REGULATION OF PRIVATE PRIMARY HEALTH CARE

A COUNTRY ASSESSMENT GUIDE

JOINT LEARNING NETWORK
For Universal Health Coverage

Technical Facilitators

Kirsten Krusell, Results for Development
Cicely Thomas, Results for Development
Emma Willerton, Results for Development
Nathan Blanchet, Results for Development
Marty Makinen, Results for Development
Aaron Pervin, Results for Development
Daniela Gutierrez, Results for Development
Kamaliah Mohd Noh, Cyberjaya University College of Medicine Sciences

Authors

Ghana
Yaw Opoku-Boateng, National Health Insurance Authority
Matthew Kyeremeh, Health Facilities Regulatory Agency

Indonesia
Rizki Mahardya, University of Gajah Mada
Burlian Mughnie, Ministry of Health
Atikah Adyas, Ministry of Health
Ahmad Jet Al Amin, An Nasher School of Public Health

Kenya
Agnes Gatome-Munyua, Swiss Centre for International Health
Charles Kandie, Ministry of Health
Samuel Kinyanjui, independent consultant
Julia Ouko, National Hospital Insurance Fund
Esther Wabuge, JLN Kenya

Malaysia
Mohd Safiee Bin Ismail, Ministry of Health
Rima Marhayu Binti Abdul Rashid, Ministry of Health

Mongolia
Enkhtsetseg (Enkhe) Bandikhuu, Ministry of Health
Oyuntsetseg (Oyuna) Purev, Ministry of Health
Batbayar Ankhbayar, independent consultant

Morocco
Hassan Semlali, Ministry of Health
Rihani Anas, Ministry of Health
Chakib Boukhalfa, National School of Public Health

This guide was produced by the Joint Learning Network for Universal Health Coverage (JLN), a community of policymakers and practitioners from around the world who jointly create practical guidance to accelerate country progress toward universal health coverage.

For questions or inquiries about this guide or other JLN activities, please contact the JLN Coordinator Team at jln-nc@r4d.org.

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CONTENTS

INTRODUCTION

This document offers guidance on assessing how a country regulates the private health sector and producing a report that offers helpful insights and recommendations. It discusses research methodology and details an eight-step assessment process, as well as the structure and content of the resulting report. Templates are provided for planning and for data collection; these can be adapted to the specific country context.

The assessment process addresses the following questions about regulating the private health sector:

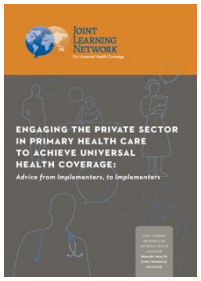
- What types of regulations are in place?
- How are the regulations implemented?
- What outcomes are achieved by those regulations?
- What resources are available for developing and implementing such regulations?

The assessment has the following scope:

- **Focus on regulation of both the private and public health sectors.** While government may play a lead role in regulation, many other actors are involved, including professional associations and consumer organizations. Regulation of the private health sector is linked to regulation of the public health sector, so these must be examined together. In many cases, specific laws, regulations, and regulatory units govern private providers while public-sector providers are assumed to be regulated by government. In other cases, both private and public providers are subject to the same regulations. The assessment covers both of these scenarios.
- **Focus on regulation of service delivery.** The assessment focuses on regulation of the process of providing primary health care (PHC) services and treatments, not on regulation of training institutions, pharmaceuticals, or medical equipment.
- **Focus on PHC.** The assessment may inevitably touch on secondary and tertiary care since regulation often covers the provision of any health service without specifying the level of care, but the focus should remain on PHC.

The JLN's PHC Initiative

In 2015, a group of committed country practitioners in the JLN PHC Initiative joined together to address the lack of international guidance on engaging with the private sector to achieve PHC-oriented universal health coverage. These practitioners formed the JLN's Private Sector Engagement (PSE) Collaborative and began sharing experiences and knowledge and compiling practical advice to support private-sector engagement. To help fill the gaps in guidance in this area, the collaborative is authoring a guide titled *Engaging the Private Sector in Primary Health Care to Achieve Universal Health Coverage: Advice from Implementers to Implementers*. The completed guide will have five modules:



Module 1. Initial Communications and Partnership Around PHC (complete)
Module 2. Provider Mapping (complete)
Module 3. Provider and Facility Regulation, Accreditation, or Empanelment (in development)
Module 4. Provider Contracting and Payment (in development)
Module 5. PHC Systems Monitoring and Evaluation (planned)

Modules 1 and 2 are available on the JLN website at www.jointlearningnetwork.org. In compiling Module 3, which focuses on ensuring the quality of private PHC through provider and facility regulation, the collaborative members conducted a literature review and found few documented experiences on regulation of private providers in low- and middle-income countries. To help fill this gap, six JLN countries—Ghana, Indonesia, Kenya, Malaysia, Mongolia, and Morocco—chose to conduct country assessments using a methodology developed by the collaborative. This guide is based on that methodology. (The resulting country assessment reports and an overview report synthesizing the experiences of all six countries—titled *Regulation of Private Primary Health Care: Lessons from Six JLN Countries*—are available on the JLN website.)

ASSESSMENT STEPS AND TIMELINE

The country assessment process has eight steps. Annex A includes a Planning Template with questions to consider in each step and a proposed timeline. It can be useful to fill in the template before starting the assessment process, even if the answers are preliminary, because doing so will help identify practical issues that may arise.

1) **Obtain funding and authorization (Month 1).** The first step is to secure resources and permissions. The institution carrying out the assessment or a local research entity may have funds available to cover staff time and other necessary support. Or it might be necessary to apply for external funding. This is also the time to obtain approvals to

conduct the research—from institutional leadership and from any ethics review boards that may oversee research in the country.

2) **Form and orient an assessment team (Month 1).** The next step is to identify institutions and individuals to carry out the assessment, including a principal investigator and a team of researchers, and to inform them about the background and objectives of the assessment and delegate tasks. If the assessment team is unable to conduct the assessment in a timely fashion, it may hire a consultant to facilitate the work. A qualified consultant must have the analytical skills, relationships with key informants, and expert knowledge to collect and analyze data and write up the results.

3) **Prepare to collect data (Month 1).** Data collection involves two phases that may be carried out concurrently: document review (secondary data collection) and interviews (primary data collection). The appropriate interview format will depend on the country context, but it should be determined early in the process so the assessment team can adequately prepare. After the team has chosen an interview format, several practical considerations remain before data collection can begin. The Planning Template in Annex A can help with preparations for both the document review and the interviews.

4) **Conduct the document review (Month 2).** Document review involves extracting key information from relevant documents assembled by the team.

5) **Conduct interviews (Month 2).** Interviews offer an opportunity to learn from key individuals with expert knowledge and experience. They also offer a way to verify and fill information gaps identified during the document review.

