitoring and supervision ▲ Poor adherence to latest protocols in practice	Procedures for method delivery	▲ Ministry of Health/reproductive health and family planning services delivery ▲ Medical school curricula	

Table 2: Contraceptive methods **Program goal:** Availability of a range of contraceptive methods				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Criteria for who may provide different contraceptive methods	Legal providers (initial and follow-up)	▲ Ministry of Health/reproductive health and family planning services delivery	
	▲ Appropriateness of criteria for sites where method can be delivered	Legal service delivery points	▲ Ministry of Health/reproductive health and family planning services delivery	
	▲ Criteria for prescription requirement ▲ Application of criteria ▲ Compliance with requirements	Prescription requirements	▲ Ministry of Health/ Drug Board ▲ Ministry of Health/reproductive health and family planning services delivery	
	▲ Availability of technical expertise to support change ▲ Time required for change process ▲ Process for bringing about change ▲ Technical qualifications of decision makers	Process for review and change of clinical standards of care	▲ Ministry of Health/reproductive health and family planning services delivery ▲ Medical school faculties	

3.4 KEY QUESTIONS FOR ASSESSING LEGAL AND REGULATORY ISSUES RELATED TO CONTRACEPTIVE METHODS

This section contains a list of the stakeholders that should be interviewed to assess the legal and regulatory context influencing contraceptive choice. Also included are questions, organized by stakeholders, to gather the information.

REGULATORY AGENCY RESPONSIBLE FOR LICENSING PHARMACIES

- Are there laws or regulations that limit the services that pharmacies can provide to youths?
- What classes of contraceptives require a prescription? What classes of contraceptives have other access restrictions (for example, consumer age, parental or spousal consent)? What classes may be distributed over-the-counter?
- Are contraceptives usually stocked openly or behind the counter? Does this vary by method?
- Which contraceptive methods cannot be sold in pharmacies?

AGENCIES LICENSING CLINICS AND PHYSICIANS' OFFICES

- How are offices categorized (for example, by specialty)? Are there restrictions about what a practitioner can do once he or she is licensed (for example, license by specialty, special licenses for certain procedures, or menstrual regulation)?
- What prescription requirements apply? Do they apply to contraceptives? Can the physician or clinic dispense family planning supplies (check by category—oral contraceptives, IUD, etc.)?
- Which contraceptive methods cannot be sold by distributors directly to doctors?
- Are there requirements for medical facilities at which certain methods, such as tubal ligations, will be provided?

DRUG WHOLESALERS AND DISTRIBUTORS

- Are there limitations on where contraceptives can be distributed? Can some methods be distributed beyond the pharmacy? If so, which ones?

RETAIL PHARMACISTS AND THEIR TRADE GROUP

- What contraceptive products does national health insurance cover? What products are sold for cash?

- What classes of contraceptives require a prescription? What classes of contraceptives have other access restrictions (for example, consumer age, parental or spousal consent)? What classes may be distributed over-the-counter?

- Are contraceptives usually stocked openly or behind the counter? Does this vary by method?

- How much knowledge do pharmacists have about modern contraception? Do they feel comfortable counseling patients (including married and unmarried youths)? Do they have informational material available for interested customers? Is it targeted to meet the needs of specific consumer groups (for example, youth)?

- Are there laws or regulations that limit the services pharmacists can provide to young people?

- Which incentives do distributors offer you to purchase and stock contraceptive products?

- What percentage of your business is family planning (by method)? What percent of your profitability is family planning (by method)?

PHYSICIANS AND PHYSICIAN GROUPS

- What regulations apply to prescribing contraceptives? To dispensing them (specify product type)? What regulations apply to specific types of patients (for example, youths or unmarried people)? Do physicians see limitations on dispensing as a problem in patient care? In achieving profitability?

- Are there restrictions that limit the types of contraceptives physicians can prescribe or the types of physicians who can prescribe certain methods?

- Are there laws or regulations that limit the types of services that physicians can provide to young people?

- To what extent do age-of-consent laws hamper the provision of youth-focused reproductive health and family planning services?

- To what extent do spousal-consent laws hamper the provision of reproductive health and family planning services to married women? Which services or contraceptive methods?

- What limitations do physicians find to expanding the provision of family planning services?

- Must the provider have special training to offer certain family planning services? What is this training? Who offers it? How long is the course? How often is the course given? Are there any requirements for periodic retraining (continuing medical education)? Is specific training required for providing youth-friendly services?

- Are there requirements for medical facilities at which certain methods, such as tubal ligations, will be provided?

- What percentage of your business is family planning (by method)? What percent of your profitability is family planning (by method)?

- What are your legal-liability concerns, if any, by contraceptive methods? What is the cost of liability insurance for contraceptive-method provision?

- What is the cost to the provider of providing time for client counseling? What is its impact on profitability?

- Where do you obtain the contraceptive methods that you provide? How do you pay for them? Are some methods too costly for you to provide or your clients to obtain?

- How does the cost of the non-contraceptive supplies required to provide the method (such as latex gloves, cotton swabs, and other disposables) compare to the cost of the contraceptives themselves?

NON-PHYSICIAN MEDICAL FAMILY PLANNING PROVIDERS (MIDWIVES AND NURSES)

- Is this group allowed to provide family planning services in private offices? Which services? Are there limitations concerning specific types of patients that can be served (for example, youths and unmarried people)? What requirements for supervision by physicians or others apply?

- Can these practitioners provide family planning services if employed by a physician? What type of license must the physician have to employ this professional to provide family planning services? (Obtain a citation to the regulation and the applicable standards.)

- Must the provider have special training to offer certain family planning services? What is this training? Who offers it? How long is the course? How often is the course given? Can private practitioners enroll in this course? At what cost? Are periodic training updates required? Is specific training required for providing youth-friendly services?

- Can the provider dispense family planning supplies? Which ones? Do limitations on dispensing them affect the viability of a private practice?

- Are there laws or regulations that limit the types of services that non-physician family planning providers can offer to young people?

- To what extent do age-of-consent laws hamper the provision of youth-focused reproductive health and family planning services?

- To what extent do spousal-consent laws hamper the provision of reproductive health and family planning services to married women? Which services or contraceptive methods?

- Are there requirements for medical facilities at which certain methods, such as IUD insertion, will be provided?

- What percentage of your business is family planning (by method)? What percent of your profitability is family planning (by method)?

- What are your legal-liability concerns, if any, by contraceptive methods? What is the cost of liability insurance for contraceptive method provision?

- What is the cost to the provider of providing time for client counseling? What is its impact on profitability?

- Where do you obtain the contraceptive methods that you provide? How do you pay for them? Are some methods too costly for you to provide or your clients to obtain?

- How does the cost of the non-contraceptive supplies required to provide the method (such as latex gloves, cotton swabs, and other disposables) compare to the cost of the contraceptives themselves?

NONPROFIT FAMILY PLANNING CLINICS

- Are waivers of generally applicable regulations required for any family planning services offered by a clinic? (For example, performing sterilizations?) How are these waivers obtained? (If waivers have been granted, try to get a case history.)

- Has a clinic been subject to a regulatory-enforcement action? For what violation? How was the situation resolved?

- What tax rules apply to nonprofit clinics? Do these rules make it difficult to use any operating surplus for service expansion or enhancement?

- If an NGO has an international affiliation, does it help or hinder it establishing a clinic? Is the affiliate's investment in the clinic subject to general controls on foreign investment? What are these controls?

- Where do you obtain the contraceptive methods that you provide? How do you pay for them? Are some methods too costly for you to provide or your clients to obtain?

- How does the cost of the non-contraceptive supplies required to provide the method (such as latex gloves, cotton swabs, and other disposables) compare to the cost of the contraceptives themselves?

- Contraceptive procurement is what percentage of your budget?

SOCIAL-MARKETING ORGANIZATIONS

- Are there limitations on where contraceptives can be distributed via social marketing? Can some methods be distributed beyond the pharmacy? If so, which ones?

HEALTH INSURERS OR SOCIAL-INSURANCE AGENCY (IF EITHER PAYS FOR SIGNIFICANT AMOUNTS OF OUTPATIENT CARE)

- Are there regulations mandating certain benefits? Do these mandated benefits include maternity care? Family planning services? Youth-targeted reproductive health and family planning prevention and care services? If so, what services are mandated?

- Can any family planning services be billed to the insurer? If so, which ones?

- Are youths covered by their parents' insurance policies?

4. SERVICE PROVIDERS

Program goal: Qualified family planning service providers in the private sector

A variety of types of service providers are necessary to make a range of contraceptive methods accessible and affordable to private-sector consumers:

- midwives may be most affordable to lower-income women
- general-practice physicians may be more accessible to rural and lower-income women than obstetric/gynecology specialists
- pharmacists may be most frequently encountered by urban couples and youth
- traditional providers may be most culturally acceptable to lower-income populations
- specialist physicians may be most likely to introduce new technologies and lead medical opinion change

In a segmented marketplace, each provider type can play an important role in ensuring that all couples in their reproductive years have access to the information, products, and services they need for good reproductive health.

The quality of medical care the array of private-sector providers delivers is important to consumers and national health-policy makers and regulators. Laws and regulations that govern the qualifications of service providers and the scope of their practice can be significant in ensuring the quality of care in the private sector. While laws are designed to safeguard consumers' health and well-being, those that govern which types of providers are allowed to provide certain services may affect their affordability and accessibility to private-sector consumers.

The private practice of every provider type is a business; consequently, the sustainability of reproductive health and family planning service delivery in the private sector depends on the profitability of each provider's practice. Laws, regulations, and policies regarding the feasibility and costs of doing business affect the long-term sustainability of family planning service provision in the private sector.

