# Legal Framework

1. The laws pertaining to the domestic production, importation, and distribution of pharmaceuticals and medical devices and supplies are readily available, clearly drafted, and easy to use.
   - A. Print copies of laws pertaining to pharmaceuticals, medical devices, and medical supplies are readily available to members of the legal profession, members of the health community, members of the business community, and the general public.
   - B. The laws and regulations are published in all official languages of the country, as well as in English.
   - C. The laws and regulations are available in print copies of the country’s legal register, as well as on an officially sanctioned, and regularly updated Internet website.
   - D. The laws and regulations related to the production, importation, and distribution of all forms of medical goods do not discriminate against potential health sector participants based upon ethnic, socio-economic, gender, national origin, socio-economic status, or any other basis.
   - E. The laws are based upon scientifically supported international best practices, such as the WHO’s International Pharmacopoeia quality assurance and dosage standards.

2. The legal framework fosters an efficient market for domestically produced medical goods.
   - A. Registration of domestically produced pharmaceutical products occurs with reasonable speed and is not excessively burdensome or expensive.
   - B. Regulatory standards related to pharmaceutical production are consistent with international best practice.
   - C. The law allows for the importation of active pharmaceutical ingredients (APIs).
   - D. Laws regulating the sale and distribution of pharmaceutical products, APIs, excipients, medical devices and medical supplies allow for competitive sourcing, certification of quality, and minimal tariffs and non-tariff barriers to importation.
   - E. Tariffs and non-tariff barriers do not actively or implicitly favor importation of pharmaceutical products over APIs.
   - F. The law establishes clear standards that are universally applied to all pharmaceutical producers with operations in the country.

3. The legal framework pertaining to the importation of internationally produced pharmaceuticals is in place.
   - A. The process for registering imported drugs in country is clear and publicly accessible both in hard copy and electronically in English.
   - B. Registration of imported drugs occurs with reasonable speed and is not excessively burdensome or expensive.
   - C. Shipment size and value limitations are not unreasonably restrictive.
   - D. The law provides the framework for the security requirements for shipping pharmaceuticals, especially controlled substances.
   - E. The law establishes a clear mandate within an agency to monitor shipments for counterfeit pharmaceuticals.
   - F. The law establishes a clear mandate and process for the customs authority to seize counterfeit pharmaceuticals.
   - G. The law requires importers to monitor shipments for the expiration date of pharmaceuticals.

4. The legal framework establishes a clear mandate for the jurisdiction of a drug and medical device regulatory agency.
A. The legal framework establishes a clear mandate outlining the jurisdiction of each of the agency’s regulatory arms.

B. The legal framework removes any ambiguities and overlapping jurisdiction, including but not exclusively matters pertaining to quality assurance, efficacy, consumer safety, etc.

C. The law clearly delineates the role and jurisdiction of agencies involved in regulation of drug and medical device importation.

D. The law clearly delineates the mandate for regulation of medical supplies.

E. The law establishes clear, simple, and universally-available dispute resolution procedures for agency decisions through an administrative forum that is appealable to a judicial body.

F. Automation plans are in place to add or improve automation where processes remain manual.

5. The importation of internationally produced pharmaceuticals is regulated effectively, and is conducted in a safe and economically efficient manner.

A. Trade laws protect access by domestic pharmaceutical and medical device manufacturers and distributors to APIs, pharmaceuticals, and medical devices.

B. Registration of imported pharmaceuticals occurs with reasonable speed and is not excessively burdensome or expensive.

C. Importation procedures are clearly defined and can be readily understood and complied with.

D. The regulatory agency is authorized to monitor the quality of imported ingredients.

E. The regulatory agency is authorized to prescribe the process of formulation of imported ingredients.

F. The Customs regulatory regime establishes a clear mandate for the seizure of counterfeit drugs.

6. Any and all SPS, standards, and technical (i.e., non-tariff) restrictions on the import of pharmaceuticals and medical devices are science-based, and do not artifically distort trade.