6) **Analyze and synthesize the data (Month 3).** This step includes triangulating among data sources, including information from documents and interviews, to identify themes, interpret findings, and develop recommendations.

7) **Write the assessment report (Months 4 and 5).** This guide provides an outline for writing the assessment report, as well as guidance on who should write the draft and who the reviewers should be. The introductory sections can be drafted before interviews begin.

8) **Disseminate the report (Month 6).** Disseminating the assessment report to target audiences—particularly those within the country who have the authority to implement the report's recommendations—may involve presenting at meetings or conferences or publishing the findings in a journal.

RESEARCH METHODOLOGY

The suggested timeline for conducting the assessment and producing the report is short—about six months. The methodology presented here is therefore not overly burdensome and can quickly yield results.

The assessment process uses a qualitative research methodology that aims to understand processes, experiences, and attitudes by asking "what," "how," and "why" questions. The approach begins with broad research questions that can evolve or be refined as the research process moves forward.

As noted earlier, data collection for the assessment involves two phases: a review of available documents (secondary data collection) and interviews (primary data collection).

Ethical Issues

The institution overseeing the assessment may require formal review by an ethics board to safeguard the dignity, rights, safety, and well-being of the research participants. The assessment process presented here generally involves minimal risk to participants. Nevertheless, it is important to address two key ethical considerations: consent and confidentiality.

Consent. It is important to ensure that all individuals who participate in the assessment are doing so freely, without coercion or pressure. They should be well informed about the objectives of the assessment and how their responses will be used, and they should be assured that declining to participate will not adversely affect them. Depending on the institution's requirements, it may be necessary to obtain written consent from interview or focus group participants. At the very least, interviewers should obtain verbal consent from each participant for the interview and for taking notes documenting the conversation.

Confidentiality. It is crucial to protect the confidentiality and privacy of research participants. This principle has implications for how data are collected and stored and for how quotes and sources are cited in the assessment report.

Document Review

A document review can provide an understanding of the context and background of health-sector regulation. Some of the information collected during this stage will be *quantitative* (e.g., number of regulators, budget available to regulatory agencies, number of monitoring visits conducted), and some will be *qualitative* (e.g., what laws and policies are in place, who the main actors are, and what their responsibilities are).

This phase will also help identify what information is available, what the information gaps are, and what types of questions will require additional investigation through interviews.

Relevant material may come from a range of sources, including:

- **Policy and strategy documents,** including the national health-sector strategy and public-private partnership policy statements.
- **Legal documents,** including laws passed by a legislative body, decrees or rules issued by government ministries or agencies, judicial orders issued by courts, and service agreements and contracts.
- **Research studies,** including peer-reviewed journal articles and studies published by nongovernmental organizations, research institutes, and international organizations.
- **Internal and external records,** including annual reports, annual health accounts, monitoring reports, meeting minutes, budgets, and terms of reference.
- **Databases,** including country health management information systems (e.g., DHIS2), finance management information systems, accreditation program tracking systems, and global databases and resources such as www.imf.org/en/data.

The challenge with a document review is to avoid getting overwhelmed by information that is not pertinent to the assessment. It is also important to track the data sources so the resulting report is well cited and credible. It is good practice to note emerging trends, findings, preliminary conclusions, or follow-up questions in a Microsoft Word or Excel document. Coding can be helpful in documenting trends. Some codes can be defined before the document review, and some can emerge from what the team notices in the data.

Interviews

Interviews are conversations that provide data to answer research questions. They offer an opportunity to learn from key informants with expert knowledge and experience, as well as a way to verify and fill information gaps identified during the document review.

Unlike with some studies, which require a random or statistically representative sample, this assessment uses *purposive sampling*, which selects participants based on their knowledge of the topic because they are most likely to provide useful information. To ensure a diversity of perspectives, it is best to begin with a list of important stakeholder groups and then identify key individuals within each group. Another useful technique is *snowball sampling* or *chain sampling*, which involves asking key informants to help identify other individuals with relevant insights. For example, a representative of a regional regulatory body might mention a private-sector facility that is complying with all regulations and a facility that is evading

enforcement efforts. Adding staff from these two facilities to the interview list would be an example of snowball sampling.

The size of the sample will depend on the complexity of the questions and the time and resources available to the assessment team. It is best to interview to more than one representative of each stakeholder group unless additional interviews are not generating new information or understanding.

Interviews can be structured in different ways, depending on the research objectives:

- **Structured interviews** use a fixed, detailed list of questions with little to no opportunity to deviate from the interview script, including the order of the questions. This approach is typically used to test specific hypotheses or answer narrow research questions and is unlikely to be suitable for this assessment.
- **Semi-structured interviews** use a topic guide that includes specific but open-ended questions and prompts. (See the sidebar below.)
- **Unstructured interviews** use a few general questions to get the conversation started. They work best when little is known about the topic.

Semi-structured interviews are the most suitable format for this assessment because the document review will have yielded useful background information and the flexible structure is helpful for gathering relevant information efficiently.

Developing Topic Guides

A topic guide can help a researcher conduct a semi-structured interview. It includes a standard introduction and conclusion script, a list of questions, and prompts that encourage the interviewee to elaborate on or clarify a response. A topic guide often starts with an icebreaker (e.g., "Tell me about your role at this organization.") and then transitions from general to specific questions and finally to any sensitive topics. A sample topic guide is found in Annex D.

The list of questions can be informed by trends, themes, findings, preliminary conclusions, or follow-up questions that arose during the document review stage. It may be necessary to develop different topic guides for each stakeholder group (e.g., facility staff, professional associations, district health management teams, national-level health policymakers).

The questions do not need to be asked in the exact order that they appear in the guide, and not all question must be asked during every interview. Topic guides can evolve as the interview process progresses.

Depending on the sensitivity of the interview topics, the level of detail sought, the availability of key informants, and interviewer skill, the format of the interview can also vary. Table 1 lists the options in increasing order of facilitation required, from written surveys to half-day workshops. To achieve the objectives of this assessment, individual and natural group discussions will likely be the most appropriate options.