There are four operational areas in which laws, regulations, and policies affect private-sector providers of reproductive health and family planning services:

- qualifications for practice
- scope of practice
- establishment of private practice
- quality control and monitoring

4.1 QUALIFICATIONS FOR PRIVATE PROVIDER PRACTICE

Regulations that establish the qualifications for practice should ensure that service providers communicate correct and current information to their clients and provide services safely and effectively. These regulations govern basic medical, nursing, midwife, and pharmaceutical school curricula; the specific family planning and reproductive health content of those curricula; and the opportunities provided for supervised pre-service clinical experience. In countries where the government subsidizes medical education, there also may be regulations that require a term of service in the public sector prior to operating a private practice.

Requirements for licensing service providers helps ensure that practitioners have completed their basic medical education and periodic re-licensing can help ensure that providers' knowledge remains current (through requirements for continuing medical education). While some private-sector practitioners see those requirements as opportunities to market expanded or improved services, others see the time and money costs of these requirements as a constraint on their ability to operate a profitable business.

Example: Uganda

Approximately half of the members of the Ugandan Private Midwives Association, a professional organization, are licensed practitioners. Many cited the difficult process and cost as factors why they have not become licensed midwives to practice in the private sector.

4.2 SCOPE OF PRIVATE PROVIDER PRACTICE

Laws and regulations also define the scope of practice allowed for each type of healthcare provider. For example, in some markets only physicians may insert IUDs. In others pharmacists are not allowed to provide injections. While these rules usually are intended to ensure that only trained and knowledgeable practitioners provide services, they are often medically unwarranted and limit the availability and affordability of services to private-sector consumers, as well as the potential for financially sustainable private practice among a variety of service providers.

Example: Honduras

In rural Honduras, nurse auxiliaries are frequently the only source of reproductive health services available. After an operations research activity that demonstrated that nurse auxiliaries were able to effectively insert IUDs, deliver Depo-Provera and take Pap smears, the Ministry of Health changed the National Women's Health Service Delivery Guidelines to authorize them to provide those services.

Example: Philippines

A new Department of Health policy allows trained midwives to insert IUDs and, thus, has expanded access to that method – especially among lower-income clients.

4.3 ESTABLISHMENT OF PRIVATE PRACTICE

A number of regulations and policies outside the area of medicine influence the establishment of a private-sector practice. These regulations (governing issues associated with the costs of opening a practice and generating income) relate to access to credit, taxes on income and sales, allowable fees for service, participation in national health-insurance schemes, and participation in health-maintenance organizations (HMO) and preferred provider networks. Obligations for public-sector service prior to private practice also affect private-sector income potential.

> **Example: Former Soviet Union nations**
>
> When these nations became independent, there was no legal framework that allowed for the provision of healthcare services, including family planning, by non-governmental entities. Legislation had to be created that allowed for the operation of the private sector in medical-services delivery.

4.4 QUALITY CONTROL OF PRIVATE SERVICES

Concern in most countries for safeguarding public health leads to regulations governing quality control and monitoring service delivery. In many markets, however, an infrastructure for quality-control monitoring of private-sector practitioners is not operational. Public-sector policy makers may have no jurisdiction over private-sector practices and medical professional associations may not have established standards for quality service delivery in the private sector or a system for monitoring and reporting adverse practice events.

The matrix in Table 3 sets out the legal and regulatory issues confronting healthcare providers who wish to work in the private sector. It is organized according to the four operational areas outlined in this section. The matrix identifies possible constraints on private practice that result from existing laws, regulations, and policies; responsible authorities; and non-regulatory factors in the environment. Following the matrix are questions that should be asked when interviewing stakeholders regarding the issues in the matrix.

Table 3: Service providers **Program goal:** Qualified family planning service providers in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
1. Qualifications for private provider practice				
▲ Providers enter practice with correct knowledge of reproductive health and family planning technology and issues, including needs of specific client groups, and with experience in service provision ▲ Providers receive updates as contraceptive products are introduced ▲ Service providers meet minimum qualifications for practice ▲ Service providers identifiable by appropriate monitoring or regulatory agencies ▲ Sufficient numbers of well-trained providers in the public and private sectors	▲ Inclusion of reproductive health and family planning in basic medical and pharmaceutical curricula ▲ Current and correct content in existing reproductive health and family planning curricula ▲ Training in client-centered/counseling approach ▲ Understanding of issues and needs of specific client groups (for example, married, unmarried, youths, poor) ▲ Pre-service opportunities for supervised clinical practice ▲ Regular contraceptive-technology updates for public- and private-sector providers	Initial qualifications and education of providers (pharmacists, general practitioners, family medicine specialists, obstetrics/gynecologists, and midwives)	▲ Ministry of Health ▲ Medical schools ▲ Professional associations	▲ Time and cost concerns of licensed service providers

Table 3: Service providers **Program goal:** Qualified family planning service providers in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Requirements for obtaining license ▲ Time and cost of obtaining license ▲ Monitoring of compliance with licensing requirements	Licensing	▲ Ministry of Health ▲ Medical schools ▲ Professional associations	
	▲ Delays in entering private practice ▲ Limited training and experience in reproductive health and family planning prior to entering private practice	Obligations for public-sector service	▲ Ministry of Health	
	▲ Absence of requirements for continuing medical education or re-licensing ▲ Inadequate quantity or content of reproductive health and family planning courses in continuing medical education	Continuing medical education/re-licensing	▲ Ministry of Health ▲ Professional associations	

Table 3: Service providers
Program goal: Qualified family planning service providers in the private sector

Desired Outcome	Issue or Constraint	Related Legal and Regulatory Areas	Responsible Authority(s)	Other Influencing Factors
2. Scope of private provider practice				
▲ Easy accessibility (by geographic location, gender of provider, type of provider) to safe, voluntary, and affordable family planning services ▲ Easy geographic accessibility to contraceptive products ▲ Safe and informed access to products and drugs ▲ Price-accessible products and drugs ▲ Range of provider types able to offer an array of family planning services	▲ Limitations on kinds of services provided by types of providers ▲ Limited understanding of issues and needs of specific client groups (for example, married, unmarried, youth, poor)	Services related to reproductive health and family planning	▲ Ministry of Health ▲ Professional associations	▲ Territorial jealousies among professional associations and types of providers (for example, physicians versus pharmacists or midwives) ▲ Revenue and income concerns of providers ▲ Costs (equipment, staff, and training) to provider of offering new services ▲ Long-held medical practices ▲ Profitability for distributors and manufacturers of expanded distribution
	▲ Limitations on outlet types and conditions where designated services may be provided	Location of practice and site of services delivered	▲ Ministry of Health ▲ Professional associations	
	▲ Limitations on types of providers who can provide different contraceptive services ▲ Limited understanding of issues and needs of specific client groups (for example, married, unmarried, youth, poor)	Products and drugs dispensed	▲ Ministry of Health ▲ Professional associations	
3. Establishment of private practice				
▲ Sufficient numbers of well-trained providers in the public and private sectors ▲ Competitive private-sector service provision	▲ Delays in entering private practice	Registration and certification of practice (obligations to public sector)	▲ Ministry of Health	▲ Allocation of providers' personal resources ▲ Credit availability ▲ Corruption ▲ Availability of non-bank lenders

Table 3: Service providers **Program goal:** Qualified family planning service providers in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
▲ Financially sustainable private-sector service delivery ▲ Affordable private-sector services available to a range of clients	▲ Cost of opening a private practice ▲ Access to financing	Business registrations and requirements	▲ Ministry of Finance ▲ Commercial banks ▲ Central bank ▲ Ministry of Commerce ▲ Local government regulators	▲ Size of investment needed ▲ Local business culture ▲ Market factors (such as willingness to pay) ▲ Political agendas of decision makers ▲ Religious beliefs of decision makers ▲ Cultural norms of decision makers
	▲ Methods used for tax-data collection ▲ Subversion of service delivery statistics ▲ Willingness to share or report service delivery statistics	Taxes	▲ Ministry of Finance ▲ Tax authorities	
	▲ Governmental or medical-association limitations on fees charged (by type of service, type of provider, or location of service delivery)	Fees for services	▲ Ministry of Health ▲ Professional associations	
	▲ Requirements for liability or other types of insurance	Insurance	▲ Ministry of Health ▲ Professional associations ▲ Business and tort law	

Table 3: Service providers **Program goal:** Qualified family planning service providers in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Requirements for participation ▲ Ease and timeliness of payments to providers in the system ▲ Types of providers eligible ▲ Types of services covered ▲ Types of consumers eligible (for example, youths)	Participation in preferred-provider networks, national health-insurance schemes, HMOs, and professional associations, for example	▲ Ministry of Health ▲ Ministry of Social Welfare (Social Security) ▲ Managing entities of HMOs, insurance companies, and provider networks	
4. Quality control of private services				
▲ Safe, voluntary and affordable family planning available to all clients ▲ Ability to monitor quality of national/regional health services	▲ Absence of or unclear performance criteria ▲ Absence of or unclear protocols for monitoring ▲ Limited infrastructure for monitoring ▲ Non-existent or limited compliance systems	Public-sector monitoring Certification and accreditation standards	▲ Ministry of Health	▲ Political needs of government ▲ MOH budget resources for monitoring compliance ▲ Good-old-boy networks and protection of friends and associates
	▲ Absence of or unclear performance criteria ▲ Absence of or unclear protocols for monitoring ▲ Limited infrastructure for monitoring ▲ Non-existent or limited compliance systems	Professional association, networks, and franchises monitoring Certification and accreditation standards	▲ Professional associations	

Table 3: Service providers **Program goal:** Qualified family planning service providers in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Absence of or unclear performance criteria ▲ Quality control ▲ Appropriateness of collected data ▲ Limited use of reported data	Reporting requirements	▲ Ministry of Health ▲ Professional associations	

4.5 KEY QUESTIONS FOR ASSESSING LEGAL AND REGULATORY ISSUES RELATED TO SERVICE PROVIDERS

This section contains a list of the stakeholders that should be interviewed to assess the legal and regulatory context related to the array of private providers offering reproductive health and family planning services and products. Also included are questions, organized by stakeholders, one can use to gather information:

REGULATORY AGENCY RESPONSIBLE FOR LICENSING PHARMACISTS

- Are there any regulations that govern pharmacy staff counseling of consumers about contraceptives (for example, staff members allowed to counsel, consumers allowed to receive counseling, or content of counseling)?
- Are there laws or regulations that limit the types of services that pharmacies can provide to young people?
- What is the process and requirements for a pharmacist to become licensed?
- What is the process and requirements for a pharmacist to establish a retail pharmacy in the private sector?
- What is the reproductive health and family planning content in the pharmacy-school curriculum?
- Are there requirements for continuing medical education and re-licensing? If so, what are they?
- What is the role of the pharmacist association in ensuring continuing professional competence? In ensuring quality service delivery? In disciplining or correcting professional mistakes?
- Who interacts most frequently with the client: the pharmacist or a pharmacy assistant or clerk?
- What is the training requirement, if any, for those secondary staff persons? What is the onsite job supervision of those secondary staff persons?
- Are pharmacists allowed by law to dispense any types of drugs without a written prescription from a physician? What is the actual practice?