A. Phytosanitary standards conform to the International Pharmacopoeia product standards established by the World Health Organization

B. Restrictions regarding size, grade, and other qualitative factors are consistent with those imposed upon locally-produced like products.

C. Regulations and laws regarding the standards and technical requirements for the import or export of medical goods do not lead to restrictions in the volume of exports or imports.

D. Laws do not prevent the importation or usage of legally-produced generic drugs once efficacy has been established.

7. The country has established a regime of domestic laws, international treaties, conventions, and agreements that support international trade.

A. The country is a member of the WTO and/or regional trade regimes.

B. The country has developed bilateral trade relations with both inter-regional and extra-regional countries with large economies.

C. Copies of all trade and customs laws and procedures are widely available to all stakeholders through publicly-available and accessible channels.

D. The legal framework pertaining to international trade is clearly drafted, well organized by subject, with proper indexing and article headings.

8. The law pertaining to Customs and other border-inspection functions enables and supports free trade.

A. The law allows for acceptance of electronic admissions as a legal document

B. Time limitations for Customs to take administrative or enforcement actions are reasonable.

C. The law requires publication of fees and formalities connected with importation and exportation, and also requires publication prior to any fee changes.

D. The legal framework requires publication of all Customs rulings.

A. Print copies of law pertaining to IPR are readily available to members of the legal profession, the business community, and others with interests in bankruptcy proceedings.
B. New laws on IPR are published according to a uniform, timely and consistently implemented procedure (such as through regular publication of an official gazette).
C. Laws related to IPR are published in all official languages of the country and written in plainly understandable language.
D. Laws and procedures pertaining to IPR are available through a variety of publicly accessible means, including libraries, Internet sites, etc, and these are regularly updated.
E. Law pertaining to IPR is user-friendly -- clearly drafted, well-organized by subject, with a table of contents at the front, and with article headings.
F. Courts post or otherwise very clearly identify the fees, procedures, and costs involved with commencing a case involving IPR.

10. The patent law provides a scope of protection commensurate with international norms.
   A. Patent law requires that:
      B. A. The invention is new.
      C. B. The invention involves an inventive step.
      D. C. The invention has industrial application.
      E. D. The patent application disclose the invention in a manner sufficiently clear and complete for the invention be carried out by a person skilled in the art.
      F. The patent holder has the following exclusive rights concerning the patent invention:
         G. A. The right to make the invention.
         H. B. The right to sell the invention.
         I. C. The right to distribute the invention.
         J. D. The right to license the invention.
         K. E. The right to import the patented invention or products made from a patent process.
         L. A patent application must be filed within a specified period after the invention has been publicly disclosed or offered for sale or it may not be patented.
         M. A patent applicant need not indicate the best mode for carrying out the invention.
         N. Patent applications are reviewed by a patent examiner, or similar official, before being granted.
         O. The law provides very limited exceptions to patent rights and little or no use by others of the subject matter of the patent without the authority of the patent holder.
         P. Decisions issued as a result of such an appeal are published and made publicly available.
         Q. The term of protection for a patent lasts at least 20 years from the filing date.
         R. Compulsory licenses, if used, comply with international obligations, and the valuation of the fee is appealable within an administrative or judicial proceeding.

11. The legal framework for quality assurance is in place, as it pertains to pharmaceutical production, distribution, warehousing, transportation, and destruction.
   A. This law provides adequate protection to workers without creating unnecessary burdens for business.
   B. This law is consistent with international best practice.
   C. This law provides for a strict/reasonable level of inspections, or audits, of facilities, to ensure compliance.
   D. This law requires the destruction of expired or damaged products.
   E. The mandate for investigation and seizure of counterfeit drugs is clearly vested within the Customs agency for products during importation, or the medical goods regulatory body for all counterfeit drugs located domestically.

12. The legal framework is in place that regulates the standards for medical devices (locally produced or imported).
   A. The law provides for the regulation of medical devices.
   B. The law establishes standards for the production of medical devices.
C. This law provides the framework that regulates the use of recycled equipment.