Table 1. Interview Formats

Format	Definition	Structure	Estimated Duration	Advantages	Disadvantages	Data Collection Method
Written survey	Researcher distributes terms of reference and a written survey to participants	Participants independently complete the written survey	N/A	May increase the chances of getting responses from busy key informants	Does not allow interviewer to give prompts or ask clarifying questions	Participants record written answers in a survey template
Individual interview	One-on-one conversation between an interviewer and key informants	Semi-structured conversation that follows a topic guide and takes place in person or over the phone	30–60 minutes	Elicits in-depth responses and may be preferable to group discussions if topics are sensitive or controversial	May be time-consuming for researchers to conduct individual interviews with all key informants	Discussion is typically documented by a dedicated notetaker (separate from the interviewer), with or without audio recording

Format	Definition	Structure	Estimated Duration	Advantages	Disadvantages	Data Collection Method
Natural group discussion	Facilitated discussion with two to four individuals from a group that is independent of the research study (e.g., staff who work the same shift at a health facility or in the same unit at the Ministry of Health (MOH)	Semi-structured conversation that follows a topic guide. Group may be convened intentionally or evolve from an individual interview (e.g., "Do you mind if my colleague joins?")	60 minutes	Well suited for observing group dynamics and norms; can be an efficient use of researcher and key informant time	Group dynamics may result in some participants not contributing their honest observations and opinions	Discussion is typically documented by a dedicated notetaker (separate from the interviewer)
Focus group discussion	Facilitated discussion with 6–10 people who meet sampling criteria	Semi-structured conversation that follows a topic guide and requires a highly skilled facilitator	90 minutes	Well-suited for capturing a broad range of ideas and opinions	Challenging to facilitate and unlikely to yield detailed individual responses; may result in data management burden	Discussions are usually audio-recorded and transcribed for analysis in addition to notetaking during the discussion
Workshop	Facilitated discussion with key informants from several stakeholder groups	Semi-structured plenary and small group conversation that follows a topic guide and requires a highly skilled facilitator	Half day	Captures a broad range of ideas and allows time for in-depth discussion and debate	Can be difficult to schedule and challenging to facilitate	Discussion is typically recorded by a dedicated notetaker and on flip chart paper

The planning template in Annex A provides a detailed list of practical issues to consider when organizing interviews, including who will schedule the interviews, where will the interviews take place, and whether a translator is needed.

Interviewing Skills

Interviewing requires a set of skills that take practice to develop. Role-playing with colleagues can be especially helpful.

Interviewers must learn to clearly explain the background and objectives of the assessment and respond to questions. They must understand confidentiality procedures and be comfortable asking for and obtaining verbal consent. Interviewers must also thoroughly understand the topic guide, including the purpose of each question and the overall flow of the interview. This will help with transitions from one question to the next and with rephrasing, reordering, or skipping questions as needed.

Here are some additional do's and don'ts for interviewers:

Do	Don't
✓ Conduct the interview in a quiet, comfortable place without distractions, and build rapport using a friendly tone of voice and body language	✗ Bias the interview by presenting your own opinions or perspectives
✓ Adapt the interviewing style to the participant's personality (e.g., animate shy individuals by being warm, and manage dominant individuals by being polite but firm)	✗ Reveal whether you agree or disagree with a given response (e.g., say "thank you" as a neutral way to acknowledge an answer instead of "good" or "that's interesting")
✓ Be flexible under changing circumstances (e.g., an individual interview may evolve into a group interview, or a participant may suddenly need to leave)	✗ Ask leading questions (e.g., say "Tell me how you reacted to the new regulation" instead of "Did you oppose the new regulation because it affects your profit margin?")
✓ Ask concrete but open-ended questions focused on how and why (e.g., "Tell me about the most recent monitoring visit at this facility" instead of "What do you think of facility monitoring?")	✗ Ask judgmental questions (e.g., say "How did you decide whether or not to conduct the monitoring visit?" instead of "Why didn't you show up for the monitoring visit?")
✓ Be an engaged listener and allow participants time to think before responding	✗ Interrupt, speak too rapidly, or jump too quickly from one subject to another

✓ Repeat back what you have heard to ensure that you have understood the participant, if necessary	✗ Correct or dispense advice to the participants
✓ Ask one question at a time	✗ Ask too many "yes" or "no" questions

Translation

If a translator is needed during interviews, choose a translator that is trusted by participants. Gender dynamics and other cultural sensitivities are important to consider. The translator should also understand the topic guide and any technical terms that might arise. The translator should be directed to provide literal sentence-by-sentence translations, not summaries or interpretations. Interviewers should maintain eye contact with the participant, not the translator, during interviews.

Audio Recording and Notetaking

Audio recording is not recommended for purposes of this assessment because it adds an additional transcription step after the interview. Using a dedicated notetaker is more efficient. If audio recording is used, however, the interviewer must obtain advance permission from participants, explaining that the rationale for recording is to accurately document and report their views. The best way to ensure accurate transcription is to have the transcriber present as a notetaker during the interview so the transcriber has a draft to work from and has context in case portions of the audio recording are unclear.

If any participant does not consent to audio recording, a notetaker must be used instead. The following are good practices for notetaking:

- When handwriting notes, begin each entry with the date, time, place, and type of data collection event (e.g., individual interview).
- Use wide margins to make it easier to expand the notes at a later time. Or use a blank topic guide with space reserved for responses.
- Use abbreviations and shorthand to capture key information quickly and accurately—do not worry about spelling or grammar or capturing direct quotes.
- Reread, organize, and expand on the raw notes soon after the interview. This might mean typing handwritten notes, expanding shorthand into sentences, filling in information gaps, or correcting misspellings.
- Confer with the interviewer soon after the interview ends to agree on two to four highlights or key messages from the interview. The interviewer can use these in

writing a brief thank-you email to the participant within two days of the interview. This shows respect for the person's time and facilitates the beginning of analysis.

Data Collection Software

Several software packages are available for storing, annotating, and analyzing qualitative data using a method called *coding*. Mastering the software can be time consuming, and the cost can be high. For projects with relatively small data sets, such as this assessment, software is likely not worth the investment. As with the document review, the assessment team can do simplified coding by simply highlighting and marking up interview notes with preset codes or codes that are developed during the process of reviewing notes. However, if members of the team have affordable access to coding software and the requisite skills, they should feel free to use them.

Confidentiality

It is important to take reasonable measures to safeguard the confidentiality of participants—even when the topic of an interview is not controversial or sensitive or when participants have given you permission to quote or cite their remarks. This is particularly true if you have collected identifying information such as name and job title.

Protecting confidentiality starts during data collection. In addition to obtaining permission to take notes or make an audio recording, the interviewer should clearly explain to participants how the information will be used and offer them an opportunity to ask questions, raise concerns, or decline participation. Data should also be stored in a secure manner. Notes should not be left out in the open or saved in unprotected computer files. Finally, the assessment report should generally not attribute opinions or remarks to anyone by name. (The following section offers suggested phrases for citing or summarizing statements by participants.)

ANALYZING AND SYNTHESIZING DATA

After the document review and interviews are completed, it's time to analyze and synthesize the *findings* to generate *conclusion*s and *recommendations*. These three terms are often used interchangeably, but the distinctions are important, as shown in Figure 1, which includes samples of each in *italics*. The assessment report will include all three.