RETAIL PHARMACISTS AND THEIR TRADE GROUP

- Are there any regulations that govern pharmacy staff counseling of consumers about contraceptives (for example, staff members allowed to counsel, consumers allowed to receive counseling, or content of counseling)?
- Are there laws or regulations that limit the types of services that pharmacists can provide to young people?

- What is the process for a pharmacist to become licensed?

- What are the process and requirements for a pharmacist to establish a retail pharmacy in the private sector?

REGULATORY AGENCY RESPONSIBLE FOR LICENSING PHYSICIANS AND NON-PHYSICIAN MEDICAL FAMILY PLANNING PROVIDERS (MIDWIVES AND NURSES)

- How are offices categorized (for example, by specialty)? Are there any restrictions on what a practitioner can do once he or she is licensed (for example, license by specialty, special licenses for certain procedures such as tubal ligation, IUD insertion, post-abortion care)?

- What services are permitted for each category of license?

- What are the prerequisites for a license in each category? Training? Physical facilities?

- Must the provider have special training to offer certain family planning services? What is this training? Who offers it? How long is the course? How often is the course given? Are there any requirements for periodic retraining (such as continuing medical education)? Is specific training required for providing youth-friendly services?

PHYSICIANS AND PHYSICIAN GROUPS

- What is the process for obtaining a license to practice medicine? What is the process for establishing a private medical practice? How long does this process usually take? What are the cost or fees for obtaining a medical license and for establishing a private practice? Which agencies must provide approvals? Which requirements appear unwarranted? What regulation or argument do government agencies cite in supporting such requirements? How do physicians manage their practices in view of these requirements?

- Which regulatory standards are most costly to comply with? (Ask for a citation to the applicable regulation.)

- What is the system for monitoring the quality of care private-practice physicians provide?

- What happens when an office or clinic is cited for non-compliance with a regulatory standard? How are such non-compliance situations managed?

- What regulations apply to prescribing contraceptives? To dispensing contraceptives (specify by product type)? Do physicians see limitations on dispensing as a problem in patient care? In achieving profitability?

- Are there restrictions that limit the types of contraceptives physicians can prescribe or the types of physicians who can prescribe certain methods (for example, a requirement that tubal ligation may only be performed by an obstetrician/gynecologist)?

- Are there laws or regulations that limit the types of services that physicians can provide to young people?
- To what extent do age-of-consent laws hamper the provision of youth-focused services?
- To what extent do spousal-consent laws hamper the provision of services to married women? Which services and contraceptive methods?
- Which requirements limit the expanded provision of family planning services by physicians in private practice?
- What is the most-profitable medical service that you provide? Why?
- What is the least-profitable medical service that you provide? Why?
- Will expanding your reproductive health and family planning business (number of clients) expand the profitability of your practice?
- Do you employ a nurse or counselor? Why or why not? If so, what is the nurse's role in your practice?
- What information, education, and communication (IEC) materials regularly are available in your waiting room for clients? Who provides them?
- Do you regularly ask about family planning as part of taking a client's history? At each subsequent visit?
- Which contraceptive method do you most often provide? Why?
- Which contraceptive method do you least often provide? Why?
- Which methods do your clients most frequently ask you for? Why?

NON-PHYSICIAN MEDICAL FAMILY PLANNING PROVIDERS (MIDWIVES AND NURSES)

- Is this group allowed to provide family planning services in private offices? Which services? Are there limitations concerning specific types of patients that can be served (for example, youth and unmarried people)? What requirements for supervision by physicians or others apply?
- Can these practitioners provide family planning services if employed by a physician? What type of license must the physician have to employ this professional to provide family planning services? (Obtain citation to the regulation and the applicable standards.)
- Must the provider have special training to offer certain family planning services? What is this training? Who offers it? How long is the course? How often is the course given? Can private practitioners enroll in this course? At what cost? Are periodic training updates required? Is specific training required for providing youth-friendly services?

- Can the provider dispense any family planning supplies? Which ones? Do any limitations on dispensing affect the viability of a private practice?

- Are there laws or regulations that limit the types of services that non-physician family planning providers can offer young people?

- To what extent do age-of-consent laws hamper the provision of youth-focused services?

- To what extent do spousal-consent laws hamper the provision of services to married women? Which services or contraceptive methods?

- What is the most-profitable medical service that you provide? Why?

- What is the least-profitable medical service that you provide? Why?

- Will expanding your reproductive health and family planning business (number of clients) expand the profitability of your practice?

- What IEC materials are regularly available in your waiting room for clients? Who provides them?

- Do you regularly ask about family planning practice as part of taking a client's history? At each subsequent visit?

- Which contraceptive method do you most often provide? Why?

- Which contraceptive method do you least often provide? Why?

- Which methods do your clients most frequently ask you for? Why?

HEALTH INSURERS OR SOCIAL-INSURANCE AGENCY (IF EITHER PAYS FOR SIGNIFICANT AMOUNTS OF OUTPATIENT CARE)

- Are there regulations mandating certain benefits? Do these mandated benefits include maternity care? Family planning services? Youth-targeted reproductive health and family planning prevention and care services? If so, what services are mandated?

- Can any family planning services be billed to the insurer as part of obstetrical or gynecological services? If so, what services can be billed?

- Are youths covered by their parents' insurance policies?

- Must the insurer cover all willing providers or does it restrict the number of practitioners with contracts? Does the insurer have any right to limit the number of practitioners in a specific category or region that can receive insurance reimbursement?

- What categories of practitioner have a right to bill the insurers? (For example, can an obstetrician, but not a general practitioner, bill for a family planning service? Can midwives bill for any services?)

5. SERVICE DELIVERY OUTLETS

Program goal: Widespread accessibility of quality family planning service delivery outlets in the private sector

The availability of reproductive health and family planning services through the private sector depends on the existence of places, or outlets, where those services can be delivered to consumers. The accessibility of private-sector services to the broadest possible spectrum of clients depends on the geographic spread of service delivery outlets, as well as on the range of services those outlets offer. Furthermore, the quality of services delivered to consumers depends at least in part on the quality standards of the outlets where those services are provided.

The fundamental legal and regulatory issue facing the private sector in reproductive health and family planning services delivery is the legality of establishing outlets in the private sector where services can be provided. Additionally, regulations and policies that constrain the types of reproductive health or family planning services that may be delivered through private-sector outlets affect not only consumers' access to needed services, but also the sustainability of private-sector healthcare operations.

There are six operational areas in which laws, regulations, and policies can affect the establishment and sustainable operation of service delivery outlets in the private sector:

- types of private-sector outlets allowed
- facility requirements
- staffing requirements
- income generation
- quality control and monitoring
- advertising and promotion

5.1 TYPES OF PRIVATE-SECTOR SERVICE DELIVERY OUTLETS

The broader the range of types of private-sector outlets allowed to provide reproductive health and family planning services, the more clients can be reached with needed services. Private medical practices (physicians, nurses, and midwives), pharmacies, traditional provider practices, NGO clinics, managed care and preferred-provider outlets, clinic network and franchised outlets, and polyclinic and hospital outlets may be able to provide services in the private-sector marketplace, if they are allowed to do so. Private-sector outlets that are able to target consumer groups with reproductive health and family planning services that consumers perceive as consistent, of high quality, and sensitive to their needs have the potential to expand access into these markets and grow their client base. Also, approaches like franchising, which emphasize youth-friendly services, and offering confidential services delivered by competent, sensitive providers may be effective in accessing hard-to-reach groups (LaVake 2003).

Example: Nigeria

Regulations restrict oral-contraceptive pill and injectable sales to pharmacies. Yet there are few pharmacies in rural areas. As a result, the Ministry of Health relaxed the regulations to permit Patent Property Medicine Vendors to re-supply pills for women with a prescription. The Pharmacists Council, however, is opposed to this reform and is trying to reverse it.

5.2 FACILITY REQUIREMENTS FOR PRIVATE-SECTOR SERVICE DELIVERY OUTLETS

Regulatory standards that set facility requirements are designed to ensure the safety and well being of clients. These standards may govern such areas as size and space configuration of outlets, availability and operation of designated equipment, maintenance and cleanliness, and identification of the outlet as a point of service delivery. Regulatory tools used to enforce these requirements include issuing licenses for operation, relicensing for continuing operation, registrations and incorporations (for NGOs, networks, HMOs, and franchises), and certifications for participation (in insurance and other types of networks).