13. Standards are in place regulating the transportation and storage of pharmaceuticals and other medical equipment/supplies.

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<td>A.</td>
<td>The law establishes minimum security protocols for active pharmaceutical ingredients.</td>
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<td>B.</td>
<td>The law provides standards for proper storage requirements in warehouse and on trucks, including but not exclusively refrigeration, ventilation, active ingredient expiration monitoring, etc.</td>
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<td>C.</td>
<td>The law provides the framework for packaging requirements.</td>
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<td>D.</td>
<td>The law provides the framework for shipping and handling requirements.</td>
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**Implementing Institutions**

1. The agency/agencies authorized to regulate pharmaceuticals and medical devices has adequate staff, training mechanisms, and processes in place to effectively regulate the industry without unnecessarily impeding health sector growth.

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<td>A.</td>
<td>The budget for the agency is allocated based upon needs, and is provided in a non-political manner.</td>
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<td>B.</td>
<td>Agency staff have a clear understanding of their agency's mandate, and actively work with the health sector to ensure sufficient pharmacovigilance and quality assurance standards.</td>
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<td>C.</td>
<td>Adequate levels of agency professional and administrative staff exist to administer the agency's mandate.</td>
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<td>D.</td>
<td>Agency staff have sufficient resources and training to accomplish their roles within the agency.</td>
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<td>E.</td>
<td>Any and all fees associated with agency investigations are clearly published, reasonable, and formal.</td>
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<td>F.</td>
<td>The agency has in place a mechanism for the private sector, civil society, and other members of government to raise competency and corruption concerns in a fair, protected environment.</td>
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<td>G.</td>
<td>Agency staff are vetted for prior criminal records and competency through a fair hiring process.</td>
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<td>H.</td>
<td>Where possible, the agency seeks to automate procedures and systems.</td>
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<td>I.</td>
<td>The agency head and their staff view their roles as administrative and ministerial.</td>
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2. The Ministry of Trade, Customs, and other institutions hold a clearly defined and adequately supported mandate to support the delivery of goods.

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<tr>
<td>A.</td>
<td>Intellectual property rights are enforced according to international standards.</td>
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<tr>
<td>B.</td>
<td>Compulsory licensing procedures and regulations are enforced consistently with international standards.</td>
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<td>C.</td>
<td>Policies are in place to impose or adhere to trade sanctions if necessary.</td>
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<td>D.</td>
<td>Collaboration exists among the Ministry of Health, Ministry of Trade, Customs, and all other agencies involved in the importation and regulation of medical goods.</td>
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3. The country's health commodity needs are supported by a public or private regional distribution center

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<td>A.</td>
<td>Warehouses and/or public distribution center(s) are adequately staffed.</td>
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<td>B.</td>
<td>Warehouses and/or public distribution center(s) have Standard Operating Procedures and training manuals in place.</td>
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<td>C.</td>
<td>Warehouses and/or public distribution center(s) have facilities to ensure that the quality of pharmaceuticals do not spoil (i.e. refrigeration)</td>
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<td>D.</td>
<td>Warehouses and/or public distribution center(s) have a set of agreed upon service levels with their clients to which they manage.</td>
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<td>E.</td>
<td>Warehouses and/or public distribution center(s) have inventory control procedures to track the expiration dates of products.</td>
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<td>F.</td>
<td>Warehouses and/or public distribution center(s) have appropriate technology.</td>
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<td>G.</td>
<td>Warehouses and/or public distribution center(s) for pharmaceuticals/medical supplies carry out periodic inventories.</td>
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H. Warehouses and/or public distribution center(s) for pharmaceuticals/medical supplies are audited periodically.

I. Warehouses and/or public distribution center(s) for pharmaceuticals/medical supplies have adequate security to protect against theft.

4. Warehouses and/or public distribution center(s) have processes in place to report on their service-level targets.
   A. Periodic reporting is in place to assess service levels.
   B. Reports are automated and publicly available.
   C. Report structure and accountability are in place for content, frequency of reporting, and responsible parties for ownership.