Figure 1. Findings, Conclusions, and Recommendations

Findings: Straightforward descriptions of evidence from documents or interviews, with little or no interpretation *Several respondents complained about their lack of ability to enforce existing regulations.*	**Conclusions:** Interpretations of the findings to address the research questions *Enforcement capacity is a major obstacle to effective regulation—it was the most-cited problem in reports and interviews.*	**Recommendations:** Suggestions for action based on the findings and conclusions *Officials with regulatory enforcement responsibility should be given additional resources to carry out their duties.*

The most useful findings are common issues that occur across data sources and the main themes that describe the data set. The following steps describe how to conduct a *thematic analysis* to identify important findings:

1) **Read and annotate notes/transcripts.** Conduct a preliminary analysis of the document review notes and interview notes as soon as possible after data collection and annotate them with comments, key words, descriptive analyses, and follow-up questions. Clearly mark these annotations as researcher analysis (not participant responses).
2) **Identify themes.** Review the annotations made in step 1 and list common themes. These themes should be somewhat abstract rather than summaries of the text. For example, they might include "staff autonomy" or "political will."
3) **Develop a coding scheme.** From the initial list of themes, develop a coding scheme with associated numbers or colors. For example, the scheme might use a code for each stakeholder group so 1 = private-sector providers, 2 = staff autonomy, and so forth. The coding scheme can evolve as categories emerge during the analysis.
4) **Code the data.** Apply the coding scheme to the entire data set. This can be done by writing codes in the margins of transcripts, using color-coded manual highlighting, or using the comments or highlighting features in a word processing program. Note that the same line of data may be associated with several different codes.

5) **Cut and paste.** After the coding is complete, divide the text into separate documents based on the codes. For example, all sections of text coded as "incentives" would be gathered into one document using word processing software and then reviewed for patterns that can inform conclusions and recommendations. During this stage, it is vital to record the original source of the data.

It can be beneficial to also look closely at the story or narrative within each interview. Does one particular interview exemplify one or more of the themes that have emerged? If so, spotlighting this story could help bring the assessment findings to life.

Next, it is important to validate the strength and accuracy of the findings. There are two main approaches for validating findings:

- **Group-to-group validation.** This approach looks at three factors: 1) how many participant groups mentioned the topic, 2) how many people within each group mentioned the topic, and 3) how much enthusiasm the topic generated among participants. A topic that meets group-to-group validation criteria will have generated a consistent amount of enthusiasm among a consistent portion of the participants across nearly all groups.
- **Triangulation.** This approach involves comparing findings across different data sources. For example, are interview results confirming what evidence in the extant literature suggests, and vice-versa? If so, the findings are likely relevant and accurate. Note, however, that differences across the data sources may also be findings in themselves. Examining "deviant cases" that do not align with the initial findings can prove illuminating.

Conclusions and Recommendations

Conclusions should always be grounded in findings—the straightforward information found in documents and conveyed in interviews. An evidence-based conclusion will, in turn, result in more informed policy recommendations or suggestions for action. The upcoming section includes detailed guidance on generating conclusions and developing recommendations.

Further Reading

Brikci, N., and J. Green. 2007. *A Guide to Using Qualitative Research Methodology.* London: Médecins Sans Frontières. http://fieldresearch.msf.org/msf/handle/10144/84230

Mack, N., and C. Woodsong, et al. 2005. *Qualitative Research Methods: A Data Collector's Field Guide.* Research Triangle Park: Family Health International. https://www.fhi360.org/sites/default/files/media/documents/Qualitative%20Research%20Methods%20-%20A%20Data%20Collector's%20Field%20Guide.pdf

WRITING THE ASSESSMENT REPORT

The following outline lays out the main sections of the report. The assessment team can add to it or omit sections to suit the country context.

1) Introduction
   a) Assessment background, objectives, scope
   b) Organization of the report
   c) Methodology
2) Secondary-Source Findings: Regulatory Context
   a) Health-sector objectives and strategy
   b) Demographic and health outcome indicators
   c) Health system indicators
3) Secondary-Source Findings: Regulatory Landscape
   a) Regulatory efforts to date
   b) Regulatory actors and resources
   c) Data for tracking and reporting on regulatory efforts and performance
4) Primary-Source Findings: Implementation and Performance of Regulatory Activities
5) Conclusions
6) Recommendations
7) References

Introduction

The introduction should briefly summarize the background, objectives, and scope of the assessment; the structure of the report; the methodology used for data collection and

analysis; and the types of documents and data reviewed. It should also specify the number of key informant interviews conducted and the number of focus group discussions (if any).

Secondary-Source Findings: Regulatory Context

This section should describe the context of the country's health-sector regulation, drawing on available documents.

Health-Sector Objectives and Strategy

Provide a brief high-level summary (e.g., improving maternal and child health outcomes or making spending by the National Health Insurance Scheme more efficient). Include citations and links to the most recent health-sector strategy document.

Demographic and Health Outcome Indicators

Using Table 2, document the country's key health and demographic indicators. Some indicators are required; others can be filled at the assessment team's discretion, depending on the health-sector objectives.

Table 2. Demographic and Health Outcome Indicators

Indicator	Measure	Year	Source(s)
Required Indicators			
Total population			
Population age distribution (%)	Age 0 to 5: Age 6 to 15: Age 16 to 64: Age 65+:		
Urban and rural population (%)	Urban: Rural:		
Poverty rate			
Infant mortality rate			
Under-5 mortality rate			

Indicator	Measure	Year	Source(s)
Maternal mortality ratio			
Top three illnesses that create demand for health services			
Optional Indicators			
HIV prevalence			
Diabetes prevalence			
Total fertility rate			
Percentage of 1-year-olds who have received DTP3			
Prenatal care coverage (4+ visits)			
Other			
Other			
Other			
Other			
Other			

Health System Indicators

Use Table 3 to document health system indicators, focusing on the public-private mix (e.g., number of facilities and personnel, utilization rates, and coverage rates) as well as key economic and political conditions that may affect the will and ability of stakeholders to regulate the health sector. Provide all monetary figures in U.S. dollars, if possible.

Table 3. Health System Indicators

Indicator	Measure	Year	Reference Document(s)
Number of hospital beds per 100,000 population	Total: Public %: Private %:		
Bed utilization rate	Public %: Private %:		
Outpatient utilization rate (visits per person per year)	Total: Public %: Private %:		
Number of outpatient facilities by type	Total: Public %: Private %:		
Number of laboratory facilities	Total: Public %: Private %:		
Number of imaging facilities	Total: Public %: Private %:		
Number of pharmacies	Total: Public %: Private %:		
Number of health workers[1] (e.g., doctors, nurses, midwives, technicians, pharmacists, health extension workers) per 1,000 population	Total: Public %: Private %:		
Percentage of population covered by a public health insurance scheme			
Percentage of population covered by a private health insurance scheme			
Per capita income (nominal and purchasing power parity)	US$: US$:		
GDP growth rate (past 5 years for which data are available)[2]	%:		
Total health expenditure (THE) per capita	US$:		
THE as a share of GDP	%:		

[1] Include major categories of health workers only
[2] Usually available from the Ministry of Finance or Central Bank websites or from www.imf.org/en/data

Indicator	Measure	Year	Reference Document(s)
General government health expenditure per capita and as a share of THE	US$: %:		
Private health expenditure per capita and as a share of THE	US$: %:		
External health expenditure per capita and as a share of THE	US$: %:		
Out-of-pocket expenditure on health per capita and as a share of THE	US$: %:		
Degree of government decentralization (e.g., federal system with primary responsibility for health at the local level)			
Key political stakeholders and the dynamics among them (e.g., prime minister, MOH, local governments with high levels of autonomy over health governance, including regulation)			

Using the data collected in Tables 2 and 3, briefly summarize the context and rationale for regulation.