From the perspective of the service delivery outlet as a business, these regulations can have a significant affect on the profitability and long-term sustainability of their operation in the private sector. Regulatory protections must be balanced with the interests of providers and clients. While regulatory standards may have a positive impact on the public health, each requirement represents an investment that must be made by the owner or operator of the facility. Other impediments affecting private service delivery outlets offering family planning services include laws and regulations related to access to credit and contracts such as deeds, leases, and purchase agreements. Insurance requirements are also important to the business aspects of outlet operation.

Example: Tanzania

Registration of nursing or maternity homes in the private sector is a long and complicated process. Moreover, registration requires that these homes be large-scale facilities that are expensive to operate, imposing unnecessarily high operating costs that require large capital investment. As a result, the registration requirements create a disincentive for many private midwives interested in establishing this service. The Tanzanian Nursing Council reviewed existing regulations and suggested significant reforms, which are awaiting final approval by the Ministry of Health.

5.3 STAFFING REQUIREMENTS FOR SERVICE DELIVERY OUTLETS

Outlet staffing requirements are intended by regulators and policy makers to ensure that qualified staff is available to clients at all service delivery outlets. When such requirements are not supported by a real need, they may constrain the number or kinds of outlets that provide family planning services and, consequently, restrict consumer access to services. Through salaries, benefits, and related considerations, the number and qualifications of staff also has a direct impact on the profitability and sustainability of service delivery outlets in the private sector. National labor policies and worker-safety

regulations, as well as laws governing employment contracts, guard staff welfare, but add to the cost of doing business and affect the flexibility with which businesses can respond to changes in the market.

5.4 INCOME GENERATION FOR SERVICE DELIVERY OUTLETS

Some entities within the private sector, as well as NGOs, may face regulatory obstacles to generating income. In situations where the ability to charge fees for services or the kinds of services and activities through which income may be generated are limited, outlet sustainability prospects are constrained. A variety of private-sector outlets may face limits on the fees they can charge for services or the types of services they can offer through regulations or unwritten policies of professional associations and governmental agencies. While participating in networks and franchise schemes may increase income prospects for private-sector service delivery outlets, the contracts governing that participation may limit charges, as well as have percentages of income that must be returned to the network or franchise owner. In such cases, local contract law becomes an important element in income generation and profitability.

Taxes and other fees, such as those for licensing, certifications, or network participation, may be based on income generated. They affect the profit realized and, therefore, outlet sustainability.

5.5 QUALITY CONTROL AND MONITORING OF SERVICE DELIVERY OUTLETS

Quality control and monitoring of service delivery through private-sector outlets is important to safeguarding client well being and public health. Establishing standards for outlet clinical operation is fundamental to quality control and is likely to be undertaken by government entities and outlet and corporate management. (Corporate standards often are designed not only to safeguard clients, but also to prevent legal and financial liability because of adverse clinical events.) The appropriateness of the clinical standards for outlets and the regularity or ease with which they are revised as medical knowledge, healthcare needs, and economic conditions change are important to their effectiveness and the long-term sustainability of the private-sector outlets they govern.

Systems for monitoring adherence to standards and required reporting may be based on both governmental and outlet and corporate information needs. The time and financial costs of fulfilling these requirements for reporting are an important business consideration in outlet operation.

5.6 ADVERTISING AND PROMOTION OF SERVICE DELIVERY OUTLETS

The ability of service delivery outlets to use advertising and promotion to generate demand for services can have a direct impact on income generation. Logos and branding can help position and link services in a way that appeals to hard-to-reach groups, including youth (LaVake 2003). Government regulation of service delivery outlets, however, may include their use of signs and mass media and the message's content. Logos or brand names are used to indicate special certifications or participation in networks or franchises and they usually are governed by contracts or licensing agreements.

The matrix in Table 4 outlines the legal and regulatory issues that confront private-sector reproductive health and family planning service delivery outlets. It is organized according to the six operational areas

described in this section. Following the matrix are questions that should be asked when interviewing stakeholders regarding the issues in the matrix.

Table 4: Service delivery outlets
Program goal: Widespread accessibility of quality family planning service delivery outlets in the private sector

Desired Outcome	Issue or Constraint	Related Legal and Regulatory Areas	Responsible Authority(s)	Other Influencing Factors
1. Types of private-sector service delivery outlets				
Availability of different types of reproductive health and family planning services in the private sector: ▲ NGO-delivered services ▲ Healthcare networks and clinic franchises ▲ Managed care and preferred-provider facilities ▲ Private-sector polyclinics and hospitals ▲ Non-physician service delivery outlets ▲ Traditional provider outlets ▲ Private-sector pharmacies	▲ Legal provision of reproductive health and family planning service delivery in the private sector	Private-sector service delivery	▲ Ministry of Health ▲ Ministry of Commerce and Industry	▲ Profitability of market
	▲ Legal provisions for establishing NGOs ▲ Legal provisions for NGO reproductive health and family planning service delivery ▲ Legal provisions for NGO fees for service ▲ Legal provisions for NGO fund raising and international donor grants	NGO-sector service delivery	▲ Ministry of Social Welfare ▲ Ministry of Health	
	▲ Legal provisions for establishing networks and franchises in the private sector ▲ Legal provisions for operating franchises and networks in reproductive health and family planning service delivery	Networks and franchises	▲ Ministry of Commerce and Industry ▲ Ministry of Health ▲ Managing entities of networks and franchises	

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Legal provisions for establishing managed care and preferred provider outlets in the private sector ▲ Provisions including reproductive health and family planning services in managed care and preferred-provider service packages	Managed care and preferred-provider outlets	▲ Ministry of Health ▲ Insurance industry ▲ Ministry of Commerce and Industry ▲ Managing entities of HMOs and networks	
	▲ Legal provisions for establishing polyclinics and hospitals in the private sector	Polyclinic and hospital outlets	▲ Ministry of Health ▲ Ministry of Commerce and Industry	
	▲ Legal provisions for establishing non-physician outlets in the private sector	Non-physician outlets (such as midwives and nurses)	▲ Ministry of Health ▲ Ministry of Commerce and Industry ▲ Professional associations	
	▲ Legal provisions for establishing traditional provider outlets in the private sector	Traditional provider outlets	▲ Ministry of Health ▲ Professional associations	
	▲ Legal provisions for establishing pharmacy outlets in the private sector	Pharmacy outlets	▲ Ministry of Commerce and Industry ▲ Ministry of Health ▲ Professional associations	

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
2. Facility requirements for private-sector service delivery outlets				
▲ Widespread availability of affordable, financially sustainable reproductive health and family planning service delivery outlets ▲ Safe and equipped facilities for service delivery ▲ All service outlets identifiable by appropriate monitoring or regulatory agencies	▲ Existence (non) of laws and regulations authorizing private-sector service provision ▲ Process: time and costs ▲ Special requirements	Registrations and incorporations (NGOs, networks, HMOs, franchises, etc.)	▲ Ministry of Commerce and Industry ▲ Ministry of Health ▲ Ministry of Social Welfare	▲ Political environment for privatization ▲ Implementation of licensing requirements (inconsistent, subject to corruption, or not monitored at all)
	▲ Requirements for obtaining facility licenses ▲ Time and cost of obtaining licenses	License to operate Re-licensing	▲ Ministry of Health ▲ Ministry of Commerce and Industry ▲ Professional associations	
	▲ Process: time and investment costs ▲ Criteria for participation	Certifications for participation (insurance and other networks)	▲ Ministry of Social Welfare ▲ Ministry of Health ▲ Insurance-industry standards	
	▲ Requirements for liability or other types of insurance	Insurance	▲ Local tort law ▲ Professional associations	
	▲ Regulations regarding collateral ▲ Commercial-loan interest rates	Affordable financing for construction and equipment costs	▲ Ministry of Finance ▲ Commercial-bank management	

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Unclear title and property rights ▲ Terms of lease: landlord and tenant rights and responsibilities ▲ Timeliness of supply of contracted goods or services ▲ Quality of goods or services provided ▲ Responsiveness to direction and services needed ▲ Measures for contractor performance ▲ Enforcement of contractual obligations	Leases and purchases (contracts and deeds)	Local contract law	
3. Staffing requirements for service delivery outlets				
▲ All service providers meet standard minimum ▲ Qualifications for certification and practice ▲ Cost-effective staffing ▲ Safe workplace	▲ Requirements for obtaining licenses ▲ Time and cost of obtaining licenses	Licenses	▲ Ministry of Health ▲ Professional associations	No tradition of workers' safety and workers' rights
	▲ Requirements for obtaining certifications ▲ Time and cost of obtaining certifications	Certifications	▲ Ministry of Health ▲ Professional associations	

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Legal requirements for employee benefits ▲ Legal requirements for employee layoffs and terminations ▲ Safety standards in the workplace ▲ Costs of compliance ▲ Developing written job descriptions, internal procedures, and protocols	Workers' rights and safety, mandated benefits	▲ Ministry of Health ▲ Ministry of Labor ▲ Corporate policy	
	▲ Legal requirements for employee benefits ▲ Legal requirements for employee layoffs and terminations ▲ Development of written job descriptions, internal procedures, and protocols	Contracts (with participating providers)	▲ Local contract law ▲ Professional associations	
4. Income generation for service delivery outlets				
▲ Financial sustainability of service delivery in the private sector ▲ Profitability of service delivery ▲ Enhanced NGO-sustainability prospects	▲ Special requirements for types and methods of service delivery ▲ Marketing and technical support promised by network or franchise ▲ Monitoring, reporting, and enforcement	Contracts (such as with networks and franchises)	▲ Local contract law ▲ Franchise and network management	▲ Long-held medical practices ▲ Territorial jealousies among types of providers ▲ Corruption