5. Public distribution centers are prepared to handle emergency situations requiring faster delivery (e.g., floods, pandemics, etc.).
   A. Processes and decision authority for emergency requests are clearly documented within standard operating procedures.
   B. Contingency planning has been completed to ensure the most likely emergency requests have been addressed.
   C. Adequate levels of reserve stock are held in regional distribution centers to plan for emergencies.
   D. Financing is in place to pay for emergency shipping and handling of goods.
   E. Communication with first-line, back-up distribution centers has been established in advance of emergency situation.
   F. Alternate delivery systems are available for delivery if standard systems are non-operational.

6. The Ministry of Health or relevant ministry provides oversight of the entire supply chain of pharmaceuticals and other medical goods.
   A. Standard Operating Procedures are in place.
   B. The ministry has a complete understanding of costs throughout the value chain: fuel, fees, informal payments, cost of alternate routes, warehousing, transport, etc.
   C. The ministry has an understanding of where bottlenecks exist and is working to alleviate them.
   D. Competition exists for the various costs throughout the supply chain: warehousing, transport, etc.
   E. Security is consistent and meets regulatory requirements throughout the supply chain.
   F. Issues of corruption within the supply chain are understood and being addressed.
   G. Drug selection committees are composed of impartial persons with the appropriate technical skills.
   H. Selection committee members are obliged to declare any conflicts of interest.
   I. Selection committee meetings take place on a regular schedule and are well-publicized so that the public can observe proceedings.
   J. Institutional checks are in place to ensure that decisions regarding drug selection are not discretionary, rather they are based on uniform criteria.
   K. Needs are reconciled with the resources being procured.
   L. Drug selection processes should ensure that the most cost-effective and appropriate drugs for a population’s health needs are chosen fairly.
   M. The degree of leakage within the supply chain is understood and being addressed.
   N. Metrics are captured on service levels and quality throughout the supply chain.
   O. Factors facilitating the sustainability of the supply chain have been considered and bolstered.

7. The process for requisitions from public health facilities, local distribution centers, and regional distribution centers is clearly defined and efficient.
   A. All paperwork is consistent and kept to a necessary minimum.
   B. Where possible, processes are automated to streamline the workflow and ease data collection.
Score

Delivering Goods

C. Automation plans are in place to add or improve automation where processes remain manual.
D. Formal hand-offs and sign-offs are date-stamped and witnessed.

8. Distribution centers and transport providers hire, train, and supervise staff based on international best practices.

A. Staff, especially subcontractors, are vetted for employment, credit, and criminal history.
B. Internal training programs maintain high levels of staff competency.

Supporting Institutions

1. The Bureau of Statistics, with the Ministry of Health, the distribution centers, and the health facilities, supports data collection around the delivery of goods.

A. Standard statistics and procedures for collection are set by the Ministry of Health.
B. Statistics collected are consistent with international best practice.
C. Distribution centers and health facilities collect and report all required statistics.
D. Mechanisms for data collection and reporting are automated.
E. Local analysis (i.e. health facility or distribution center level) is conducted for process improvement at the local level.
F. Macro analysis is conducted by the Bureau of Statistics with reporting to the Ministry of Health to evaluate the entire supply chain.
G. Household level national demographic and health surveys are completed on a periodic basis to provide policy makers information to assess the health needs of the country.
H. Facility-level surveys are completed to assess outcomes by facility, as well as capacity and quality of the infrastructure.
I. Patient surveys are completed to assess outcomes and perceptions by facility, region, etc.
J. Data regarding adverse drug reactions are monitored and aggregated.
K. Monitoring throughout the supply chain for delivering goods provides the information necessary on the efficiency of the infrastructure.
L. Data are easily disaggregated by region/district/locality to allow for evaluation of local needs.
M. Existing reporting structures meet the basic reporting needs of outside donors.
N. Reporting to the Ministry of Health and elected government officials occurs on a periodic basis.
O. The aggregated data sets are publicly available upon request free of charge or for a nominal fee.