Secondary-Source Findings: Regulatory Landscape

This section provides an overview of the country's regulatory landscape.

Regulatory Efforts to Date

Use Table 4 to summarize the regulatory mechanisms, regulatory instruments, targets of regulation, rationale for instruments and targets, status of implementation, changes over time, and reference documents. The table includes sample content in *italics*.

Table 4. Regulatory Mechanisms

Instrument(s)	Target(s)	Rationale[3] *(Stated or Inferred)*	Implementation Status	Source(s)
Mechanism: **Command and control**—legal requirements accompanied by sanctions for noncompliance				
Law requiring licensing of health personnel or minimum facility conditions *Law establishing a right to quality health care, with definitions that might include maximum waiting times* *Law stipulating geographic distribution of public and private facilities* *Law requiring facilities to post and comply with the official fee schedule*	*Health personnel*	*To improve the quality of care in line with objectives stated in the health-sector strategy*	*Law passed by Parliament in 2002 and implemented in phases starting in 2004, with the aim of licensing 50% of facilities and health personnel by 2006. In 2006, the implementation process was changed because licensing was burdensome for the MOH. An external regulatory body took on licensing and from 2006 to 2010 licensed remaining facilities and personnel previously unlicensed by the MOH.*	*Law 805-02.A, Health Sector Strategy 2000–2010*
Mechanism: **Incentives (financial)**—financial rewards or penalties to influence provider behavior				
Performance-based payments to private providers who meet quality indicators *Public-sector contracts with private providers who meet certain quality (certification or accreditation) or performance requirements* *Low-interest government loans to private providers to encourage growth in the private health sector*	*Private providers*	*To improve the quality of private-sector care and promote growth of the private sector*	*NHIS began using performance indicators developed by the MOH to contract with the private sector in 2011.*	*NHIS contracting manual (2011), Health Sector Strategy 2010–2020*

[3] Often stated in the introduction or preamble of the law or regulation

Instrument(s)	Target(s)	Rationale[3] *(Stated or Inferred)*	Implementation Status	Source(s)
Mechanism: **Incentives (nonfinancial)**—nonfinancial rewards or penalties to influence provider behavior				
Training and development opportunities for private providers in rural areas *Government-disseminated facility performance reports to educate consumers and induce competition among providers* *Government recognition of high-performing facilities using a "seal of approval" or star rating*	*Private providers and facilities*	*To improve the quality of private-sector care and promote growth of the private sector to serve populations not currently reached by government services*	*Health Facility Regulatory Council began working with the MOH to develop star ratings in 2012. This developed into a Health Facility Regulatory Council accreditation strategy that was launched in 2013.*	*Health Facility Regulatory Council accreditation strategy (2013)*
Mechanism: **Self-regulation**—standards set by provider or professional groups for their own members				
Voluntary facility accreditation and personnel certification (and recertification) by professional organizations *Standard treatment guidelines issued by professional organizations* *Peer review from professional organizations*	*Facilities and personnel*	*To improve quality of care*	*Professional midwives' organization developed standard treatment guidelines in 2012 and met with the MOH in 2013 to launch them.*	*Midwifery standard treatment guidelines (2013)*
Mechanism: **Other**				

Regulatory Actors and Resources

Describe the actors and institutions that are responsible for developing and implementing the regulations documented above, the resources available to them, and how they interact or conflict. Use Table 5 to document this information. (The table includes sample content in *italics*.) Also develop a hand-drawn or digital map that illustrates the relationships among the regulatory actors and the areas of overlap or conflict.

The following are typical regulatory actors and relevant questions about them.

National Government

- Developing Regulations
    - What legislative bodies are responsible for updating and developing new health-sector regulations (e.g., health committee of the national assembly)?
    - How do the legislative bodies solicit input from stakeholders?
    - How are regulations or changes to regulations proposed (by the legislature, MOH, or other)?
    - How do the executive bodies solicit input from stakeholders or propose regulations or changes to regulations?

- Implementing Regulations
    - What national ministry or agency has primary responsibility for regulating the health sector?
    - What units or departments are responsible for regulation, and where are they in the hierarchy of the ministry or agency?
    - What is the role or mandate of the ministry/unit?
    - What laws, if any, stipulate the role of the ministry/unit?
    - What is the ministry/unit's relationship with other regulators (e.g., health financing agency, consumers)?

National Health Financing Agency

- What is the regulatory role or mandate of the agency?
- What laws, if any, stipulate the regulatory role of the agency?
- Describe the agency's relationship with other regulators (e.g., MOH, accreditation organizations).

Subnational Government

- Developing Regulations
    - What legislative bodies are responsible for updating and developing new health-sector regulations (e.g., state health committee)?
    - How do the legislative bodies solicit input from stakeholders?
    - How are regulations or changes to regulations proposed (by the legislature, MOH, or other)?
    - How do executive bodies solicit input from stakeholders or propose regulations or changes to regulations?

- Implementing Regulations
    - What subnational body has primary responsibility for regulating the health sector?
    - What units or departments are responsible for regulation, and where are they in the hierarchy of the subnational body?
    - What is the regulatory role or mandate of the subnational body/unit?
    - What laws, if any, stipulate the regulatory role of the subnational body/unit?
    - Describe the subnational body/unit's relationship with other regulators (e.g., MOH, accreditation organizations).

Statutory Boards[4]

- What is the regulatory role or mandate of the board?
- What laws stipulate the regulatory role of the board?
- How is the board governed? What unit appoints board members? What unit does the board report to?
- Describe the board's relationship with other regulators (e.g., MOH).

Accreditation Organizations

- What is the regulatory role or mandate of the accreditation organization?
- What laws, if any, stipulate the regulatory role of the accreditation organization?
- How is the accreditation organization governed? How, if at all, are board members appointed? Who or what unit does the board report to?
- Describe accreditation membership.
- Describe the accreditation organization's relationship with other regulators (e.g., health financing agency, MOH).

Professional Associations

- What is the regulatory role or mandate of professional associations?
- What laws, if any, stipulate the regulatory role of professional associations?
- How are the professional associations governed? How, if at all, are board members appointed? Who or what unit does the board report to?