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
▲ Affordable service delivery for targeted clients	▲ Ability of NGOs to charge fees for services ▲ Kinds of services and products NGOs can charge fees for or sell	NGO governance	▲ Ministry of Social Affairs ▲ Ministry of Finance ▲ Donor regulations	▲ Cultural expectations of charities ▲ Perceived or real competition with private-practice providers
	▲ Government controls of prices ▲ Network and franchise pricing agreements	Fees and pricing	▲ Franchise and network management ▲ Professional associations ▲ Ministry of Health	
	▲ Restrictions on kinds of services that can be offered (by type of outlet)	Services and other activities	▲ Ministry of Health ▲ Professional associations ▲ Franchise and network management	
	▲ Kinds and rates ▲ Requirements for reporting and collection	Taxes and other fees	▲ Ministry of Finance	
5. Quality control and monitoring of service delivery outlets				
Continuing safe and voluntary service delivery	▲ Standards of service delivery ▲ Enforcement ▲ Shortage of qualified Ministry manpower	▲ Public-sector monitoring ▲ Certification and accreditation standards	Ministry of Health	▲ Lack of interest or understanding of importance of quality ▲ Budget
	▲ Standards of service delivery for networks and franchises (absent, poorly defined, out-of-date) ▲ Inadequate enforcement of standards for networks and franchises	▲ Network and franchise monitoring ▲ Certification and accreditation standards	Franchise and network management	

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Standards of service delivery (absent, poorly defined, out-of-date) ▲ Inadequate systems for supervision and medical audits	Internal monitoring	▲ Facility management ▲ Professional associations	
	▲ Obligations to public sector, network, or franchise	Reporting requirements	▲ Facility management	
	▲ Standards of service delivery (absent, poorly defined, out-of-date) ▲ Inadequate systems for informed consent	Standards of service delivery (including informed consent)	▲ Facility management	
	▲ Regularity of review ▲ Timeliness of revisions ▲ Availability of technical expertise ▲ Dissemination of changes and staff training	Process for revision of standards	▲ Facility management	
6. Advertising and promotion of service delivery outlets				
▲ Services available to all who desire them ▲ Increased service revenues	Restrictions on size, type, and placement of signs	Signs	▲ Professional associations ▲ Ministry of Information and Media	▲ Long-held professional practices ▲ Fear of competition ▲ Territorial jealousies
	Restrictions on use of media for advertising and promoting healthcare facilities and services	Mass media	▲ Professional associations ▲ Ministry of Information and Media ▲ Ministry of Health	

Table 4: Service delivery outlets **Program goal:** Widespread accessibility of quality family planning service delivery outlets in the private sector				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
▲ Maximum number of opportunities to reach clients with information and prompt service delivery	Restrictions on message content	Message	▲ Professional associations ▲ Ministry of Information and Media ▲ Ministry of Health	▲ Insufficient profitability or value ▲ Perceptions of appropriate professional practices ▲ Attitudes and biases regarding marketing to specific types of clients (such as youth)
	Regulatory limitations on establishing referral networks	Referrals and referral networks	▲ Professional associations	

5.7 KEY QUESTIONS FOR ASSESSING LEGAL AND REGULATORY ISSUES RELATED TO SERVICE DELIVERY OUTLETS

This section contains a list of the stakeholders that should be interviewed to assess the legal and regulatory context related to service delivery outlets. Also included are questions, organized by stakeholders, one can use to gather the information.

REGULATORY AGENCY RESPONSIBLE FOR LICENSING PHARMACIES

- Are there any regulations that govern pharmacy staff counseling of consumers about contraceptives (for example, staff members allowed to counsel, consumers allowed to receive counseling, or content of counseling)?
- Are there laws or regulations that limit the types of services that pharmacies can provide to young people?
- What are the requirements for a space to become a retail pharmacy (for example, size, available utilities, and layout)?
- Who inspects the space prior to the opening of the pharmacy?
- What are the problems associated with inspecting and approving a space for becoming a retail pharmacy?
- What is the usual size and layout of a retail pharmacy in this market? To what extent must a client ask for what he or she wants, rather than getting the product from the shelf?
- What is the usual availability of space for point-of-sale advertising and display of informational brochures and handouts?
- Are contraceptives usually stocked openly or behind the counter? Does this vary by method?
- Do pharmacies usually have sufficient space for private customer counseling?
- What are the largest costs associated with establishing a retail pharmacy?
- Are there any restrictions on how many pharmacies one individual may own?

RETAIL PHARMACISTS AND THEIR TRADE GROUP

- Are there any regulations that govern pharmacy staff counseling of consumers about contraceptives (for example, staff members allowed to counsel, consumers allowed to receive counseling, or content of counseling)?

- Are there laws or regulations that limit the types of services that pharmacies can provide to young people?
- What are the requirements for a space to become a retail pharmacy (for example, size, available utilities, and layout)?
- Who inspects the space prior to the opening of the pharmacy?
- What are the problems associated with inspecting and approving a space for becoming a retail pharmacy?
- What is the usual size and layout of a retail pharmacy in this market? To what extent must a client ask for what he or she wants, rather than getting the product directly from the shelf?
- What is the usual availability of space for point-of-sale advertising and display of informational brochures and handouts?
- Are contraceptives usually stocked openly or behind the counter? Does this vary by method?
- Do pharmacies usually have sufficient space for private customer counseling?
- What are the largest costs associated with establishing a retail pharmacy?

AGENCIES LICENSING CLINICS AND PHYSICIANS' OFFICES

- What are the facility requirements for opening a private medical practice? Are there inspections? Is approval of the space required prior to its use as a medical office? If so, by whom?
- What are the costs associated with opening a private medical practice? What equipment, if any, is required?
- What operational requirements apply to a licensed office or clinic in each category? Records? Staffing?
- What approvals are required to start an office or clinic? Are there any capacity controls (such as a certificate of need)? If there are capacity controls, what standards are used to determine need?
- Who approves initial licenses? How much discretion does he or she have? How long does the license-approval process take?
- Are physicians' offices subject to periodic inspection? For what requirements? How often?
- Are clinics subject to periodic inspection? For what requirements? How often?
- What is done when an office or clinic fails an inspection? What sanctions are imposed? (Ask for an example of a recent enforcement action.)
- Can the physician or clinic dispense family planning supplies at this facility (check by category, such as oral contraceptives and IUDs)?

- Must a government-employed physician obtain approval to establish a private practice? Who grants this approval? What criteria are used in granting the approval for private practice? Can the practice be conducted in government facilities? Are such practices subject to regular inspection?

- Are there any laws that govern the ability to establish franchises or networks among clinics or physician offices in this market or country?

- What requirements exist regarding governing equipment that must be present in a policlinic, a private physicians' office for provision of tubal ligation, for IUD insertion? Are there requirements for clinic size or layout (for example, bathrooms or ambulance access) for inclusion in national insurance schemes?

PHYSICIANS AND PHYSICIAN GROUPS

- What problems do physicians encounter in establishing private practices? Which agencies must provide approvals? What barriers are most prevalent and difficult to overcome? What regulations do government agencies cite when supporting such requirements? How do physicians manage their practices in view of these requirements?

- What are the costs associated with opening a private medical practice? What equipment is required? What regulatory standards are the most costly? (Ask for a citation to the applicable regulation.)

- How often is the private office or clinic inspected? By what official? Does this vary with the type of practice?

- Are physicians' offices subject to periodic inspection? For what requirements? How often?

- Are clinics subject to periodic inspection? For what requirements? How often?

- What happens when the office or clinic is cited for regulatory violations? How are these violations resolved?

- What are the facility requirements for opening a private medical practice? Are there inspections? Is approval of the space required prior to its use as a medical office? If so, by whom?

- What approvals are required to start an office or clinic? Are there any capacity controls (such as a certificate of need)? If there are capacity controls, what standards are used to determine need?

- Who approves initial licenses? How much discretion does he or she have? How long does the license-approval process take?

- Can the physician or clinic dispense family planning supplies at this facility (check by category, such as oral contraceptives and IUDs)?

- Must a government-employed physician obtain approval to establish a private practice? Who grants this approval? What criteria are used in granting the approval for private practice? Can the practice be conducted in government facilities? Are such practices subject to regular inspection?

- Are there regulations governing the ability to advertise the services of this private practice or clinic?

- Are there regulations governing signs this private practice or clinic uses?
- Are there regulations that govern how close you can be located to another clinic or private practice?
- Are there regulations that govern how close your clinic or private practice must be located to a pharmacy?

NON-PHYSICIAN MEDICAL FAMILY PLANNING PROVIDERS (MIDWIVES AND NURSES)

- What problems do providers encounter when establishing private practices? Which agencies must provide approvals? What barriers are most prevalent and difficult to overcome? What regulations do government agencies cite when supporting such requirements? How do providers manage their practices in view of these requirements?
- What are the costs associated with opening a private practice? What equipment is required? What regulatory standards are the most costly? (Ask for a citation to the applicable regulation.)
- How often is the private office or clinic inspected? By what official? Does this vary with the type of practice?
- Are providers' offices subject to periodic inspection? For what requirements? How often?
- Are clinics subject to periodic inspection? For what requirements? How often?
- What happens when the office or clinic is cited for regulatory violations? How are these violations resolved?
- What are the facility requirements for opening a private practice? Are there inspections? Is approval of the space required prior to its use as a medical office? If so, by whom?
- What approvals are required to start an office or clinic? Are there any capacity controls (such as a certificate of need)? If there are capacity controls, what standards are used to determine need?
- Who approves initial licenses? How much discretion does he or she have? How long does the license-approval process take?
- Can the provider or clinic dispense family planning supplies at this facility (check by category, such as oral contraceptives and IUDs)?
- Must a government-employed provider obtain approval to establish a private practice? Who grants this approval? What criteria are used in granting the approval for private practice? Can the practice be conducted in government facilities? Are such practices subject to regular inspection?
- Are there regulations governing the ability to advertise the services of this private practice or clinic?
- Are there regulations governing signs this private practice or clinic uses?

- Are there regulations that govern how close you can be located to another clinic or private practice?

- Are there regulations that govern how close your clinic or private practice must be located to a pharmacy?

NONPROFIT FAMILY PLANNING CLINICS

- Do regular clinic or physician's office regulations apply to the organization? Are there any restrictions on the type of organization that can obtain a clinic license?

- What problems were encountered in obtaining initial approvals for the clinic? Is any determination of need required? What standards are use to determine need? At what level in the health bureaucracy are decisions concerning the license application made?

- Are waivers of generally applicable regulations required for any family planning services offered by a clinic (for example, performing sterilizations?)? How are these waivers obtained? (If waivers have been granted, try to get a case history.)

- Are there licenses or approvals, in addition to licensing by the health authority, that a clinic must obtain? Municipal approvals? Building approvals? How difficult is it to obtain such approvals?

- Is the clinic subject to regular inspection? If so, by what agencies? What requirements are enforced? What criteria are used for compliance?

- Has a clinic been subject to a regulatory enforcement action? If so, for what violation? How was the situation resolved?

- What tax rules apply to the nonprofit clinic? Do these rules make it difficult to use any operating surplus for service expansion or enhancement?

- If the NGO has an international affiliation, did it help or hinder the establishing the clinic? Is the affiliate's investment in the clinic subject to general controls on foreign investment? What are these controls?

- Are there regulations governing the ability to advertise the services of this practice or clinic?

- Are there regulations governing signs this practice or clinic uses?

- Are there regulations that govern how close you can be located to another clinic or private practice?

- Are there regulations that govern how close your clinic or practice must be located to a pharmacy?

6. AWARENESS ABOUT PRODUCTS AND SERVICES

Program goal: Increased awareness about products and services

Effective reproductive health and family planning service delivery depends on two programmatic supports:

- consistent availability of high-quality products, methods, and service providers
- awareness about where to find those products, methods, and services

There are significant numbers of women in their fertile years in almost all national markets who have unmet needs for reproductive health and contraceptive services. Some couples may be disposed to use contraceptives, but do not have sufficient information about where to get them, their affordability, safety, or suitability to their circumstances. Others may not appreciate the benefits of child spacing, for example, and want to have to their children at close intervals. Young couples, especially unmarried ones, often are discouraged from seeking the information, products, and services they want or need because of negative attitudes from service providers, family members, and others. Raising individual and public awareness about the range of safe, voluntary, and affordable contraceptive options; dispelling rumors and myths about their use; and educating couples about healthy child-spacing practices is key to ensuring that couples have the information to make the best decisions for them and their families.

There are three principal tools that can be used to raise awareness about family planning products and services:

- advertising and promotion
- IEC
- referrals and referral networks and partnerships

The extent to which program implementers and private-sector participants can use these tools is often an indicator of how successfully demand for contraceptive products and services will be increased and supported.

6.1 ADVERTISING AND PROMOTION

Advertising and promotion is an especially important tool for the commercial or private sector. Use of mass media to convey messages repeatedly to large audiences is an efficient, but often costly means of raising awareness about brands and services. In addition to the cost of mass-media advertising, limitations on the private sector's use of advertising and promotion include regulations and policies that restrict advertising about family planning and contraceptives, brand-specific ethical pharmaceutical products, and professional services. Health and media regulators also may require that they approve any family planning-related messages that appear in the mass media. The timeliness of the approval process,

the criteria used in granting approval, and the qualifications of the decision makers all affect the private sector's effective use of advertising in generating demand.

> **Example: Multiple countries**
>
> Brand name advertising of ethical pharmaceutical products, including hormonal contraceptives, in the mass media is banned in many countries. Commercial manufacturers, importers, and distributors are reluctant to invest in the general advertising and promotion of contraceptive methods, however, because they fear that their investment will benefit their competition as well.

Promotion of products within the trade (physicians, nurses, midwives, pharmacists, and other retailers) and to consumers is important for getting introductory products on the shelves and encouraging their trial. Governmental regulations and corporate policies may limit promotional opportunities, as corporate budget concerns often dictate the types of providers that representatives of pharmaceutical companies may visit.

> **Example: Jordan**
>
> The medical association so strictly regulated advertising in the mass media about physicians' private practices that only a physician's name, address, degree, and specialty could be publicized. Even the size of type that could be used in print ads was specified. Such strictures made the mass-media promotion of physician's participation in family planning program networks impossible.

6.2 IEC

Personal communication is an essential part of effective behavior-change campaigns and is also an important channel for reinforcing and empowering mass-media sales messages among consumers. IEC facilitates effective personal communication between private-sector service providers and their clients. Among young people, youth peer educators are often the most effective communicators to provide information about pregnancy prevention and where to go for services. Community-based workers are also effective providers of information and contraceptives and they can generate demand for clinic-based services. The effectiveness of this personal communication may be influenced by standards of practice for client counseling and informed choice, as well as by requirements for pre- and post-service training of healthcare providers in counseling.

> **Example: Indonesia**
>
> Because of Islamic religious beliefs that prohibit defacement of the body, family planning policy makers did not allow tubal ligation to be promoted to family planning clients as one of the contraceptive methods the government endorsed.

6.3 REFERRALS AND REFERRAL NETWORKS AND PARTNERSHIPS

Referrals and referral networks and partnerships are other tools that use the power of personal communication to foster adoption and continuation of contraceptive use. Such systems take advantage of an eligible client's entry into the healthcare delivery system for any related service to discuss reproductive health benefits and choices and to facilitate the client obtaining desired family planning services. Especially when these referrals and referral networks operate among private-sector service providers, they generate family planning business for participating providers, thus supporting the long-term sustainability of family planning service delivery in the private sector.

The success with which referral networks operate may be affected by regulations and policies that govern interagency or interprofession collaboration, facility management, and exposure of other specialty providers to family planning and reproductive health training.

The matrix in Table 5 sets out the legal and regulatory issues that often are encountered as reproductive health and family planning program planners and implementers work to generate and support demand for service delivery in the private sector. Regulations and policies that may constrain raising awareness, entities with the regulatory responsibility for each constraining factor, and other forces that may influence desired outcomes also are identified. Following the matrix are questions that should be asked when interviewing stakeholders regarding the issues listed in this section.

Table 5: Awareness about products and services
Program goal: Increased awareness about products and services

Desired Outcome	Issue or Constraint	Related Legal and Regulatory Areas	Responsible Authority(s)	Other Influencing Factors
1. Advertising and promotion				
▲ Wide consumer knowledge of service availability and service-outlet points ▲ Maximum number of channels for reaching users with behavior-promotional messages and product information ▲ Truth of advertising (no false or misleading claims) ▲ Commercial-sector participation in costs of IEC and advertising and promotion of methods and brands ▲ Range of providers exposed to targeted or new products and technologies	▲ Limitations on advertising contraceptives ▲ Limitations on promoting family planning ▲ Limitations on marketing to specific consumer groups (for example, youth)	Contraceptives in general	▲ Ministry of Information and Media ▲ Ministry of Health	▲ Profitability and budget priorities of pharmaceutical manufacturers ▲ Profitability and budget priorities of private providers ▲ Fears of political, religious, and cultural backlash ▲ Territorial jealousies among types of service providers (for example, physicians versus pharmacists or midwives) ▲ Manufacturers' and distributors' marketing budgets
	▲ Limitations on brand-specific advertising of ethical pharmaceutical products	Brand specific, ethical pharmaceuticals	▲ Ministry of Information and Media ▲ Ministry of Health	
	▲ Limitations on advertising of professional services	Professional practices, offices, and networks	▲ Professional associations ▲ Ministry of Information and Media ▲ Ministry of Health	
	▲ Timeliness of process ▲ Criteria used for judgment and approval ▲ Qualifications of those making judgments and giving approvals	Message approval	▲ Ministry of Information and Media ▲ Ministry of Health	
	▲ Restrictions on media in which messages may appear	Media	▲ Ministry of Information and Media ▲ Ministry of Health	
	▲ Restrictions on types of providers allowed to receive samples from distributors and medical representatives	Product sampling	▲ Ministry of Health ▲ Manufacturer management	

Table 5: Awareness about products and services **Program goal:** Increased awareness about products and services				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Restrictions on types of providers allowed to receive promotional materials from distributors and medical representatives	Product detailing	▲ Ministry of Health ▲ Manufacturer management	
2. IEC				
▲ Informed choice ▲ Client focus ▲ Range of opportunities to reach targeted consumers with messages	▲ No existing standards ▲ Incorrect or outdated standards ▲ Inadequate process for disseminating standards and training in their application ▲ Limited monitoring and supervision	Standards of practice for counseling and informed consent	▲ Ministry of Health ▲ Medical school curricula	▲ Religious beliefs ▲ Cultural norms ▲ Long-held, but incorrect medical opinions ▲ Media fears of political or religious reprisals ▲ Attitudes and biases regarding marketing to specific types of clients ▲ Understanding IEC needs of specific consumer groups (for example, married, unmarried, youth, and poor)
	▲ Timeliness of process ▲ Criteria used for judgment and approval ▲ Qualifications of those making judgments and giving approvals ▲ Adequacy of product-use information for specific consumer groups (for example, product instructions and referral information targeting youths)	Message approval	▲ Ministry of Health ▲ Facility management	

Table 5: Awareness about products and services **Program goal:** Increased awareness about products and services				
Desired Outcome	**Issue or Constraint**	**Related Legal and Regulatory Areas**	**Responsible Authority(s)**	**Other Influencing Factors**
	▲ Limitations on types of media that can be used to reach targeted segments ▲ Limitations on marketing to specific consumer groups (for example, youth)	Media	▲ Ministry of Information and Media ▲ Ministry of Health	
3. Referrals and referral networks and partnerships				
▲ Maximum number of opportunities to provide people, including clients, with information about contraceptive options and information about where to access those options	▲ Reproductive health and family planning training for other specialty providers ▲ Absence of comprehensive referral process	Inter-department or inter-agency collaboration	▲ Facility management ▲ Department management	▲ Provider indifference ▲ Territorial jealousies ▲ Existing and perceived workloads

6.4 KEY QUESTIONS FOR ASSESSING LEGAL AND REGULATORY ISSUES RELATED TO RAISING AWARENESS ON SERVICES AND PRODUCTS

This section contains a list of the stakeholders that should be interviewed to assess the legal and regulatory issues confronting generating and supporting demand for service delivery in the private sector. Also included are questions, organized by stakeholders, one can use to gather information.