[4] Autonomous bodies created through legislation to perform a specific function, such as overseeing the safety of drugs and medical equipment

- Describe the relationship of professional associations with other regulators (e.g., MOH, consumers).

Consumers

- What role, if any, do consumers play in helping to regulate the health sector (e.g., complaints, lawsuits, representation on boards or commissions)?
- What civil society organizations, if any, represent consumer interests, and what role do they play?
- What laws, if any, stipulate consumer rights in terms of health care?

Table 5. Roles of Regulatory Actors

Regulatory Actor	Regulatory Role		Interaction with Other Actors (Collaborations or Conflicts)
	Development	Implementation	
National government (specify ministry and unit/department)			
National health financing agency			
Subnational government			
Statutory boards			
Accreditation organizations			
Professional associations	*Advocate for representation on the MOH regulation development steering committee. Attend MOH-led stakeholder meetings to give feedback on regulation development.*	*Provide education and training to members on regulations.*	*Not included in development and implementation of regulations developed by the national health financing agency. Work collaboratively with the MOH, which relies on professional associations to represent providers and disseminate information about regulations to association members.*

Consumers / civil society organizations			
Other			

Use Table 6 to document the resources available to the regulatory actors. (The table includes sample content in italics.)

Table 6. Resources for Regulation

Regulatory Actor	Technical and Support Staff (numbers and qualifications)	Budget (US$ and Source)	Other Resources
National government (specify ministry and unit/department)			
National health financing agency			
Subnational government			
Statutory boards			
Accreditation organizations	*5 accreditation officers 3 support staff (drivers, office support)*	*$10,000 annually, raised through fees*	*Vehicles and fuel for monitoring visits Paper forms or electronic tablets for recording results of monitoring visits*
Professional associations			
Consumers / civil society organizations			
Other			

Data for Tracking and Reporting on Regulatory Efforts and Performance

Describe the data sources for tracking and reporting and related processes. Use Table 7 to document this information. (The table includes sample content in *italics*.)

Key questions include:

- What information systems are used to track regulatory efforts (e.g., online databases, registers)?
- How often is the information collected (e.g., monthly, quarterly, annually)?
- Where, if at all, is information on health-sector regulation published or publicly available (e.g., annual reports, website)?
- What kind of information is published or publicly available?
- Are dedicated staff or funds available for tracking and reporting?

Table 7. Regulatory Activities and Performance

Regulatory Activity	Performance Indicators (show numerator and denominator if possible)	Performance Period	Source
Applications to open new facility processed	*50% (20 out of 40) of applications received in 2016 evaluated*	*Jan–Dec 2016*	*Internal tracking system*
Accreditation surveys conducted			
Facility inspections conducted			
Sanctions imposed on facilities for failed inspections			
Complaints received			
Complaints reviewed			
Sanctions imposed on facilities due to complaints			

Sanctions imposed on provider personnel due to complaints			
Incentive payments made for achieving quality or other targets			
Other			

Using the information collected about the regulatory landscape, briefly summarize the findings. Consider the following questions:

- How do existing health-sector regulations align with broader health system objectives?
- What is the rationale for the regulations currently in force?
- How have existing regulatory efforts evolved over time?
- What was the rationale for adding or modifying previous mechanisms and instruments?
- Describe the balance between incentive and command and control regulations.
- To what extent do regulations govern a mix of health system inputs (infrastructure and staffing), outputs (type or number of services delivered), and outcomes (quality of care indicators)?
- How effective is the division of regulatory responsibilities? Are there duplications or gaps?
- To what extent does the regulatory role of the government align with its capacity?
- How, if at all, do resource constraints affect the effectiveness of health-sector regulations?
- What information systems are in place to routinely track and report on regulatory efforts?
- To what extent do performance indicators show that regulatory actors are active (e.g., proactively visiting poorly performing facilities) or passive (e.g., awaiting complaints)?

Primary-Source Findings: Implementation and Performance of Regulatory Activities

This section documents how current regulatory activities are being implemented in practice and identifies gaps between theory and practice. It relies on primary data collection from

interviews with key stakeholders (including policymakers, regulatory unit staff, regulatory targets, legislators, consumers, academics, and media).

Use Table 8 to document important information from interviews about the status of health-sector regulation and regulatory performance. Use this information to write a brief summary of the findings. The table includes sample content in *italics*.

Table 8. Implementation and Performance of Regulatory Activities

Stakeholder	Interview Date	Are regulations fulfilling their mandate? 1 = strongly disagree 2= disagree 3 = neutral 4 = agree 5 = strongly agree	Implementation and Performance Strengths	Implementation and Performance Weaknesses	Suggested Changes
Regulators *Members of MOH M&E Unit*	*10 April 2017*	*5*	*Accreditation protocol is thorough*	*Misalignment of MOH licensing and NHIS credentialing processes Accreditation applies only to tertiary hospitals*	*Streamline licensing and credentialing process—empower external regulatory agency to run the process and require MOH and NHIA to use the results Meet with private-sector representatives to ensure that they have opportunities to provide input on streamlining licensing/ credentialing processes*
Regulatory targets (e.g., representatives of professional or provider association)					
Consumers (e.g., as represented by civil society organizations)					

Stakeholder	Interview Date	Are regulations fulfilling their mandate? 1 = strongly disagree 2= disagree 3 = neutral 4 = agree 5 = strongly agree	Implementation and Performance Strengths	Implementation and Performance Weaknesses	Suggested Changes
Academics (e.g., key professors at medical training institutions)					
Legislators (e.g., members of health or social sector committees)					
Media (e.g., radio, newspapers, TV, or web-based media covering health issues)					

Confidentiality

In writing the assessment report, it is important to safeguard the confidentiality of participants. Avoid attributing specific quotes, paraphrases, or opinions to an individual without that person's express permission. It is acceptable to link opinions with stakeholder groups, however, using terms such as *all*, *most*, *many*, *some*, *few*, or *none* to describe the proportion of the group that expressed a particular opinion (e.g., "Nearly all private-sector providers expressed frustration with the sporadic nature of facility monitoring visits. This view was shared by many public-sector providers.")

Conclusions

This section synthesizes the findings from the earlier sections and assesses key strengths and weaknesses of the overall regulatory system, highlighting issues related to the regulation of private providers. The following questions may be helpful in synthesizing the information.

- Explain the lessons learned from implementing health-sector regulation, particularly related to the private health sector.
  - What are the major successes of regulation efforts in your country?
  - What are the major weaknesses?
- What could policymakers have done differently to implement a more effective regulatory system?
- What recommendations would policymakers in your country make to policymakers in other countries to implement an effective regulatory system?

Recommendations

This section should identify approaches for improving the regulatory system based on the strengths and weaknesses identified in the preceding sections. Use Table 9 to briefly describe several recommendations for improving the overall system, highlighting changes that will specifically strengthen regulation of private providers. (The table includes sample content in *italics*.) Consider how the recommendations might be prioritized. Write a brief narrative to accompany the table in the report.

Table 9. Recommendations

Recommendation	Rationale	Impact on Private Health Sector	Priority Level
Advocate for a budget line item to fund staff and resources for the MOH's quality monitoring efforts.	*The government has a well-designed facility accreditation program and legal authority to enforce sanctions for noncompliance, but it lacks the resources to conduct accreditation and monitoring visits.*	*As more resources become available to accredit and monitor private facilities, the network of facilities from which the government can purchase high-quality health services will become more robust.*	*1*
Strengthen capacity to design, award, and enforce contracts with accredited private providers to deliver PHC services.	*The few current contracts with the private sector are not well designed or enforced, resulting in inefficiencies and quality-of-care issues.*	*Effective enforcement of contractual requirements will improve quality of care as providers compete for bids.*	*2*

References

This section should include all source citations, preferably in the form of endnotes rather than footnotes, and should be on a separate page after the end of the main text. Carefully review the accuracy, completeness, and consistency of all citations and use a standard note style. An additional bibliography is not necessary.

ANNEX A. PLANNING TEMPLATE

Implementation Step		Planning Questions	Responses	Proposed Timeline	Questions/ Notes
1	Obtain funding and authorization	Do you anticipate a need for funding to implement the assessment? If so, what expenses do you expect to have?			
		What funding sources might be available?			
		What do you need to do access the funding sources listed above?			
		Does your institution require formal approval from management or leadership before beginning new research studies?			
		Does your institution require ethics review of new research studies? If so, what materials do you need to submit to the review board?			
2	Form and orient a research team	Designate a principal investigator (lead researcher) to manage implementation of the assessment.			
		What institutions would ideally be involved in preparing the assessment? (You will specify their roles in steps 4–8 below.)			
		Will you include a representative of the private sector on the assessment team?			
		What is the capacity of the actors and institutions above to participate in preparing the assessment (e.g., time, expertise)?			
		Do you plan to engage a consultant to assist with preparing the assessment?			
3	Prepare to collect data	Based on the research methodology provided in this document, do you anticipate conducting individual interviews, group interviews, workshops, or focus group discussions?			

Implementation Step		Planning Questions	Responses	Proposed Timeline	Questions/ Notes
4	Conduct document review	What types of documents and records are easily accessible for review?			
		What types of documents and records might be challenging to obtain?			
		Who will identify and then collect relevant documents?			
		How will collected documents be filed and organized?			
		Who will review documents and records, and how will that person keep track of findings?			
5	Conduct interviews	Who will identify potential participants for interviews and/or workshops?			
		How will the potential participants be identified?			
		Who will handle the logistics of interviews and/or workshops (e.g., scheduling, booking the location, ordering refreshments)?			
		Who will conduct the interviews and/or moderate the workshops?			
		Who will take notes during interviews and/or workshops?			
		Will interviews, focus group discussions, and/or workshops be audio recorded? (*Note: This approach is not recommended but may be a country preference.*)			
		If yes, who will transcribe the interviews?			
		How will interview notes/transcripts be organized?			
		Who will complete the tables and answer the questions in the assessment guide?			
6	Analyze and synthesize the data	Who will analyze the data?			
		How will the data be analyzed (e.g., cross-referencing documents and interviews)?			

Implementation Step		Planning Questions	Responses	Proposed Timeline	Questions/ Notes
		Who will synthesize the conclusions and develop recommendations?			
		How will conclusions and recommendations be validated (e.g., stakeholder workshop, assessment review process)?			
7	Write the assessment report	Who will write the draft assessment report?			
		Who will review and provide comment on drafts of the assessment report?			
		Who will proofread and format the assessment report?			
8	Disseminate the assessment report	How will you validate the findings of the assessment before publication of the report?			
		Who will approve the final assessment report for publication?			
		How do you plan to disseminate the final assessment report within the country?			
		Who will be the target audiences of the assessment?			
		How will you ensure that the assessment translates to follow-up action?			
		How will you obtain funds for dissemination efforts?			

ANNEX B. TERMS OF REFERENCE

Term	Definition
accreditation	The process of ensuring that facilities or practitioners meet a base level of quality or training.
decentralization	The transfer of power and accountability to lower levels of a system. Decentralization policies range from the transfer of limited powers to lower management levels within current health management structures and financing mechanisms to political transfer of responsibility for government health service delivery from the national government to subnational governments (such as state, province, or municipality).
external health expenditure	The sum of spending on health services and goods by foreign agencies such as government donors or external charities.
general government health expenditure	The sum of outlays by government entities to purchase health care services and goods.
gross domestic product (GDP)	An aggregate measure of the value of production within a country.
infant mortality rate	The probability of a child born in a specific year or period dying before reaching the age of 1, if subject to age-specific mortality rates of that period.
maternal mortality ratio	Number of maternal deaths per 100,000 live births during a specified time period (usually one year).
out-of-pocket expenditure	Consumer spending for medical care that is not covered by insurance. Out-of-pocket expenditure includes deductibles, coinsurance, and copayments for covered services plus all charges for services that aren't covered.
poverty rate	The ratio of the number of people whose income falls below the poverty line, which is considered to be half the median household income of the total population. The poverty rate is also calculated by age group: children (ages 0–17), working-age adults, and the elderly (ages 66 and older). Note that two countries with the same poverty rate may differ in terms of the relative income level of the poor.
private sector	Generally, all nongovernment providers, including for-profit and nonprofit entities. In the health sector, these include private and nonprofit hospitals, doctors, and pharmacies; traditional healers; faith-based providers; private health insurance mechanisms (including community-based and employer-sponsored voluntary insurance); and corporate philanthropic providers.

Term	Definition
regulation	The imposition of rules backed by the use of penalties or incentives to ensure compliance with standards. In the health sector, these standards govern the safety and quality of health services (including diagnostics). Regulations may include licensing for the opening of a facility, provider certification or accreditation, and incentives to promote quality service provision. The common understanding of regulation centers on government activities that constrain behavior, also known as command and control mechanisms. Regulations can also promote behaviors through incentives. While the government may play a lead role in regulation, many other actors and institutions are involved, particularly in the health sector. These might include professional associations and consumer organizations. Health-sector regulation includes a wide range of regulatory activities and actors that affect both the public and private health sectors.
regulatory actors	Individuals and institutions that are responsible for regulation and regulatory efforts.
standard treatment guidelines	Systematically developed guidance that helps providers decide on appropriate treatments for specific clinical problems. Standard treatment guidelines usually reflect medical consensus on the optimal treatment options within a health system and aim to improve care delivery at all levels.
statutory board	An autonomous body created through legislation that performs a specific function, such as overseeing the safety of drugs and medical equipment.
private health expenditure	The sum of direct (out-of-pocket) household spending, private insurance premiums paid, charitable donations, and direct service payments made by private entrepreneurs.
total health expenditure (THE)	The sum of general government health expenditure, private health expenditure, and external health expenditure.
total population	For census purposes, all persons falling within the scope of the census. In the broadest sense, the total population may comprise all usual residents of the country or all persons present in the country at the time of the census.
under-5 mortality rate	The probability of a child born in a specific year or period dying before reaching the age of 5, if subject to age-specific mortality rates of that period.