REGULATORY AGENCY RESPONSIBLE FOR LICENSING PHARMACIES

- Are there any regulations that govern the display of information concerning contraceptives?
- Are there any regulations that govern pharmacy staff counseling of consumers about contraceptives (for example, staff members allowed to counsel, consumers allowed to receive counseling, or content of counseling)?

ADVERTISING AGENCIES AND ADVERTISERS

- Are there any formal regulations limiting the content of advertisements for contraceptives? Are there restrictions on advertising of branded products versus generic ones? What agency or organization approves advertising content?
- Are there any formal regulations limiting the content of advertisements for family planning services? What agency or organization approves advertising content?
- Has the advertiser submitted advertisements for family planning or similar services? What is the response, by media type or media outlet?
- Does the government permit advertising of youth-targeted services? What programs or products have been advertised so far and for how long?
- Ask the advertiser to describe advertisements that were submitted and the changes that were required.

DRUG MANUFACTURERS AND IMPORTERS

- Are there any formal regulations limiting the content of advertisements for contraceptives? Are there restrictions on advertising of branded products versus generic ones? What agency or organization approves advertising content?
- Does the company send sales personnel to pharmacists? To doctors? To midwives? What is the practitioner's level of knowledge about the product prior to the sales contact? Do pharmacists or practitioners distribute informational materials the marketer provides to patients?

SOCIAL-MARKETING ORGANIZATIONS

- Do health officials affect the content of information or advertising the organization distributes? What is the basis for their intervention?
- Are media outlets open to the marketer? Under what conditions? What content restrictions have been applied to advertising messages? Do any restrictions apply to youth-targeted messages? Are there restrictions on advertising of branded products versus generic ones?
- Does the organization send sales personnel to pharmacists? To doctors? To midwives? What is the practitioner's level of knowledge about the product prior to the sales contact? Do pharmacists or practitioners distribute informational materials the marketer provides to patients?

PHYSICIANS AND PHYSICIAN GROUPS

- Are there regulations governing the ability to advertise the services of this private practice or clinic?
- Are there regulations governing signs this private practice or clinic uses?
- Are there regulations that govern how close you can be located to another clinic or private practice?
- Are there regulations that govern how close your clinic or private practice must be located to a pharmacy?

NON-PHYSICIAN MEDICAL FAMILY PLANNING PROVIDERS (MIDWIVES AND NURSES)

- Are there regulations governing the ability to advertise the services of this private practice or clinic?
- Are there regulations governing signs this private practice or clinic uses?
- Are there regulations that govern how close you can be located to another clinic or private practice?
- Are there regulations that govern how close your clinic or private practice must be located to a pharmacy?

NONPROFIT FAMILY PLANNING CLINICS

- Are there regulations governing the ability to advertise the services of this practice or clinic?
- Are there regulations governing signs this practice or clinic uses?
- Are there regulations that govern how close you can be located to another clinic or private practice?
- Are there regulations that govern how close your clinic or practice must be located to a pharmacy?

7. PRACTICAL POINTERS FOR CONDUCTING REGULATORY ASSESSMENTS

While the first part of this guide helped the reader identify potential legal and regulatory issues that his or her program might encounter, this chapter provides suggestions on conducting a legal and regulatory assessment based on field experience. This chapter was adapted from *Practical Pointers for Conducting Commercial Sector Family Planning Regulatory Assessments* (Feeley 1997). The following practical pointers will help program designers and implementers conduct an assessment by researching local laws and regulations and interviewing stakeholders. Working with a local attorney also can add legal expertise and value to the assessment.

7.1 INSIST ON GETTING TEXTS OF LAWS AND REGULATIONS AND INDEPENDENT TRANSLATIONS

It is surprising how often a person being interviewed will describe the content of a regulation without having read it. Sometimes the content described will reflect the individual's biases. Whenever a respondent refers to a regulation, ask for a copy, or at least a citation to the appropriate gazette, administrative circular, law, or other controlling document. Obtain this information and have it translated independently. If the language seems inconsistent with statements in the interview, you may want to return and review the text with the respondent. Careful study of the text may suggest that the laws and regulations provide more or less flexibility than is exercised. When the goal is to increase options, ask the respondent if the apparent flexibility in the regulation can be used to expand the number of family planning providers, the services they offer, or the clients they serve. Ask why this flexibility has not been used.

7.2 USE CONSISTENT QUESTIONS WITH FLEXIBLE FOLLOW-UP ACROSS ALL THE SOURCES INTERVIEWED

Interviews must be designed to get consistent information, but the interviewer must respond promptly to statements that suggest inconsistencies or identify previously unrecognized requirements. Start with a list of questions (those in chapters two through six) and try to cover all of them in the interview. In particular, when both regulator and regulated are being interviewed, be sure to cover the same topics with each.

7.3 DOCUMENT INTERVIEW NOTES PROMPTLY

After two or three days of interviewing all of the parties in a regulatory system, it becomes difficult to remember who said what. When you start getting different interpretations, it can be difficult to go back to the sources to resolve discrepancies. Document your interview notes every night. If your team splits up to interview different parties, you can share your experiences through the notes. The notes then become the most important source as the team assembles recommendations and the final report.

7.4 ASSESS THE IMPACT OF REGULATORY REFORM ON PROVIDERS BASED ON THE NUMBER AND TYPE OF PROVIDERS WHO THE CHANGES WOULD AFFECT

The importance of a particular regulation depends on the number of providers who are subject to it. If there are few obstetrical specialists in a country, it is more important to see that regulations permit general practitioners to provide family planning services. Where there are a reasonable number of specialists, then it may be less important to encourage general practitioners as family planning providers.

However, it is difficult to get accurate estimates by locality of the number of service providers within a category. Registries or medical association membership lists, if they exist, are often out of date, as there is no standard updating procedure and licenses may be granted for life. A government ministry may have good information on the physicians employed in the public sector, but no knowledge of the number who practice privately (instead of or in addition to practicing in the public sector). It may be necessary to use two or three estimating techniques to get an idea of the number of private practitioners in a regulatory category.

An important issue can be the training required for providing clinical methods (for example, IUDs or sterilizations). Therefore, in addition to estimating the number of practitioners subject to each regulation, it is necessary to determine the average level of clinical education for each type of provider. For example, a desire to guarantee the highest level of quality for family planning services may make it necessary to focus first on improving clinical training for general practitioners and, only when the quality of their services have improved, encourage them to broaden their provision of clinical family planning services.

7.5 DETERMINE THE LICENSING STANDARDS USED FOR NONPROFIT AND NONGOVERNMENTAL ORGANIZATION CLINICS

Regulatory policies can constrain the ability of nonprofit organizations to provide family planning services, because these organizations are generally held to the same licensing standards as for-profit clinics or pharmacies. Therefore, determine the licensing standards used for nonprofit clinics. Explore with the regulators the possibility of making exceptions to the regulations, or creating a special category of regulations, for well-funded and well-managed nonprofit clinics (for example, NGOs). For example, some countries permit a nonprofit clinic to perform certain procedures even when private clinics are restricted from offering the same services.

In Vietnam, for example, NGOs are allowed to perform outpatient sterilizations, which require highly trained personnel, while the government is reluctant to allow less-complex IUD insertions in private clinics. Although private obstetricians and midwives can provide these clinical services with the approval of Provincial health authorities, such approvals are not being granted.

It is also important to determine whether nonprofit organizations are treated differently from other clinics under laws that govern corporate formation or taxation. Is a surplus of revenues over expenses earned by a nonprofit subject to taxation? If so, this regulation will limit the nonprofit's ability to expand its services using surpluses earned from existing operations. In some countries, it may be difficult to form a nonprofit organization that provides health services.

7.6 SEARCH FOR AND UNDERSTAND THE RAMIFICATIONS OF UNWRITTEN, INFORMAL REGULATIONS

Even in the United States, not every criterion used in establishing regulatory compliance is catalogued or published. For this reason, it is important to learn as much as possible about the standards actually used in making inspections. If possible, accompany an inspector or look at reports citing regulatory violations. What constitutes an unacceptable level of hygiene or adequate space? It is not necessary to suggest that some different standard be enshrined in law, but it may be helpful to encourage the country to analyze the costs and benefits of such *de facto* standards and to examine whether a more-lenient alternative standard would provide an acceptable level of quality. If, as in many countries, the discretion left to inspectors is an invitation to corruption, then it may be necessary to consider including a revised and reasonable standard in written regulations.

7.7 CONSIDER THE COMMERCIAL NEEDS OF THE PRIVATE SECTOR AS YOU ANALYZE REGULATIONS

Attempts to craft regulations to respect the economics of commercial practice can have a positive effect on the provider's willingness to expand family planning services. Therefore, it is important to understand the economic forces that drive the commercial sector and to suggest reforms that are consistent with these forces. For example, in Romania the Promoting Financial Investments and Transfers (PROFIT) project found that the state health department's delays in paying pharmacies for prescription drugs created a cash-flow crunch for pharmacists. Contraceptives do not require a prescription and are not covered by the insurance available to most Romanians. Thus, contraceptive sales and direct payment from users can help create cash flow for the pharmacist. A strategy that reinforced this self-interest showed potential for expanding the distribution of contraceptives through pharmacies.