ANNEX C. SAMPLE CONSULTANT SCOPE OF WORK

Assessment of Private Health-Sector Regulation in [COUNTRY]

Assessment Objective

The objective of this country assessment is to document the following:

- What types of regulations govern the private health sector in [COUNTRY]
- How have private health-sector regulations been implemented in [COUNTRY]
- What outcomes are achieved by regulations implemented in [COUNTRY]
- What resources are available for developing and implementing regulations in [COUNTRY]

Consultant Scope of Work

The Consultant will work in close collaboration with the country assessment team and technical facilitators to implement the assessment by carrying out the following tasks:

- Adapt the assessment guide to the local setting
- Review research documents and conduct qualitative data collection
  - Identify stakeholders to collect data from
  - Select the method of qualitative data collection (e.g., individual interviews, workshops, focus groups)
- Analyze and synthesize the data collected
- Draft and finalize the assessment report, which will include tables, charts, and narrative to summarize the findings as laid out in the assessment guide
- Present the results to interested stakeholders

Desired Qualifications

- Extensive knowledge of the health system, health system regulation, and private health sector in [COUNTRY]
- Experience with qualitative research design, data collection, and analysis, including conducting key informant interviews and focus group discussions
- Experience leading and facilitating research teams
- Excellent oral and written communication skills in the local language and in English
- Excellent Microsoft Office skills

- Proven ability to develop effective working relationships with government officials at all levels, local organizations, and other program partners
- Keen ability to anticipate next steps, demonstrate initiative, exercise discretion, apply sound judgment, and work well both independently and collaboratively as a member of a team

ANNEX D. SAMPLE TOPIC GUIDE

Standard Introduction

- Thank you for taking the time to meet with us today. Our names are [NAMES], and we work at [ORGANIZATION], focusing on [DESCRIPTION OF WORK].
- We are conducting an assessment of health-sector regulations in [COUNTRY] to help the government engage more effectively with the private sector and increase access to primary health care services.
- As part of this work, we are conducting interviews with a number of stakeholders involved in developing and implementing health-sector regulations, as well as stakeholders affected by health-sector regulations.
- We have a list of questions we'd like to ask you, and we encourage you to be candid with your answers and comments. There are no right or wrong answers—we are simply looking for your opinions and perspectives.
- We aim to keep this interview to [XX minutes]. Your responses will be kept private, and notes from the discussion will not be shared with anyone outside of our research team. Any information you provide will be combined with information collected from various other sources and will not be attributed to you personally. Your participation is completely voluntary.
- We would like to take notes during our discussion to ensure that we accurately capture the information and views you share. These notes will be for our team's use only. Is this okay with you?
- Do you have any questions for me before we begin?

Illustrative Questions

1) **Icebreaker:** To start, please describe your role at [UNIT/DEPARTMENT/AGENCY/ORGANIZATION].

2) **Question 1 (General):** Tell me about the most successful monitoring visit you have conducted in the past year.

   a) **Prompt 1:** What factors made the visit so successful?

   b) **Prompt 2:** What policy changes would be needed to replicate this success?

3) **Question 2 (Specific):** How, if it all, has the amount of resources available to support monitoring visits changed over the past year?

   a) **Prompt 1:** Have more staff been assigned to the unit?

   b) **Prompt 2:** Has the unit's budget increased?

   c) **Prompt 3:** Has additional equipment, such as vehicles or tablets, been acquired?

Standard Conclusion

- Thank you. Those are all the questions I have. Is there anything else you would like to add?
- [To NOTETAKER] Are there any points you'd like to clarify before we conclude the interview?
- Thank you again for your time and your willingness to speak with us today.
- We expect to publish this assessment report in [DATE].
- In the meantime, don't hesitate to contact us with any questions.

ANNEX E. KEY TERMS

accreditation. A formal process by which a recognized body, usually a nongovernmental organization (NGO), assesses and recognizes that a health care facility meets applicable predetermined and published standards.

capitation. Payment to a health care provider based on an agreed-upon amount per person covered or enrolled for a specified package of covered services.

credentialing. The process of obtaining, verifying, and assessing the qualifications of health care providers to authorize them to provide specific patient services.

decentralization. The transfer of power arrangements and accountability systems to lower management levels. In public health care, this ranges from the transfer of limited powers to lower levels within current health management structures and financing mechanisms to political transfer of responsibility for government health service delivery from the national government to subnational governments (such as states, provinces, or municipalities).

primary health care (PHC). The provision of outpatient nonsecondary and nontertiary preventive, promotive, and curative care, with a particular focus on ensuring the delivery of quality health interventions to address the highest disease burdens. PHC services include:

- **preventive services** that protect against illness or diseases (e.g., family planning, prenatal care, immunizations)
- **promotive services** that encourage well-being and healthy living (e.g., sanitation, good nutrition, smoking deterrence, mental health)
- **curative services** that treat and reduce the probability of disability and death due to entry-level and common high-burden diseases (e.g., deliveries, respiratory illnesses, childhood illnesses)

private health sector. Generally, all nonstate health providers, including for-profit and nonprofit entities. These include hospitals, doctors, pharmacies, traditional healers, faith-based organizations, private health insurance mechanisms (including community-based and employer-sponsored voluntary insurance), and corporate philanthropic organizations created by the private sector for social responsibility.

private-sector engagement. A government's deliberate, systematic collaboration with the private health sector according to national health priorities, beyond individual interventions and programs.

regulation. Broadly defined as the imposition of rules backed by the use of penalties or incentives to ensure compliance with standards. In the case of PHC, regulation covers the safety and quality of health services and diagnostics and may also include licensing for the opening of facilities, certification or accreditation of ongoing provision of services, and incentives to promote quality service provision.

regulatory mechanism. An activity, process, procedure, requirement, or standard that is used to regulate a targeted actor and/or activity.

regulatory regime. The actors involved in developing, interpreting, and implementing health-sector regulations.

universal health coverage (UHC). Ensuring that all people can use the promotive, preventive, curative, rehabilitative, and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.15 This definition of UHC embodies three related objectives:

- **equity** in access to health services: Those who need the services should receive them, and services should not be available only to those who can pay for them.
- **quality** of health services: Health services should be good enough to improve the health of those who receive services and should also ensure patient safety.
- **financial risk protection:** The charges to users for health services should not put them at risk of financial hardship.