Public-sector regulators do not necessarily consider the economics of commercial practice. Often, a regulation may cause a major increase in cost or a decrease in the supply of services with only marginal benefits to quality. For example, regulations may require long training programs for those who seek certification as a family planning provider. Such programs may be feasible for a public-sector physician on training leave, but not for a commercial sector physician for whom time is money. Thus, a reasonable target for regulatory reform would be to adjust the training requirements so that they could be met with courses offered in the evenings or on weekends, or to grant certification after an applicant passes a competency exam.

7.8 UNDERSTAND THE RAMIFICATIONS OF TAX AND TRADE BARRIERS AT THE RETAIL LEVEL

Importers and distributors are usually well-versed in tax and trade issues and are accessible sources of information. In a limited number of countries, foreign-exchange controls may be the most important single barrier to contraceptive imports. Any study must determine the current, as well as historic, effect of such barriers. In Romania, PROFIT found that exchange controls had been a major barrier. Shortly before the study, this barrier was removed and currencies became freely convertible. However, rapidly depreciating exchange rates, combined with retail-price controls, continued to discourage importing commodities because importers were concerned that they could not recapture the initial foreign exchange cost at regulated local currency prices. A regulatory assessment must be careful to take into account price controls, as well as the effect of foreign exchange.

7.9 IDENTIFY HIDDEN ADVERTISING AND PROMOTION REGULATIONS

Advertising and promotion regulations often are not well-documented or stipulated, unlike requirements for drug registration or provider certification. For example, in authoritarian countries, the government may have unwritten policies about advertising or program content. The acceptability of different images or phrases will vary depending on the biases of the editors or publishers. State-owned media may be subject to restrictions that are not always explicit. Even private media outlets may have *de facto* policies about sensitive subjects, such as contraception, which reflect the positions of the owners, advertisers, or audience. The best way to identify these unwritten policies is to talk to advertisers and advertising agencies about problems they have experienced in placing advertisements or developing public-relations materials. In Vietnam, a social-marketing agency selling condoms showed the study team advertisements that had been accepted by the national media and those that have been rejected, thereby revealing some of the problems PROFIT could expect to encounter.

7.10 SEEK INFORMATION FROM MULTIPLE PERSPECTIVES

Lawyers struggle to write definitive documents proscribing or prescribing conduct by the commercial sector, but in the real world, application of these statutes and regulations may be less clear-cut. For example, laws may be written, but the implementing regulations may never be issued or may be enforced only sporadically. Even where regulatory language appears explicit, there is often substantial room for administrative interpretation. It is important to understand the real regulatory climate—what individuals or companies in the commodity production and distribution chain or in the provision of family planning services experience.

The process of triangulating the real regulatory world involves researching the appropriate documents and talking to the regulators and the regulated. While drug registration and import rules are set at the national level, rules that affect medical providers and pharmacies usually are implemented at the provincial or local level, even in nations with a strong centralized government. Therefore, it is important to interview regulators at all levels, as well as individual providers or provider organizations.

7.11 FACTOR FAMILY PLANNING SURVEY DATA INTO THE REGULATORY ANALYSIS

Review the most recent surveys of family planning practices, including Demographic and Health Surveys and the Center for Disease Control's Reproductive Health Surveys. These data should not only show the level of contraceptive knowledge and prevalence, but also the current sources for contraceptive users. While these surveys generally target women in their reproductive age, in some countries male components have been added, and in other countries young adult modules have been added.

8. A QUESTION OF STRATEGY

After completing a legal and regulatory assessment—by identifying, analyzing, and prioritizing potential legal and regulatory barriers—one should devise a strategy to address constraints that affect family planning and reproductive health programs. In a few cases, the strategy may focus on taking advantage of an opportunity in the political environment to change a legal or regulatory barrier. More often than not, however, the strategy involves working within the existing legal and regulatory framework.

Selecting the most appropriate strategy depends on the program's goals, the barriers identified in the assessment, and the likelihood of being able to change the barriers. Although this guide focuses on the assessment phase, this chapter provides an overview of the types of strategies, as well as examples from the PROFIT, Commercial Market Strategies (CMS), and Private Sector Program (PSP) projects. This chapter is adapted from *Practical Pointers for Conducting Commercial Sector Family Planning Regulatory Assessments* (Feeley 1997).

8.1 STRATEGY ONE: WORK WITHIN THE EXISTING REGULATORY CLIMATE

Often it is easier to work within the regulatory framework because of the difficulty in changing laws or policies. The CMS project in Morocco faced a potential barrier to the continued success of its social marketing program after the project ended. CMS managed a social marketing program for oral contraceptives in which existing pill brands from Wyeth and Schering were marketed and promoted under an umbrella brand called *Kinat Al Hilal* (Pill of the Moon). In exchange for research and promotional support from CMS, Wyeth and Schering lowered their prices by 20 percent. Although these manufacturers were committed to continuing the program after the end of the CMS project, they faced a legal barrier because private companies are not allowed to advertise contraceptives in Morocco. Without promotional activities the social marketing program's ability to increase the use of contraceptive pills would be compromised.

To avoid terminating the program, CMS opted to work within the existing legal and regulatory climate. Before leaving Morocco CMS recommended that ownership of the *Kinat Al Hilal* brand be transferred to an NGO, such as the local family planning association. That association would conduct promotional activities for the social marketing brand. CMS brokered discussions with the manufacturers, USAID, the NGO, and the Ministry of Health so that the social marketing program could continue beyond the CMS project.

8.2 STRATEGY TWO: MODIFY WAYS IN WHICH REGULATIONS ARE IMPLEMENTED

Some countries have a neutral or positive official attitude towards the commercial sector, yet government requirements and restrictions obstruct commercial-sector expansion. In Ethiopia a PSP task order was charged with expanding the role of private companies and private service providers in the provision of high-quality health care packages, especially for HIV/AIDS and tuberculosis. To achieve this goal, PSP/Ethiopia worked with private companies to include tuberculosis treatment (with directly observed treatment, short-course) in their clinics. Upon surveying companies and their workplace

programs, PSP/Ethiopia found that many businesses also supported HIV/AIDS treatment, but not through their own clinics. Although those clinics were equipped with trained personnel, the private sector was not legally allowed to provide ARV services in Ethiopia.

PSP/Ethiopia learned that one company already was distributing ARVs through its clinics, reaching approximately 200,000 people in its catchment area. Despite the legal restriction on private providers, this company received approval from the government to provide ARV therapy— the first such approval for private providers in Ethiopia. This apparent exception to the restriction is most likely because the company's clinics are the only functioning health system in that catchment area. PSP/Ethiopia is conducting an assessment to determine the circumstances of this case and how it can be replicated, allowing more private companies to use their resources to expand ARV services.

8.3 STRATEGY THREE: LOOK FOR OPPORTUNITIES

In most countries there are entrenched interests that oppose changes or reforms to laws and regulations. Hence the best strategy is to find a way around these groups. In Romania PROFIT found that a conservative coalition of obstetricians opposed easing requirements that restricted the availability of modern family planning services by physicians. Most of these obstetricians had been trained during the communist regime and had little knowledge of modern hormonal contraceptives. In addition they often profited from providing abortions. These interests opposed any change in a requirement that called for six months of special training—on top of internal medicine or obstetrical qualifications—before a physician could provide family planning services.

Romanian law, however, permits pharmacists to dispense oral contraceptives without a prescription. Pharmacies in Romania have been privatized and generally are run by educated pharmacists, many of who are women. Because of delays in payment for state-subsidized prescription drugs, pharmacists have an incentive to sell products, such as oral contraceptives for cash. Barriers to registering and importing oral contraceptives are low, with a number of products already registered. The media are open to advertising and public-relations messages about contraception. Rather than trying to ease the restrictions, thereby incurring opposition from obstetricians within the Ministry of Health, PROFIT suggested providing pharmacists with more education so that they could advise their clients about family planning. Simultaneously PROFIT used the mass media to spread the word that safe and effective alternatives to abortion were available. Elements of the regulatory climate that were favorable to commercial-sector family planning initiatives were exploited without attempting to change unfavorable regulations. This strategy was the first step to minimize opposition from powerful stakeholders. Today in Romania many obstetrician-gynecologists and general practitioners offer family planning methods.

8.4 STRATEGY FOUR: CHANGE THE LAW OR REGULATION

This path is the most difficult strategy, as it requires a long-term commitment. Building a coalition to support a change in regulation, then implementing that change, can take years. The process also can create enemies who can block your efforts, underscoring the need to manage the process and anticipate opposition and roadblocks. As a result, program planners should consider the benefits of the regulatory change against the difficulties in trying to make the change, as well as whether the reform can occur within a project's lifetime. Otherwise consider one of the easier, more reliable approaches outlined previously.

Occasionally there is a ground swell of support for changing a law or regulation to address a current crisis. In Zambia the Ministry of Health is struggling to address the shortage of physicians in the health

system and is looking at the private sector as a possible solution. According to the National Health Strategic Plan, one of the Ministry of Health's strategies is to "harness public/private partnerships in the delivery of public health services." Currently, clinical officers, nurses, and nurse midwives offer the majority of health care in Zambia, and these providers have great potential to provide needed health services to the population through private practices. Yet a PSP-*One* assessment revealed potential barriers to expanding the nascent private sector in Zambia. For example, while the Nursing Council's laws permitted private nursing practices, the Medical Council was the only entity that licensed clinics and it insisted on physician control, despite the acute shortage of doctors in the country.

Critical stakeholders (the Medical and Nursing Councils) recognized a statutory update was overdue and believed the time was right to approach the Ministry of Health to make legal and regulatory reforms. PSP-*One* provided technical assistance to the Medical and Nursing Councils to conduct the review. As a result, the Medical and Nursing Councils were able to review the Health Protection Law that regulates registration of health professionals and licensing and accrediting health facilities and propose reforms to the ministry.

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