2. The community of Customs Brokers/Agents, Freight Forwarders, and Security is sufficient to service the country and renders services in an efficient, transparent and lawful manner.

A. The quantity and quality of the following providers is sufficient, and their cost is reasonable:
B. i. Freight forwarders (logistics)
C. ii. Brokers/Agents (formalities)
D. iii. Security agents
E. Brokers/Agents and Forwarder operators:
F. i. Provide and maintain accurate data to Customs, including the classification, shipper and consignee name and address, first and second notification parties, description, weight, quantity, and unit of measure of cargo being cleared.
G. ii. are well trained and knowledgeable in Customs Procedures and tariff requirements.
H. iii. Implement know-your-customer rules or rules otherwise dealing with the reliability of clients.
I. iv. Are able to trace shipments to point of origin.
J. v. Report to Customs suspicious and irregular activities.
K. vi. Train importers and exporters regarding documentary procedures and requirements.
L. vii. Maintain automated interface with Customs
M. Experienced local consultants and service providers are available to assist with trade missions, marketing, and other trade promotion activities.
N. Brokers/Agents and Forwarder operators have an active and functioning organization that interfaces with Customs and other institutions.

3. There is an adequate supply of insurance providers for the trade in pharmaceuticals and medical devices and goods.
   A. The quality of insurance, bonds, and guarantee providers is sufficient.
   B. The quantity of insurance, bonds, and guarantee providers is sufficient.
   C. The cost of insurance, bonds, and guarantee providers is reasonable.
   D. Public domestic and/or international financial institutions provide assistance in obtaining insurance.
   E. Private insurance companies offer insurance products suitable for trade in pharmaceuticals and other medical goods.

4. A national public laboratory exists to support the drug regulatory agency.
   A. Processes for verifying the quality and efficacy of questionable goods are in place.
   B. Processes for verifying the quantity of questionable goods are in place.
   C. The public laboratory has adequate staff with sufficient training to meet existing needs.

5. There is an adequate supply of security providers for warehousing/distribution centers and transport.
   A. The quantity of security providers is sufficient.
   B. The quality of security providers is sufficient.
   C. The cost of security providers is reasonable.

6. There is an adequate supply of transportation providers.
   A. The quantity of transport providers is sufficient.
   B. The quality of transport providers is sufficient.
   C. The cost of transport providers is reasonable.
   D. Transport routes are mapped out and without significant risk of theft or bribe solicitation.

7. The Ministry of Transportation ensures that routes between the manufacturer/port, regional distribution center(s), local distribution center(s), and health facilities are sufficient and navigable year round.
   A. The Ministry of Transportation works with Law Enforcement to ensure safe passage along routes.
   B. The Ministry of Transportation has mechanisms in place to ensure the upkeep of routes (roads, rails, etc.)

8. Trade, industry, and medical associations effectively contribute to a business environment that supports the delivery of goods.
   A. Associations promote and herald their members who demonstrate high quality practices.
   B. In all viable sectors, trade, industry, and medical associations are active in public dialogue pertaining to opportunities in health.
   C. Trade, industry, and medical associations have affiliations with international health organizations and are involved in the harmonization of laws and practice with international standards.
   D. Trade, industry, and medical associations provide lists of professional service providers including doctors and nurses that can provide assistance to their members.
   E. Trade, industry, and medical associations effectively represent the private sector in public debate over updates and changes in legal framework pertaining to health.

Social Dynamics
1. NGOs, donors, and the private sector support regulatory and administrative capacity building and sustainability within the public sector rather than dependence.
   
   A. The Ministry of Health has a complete understanding of the roles of all NGOs and donors that are in place, actively coordinates donor support activities, and has established a strategy emphasizing sustainable capacity strengthening processes.
   
   B. The private sector has direct, formal channels to identify and report upon capacity gaps within government entities.
   
   C. The government works with NGOs and donors in an attempt to make sure that efforts flow through established channels rather than building new infrastructure with the goal of capacity building and sustainability.
   
   D. NGOs and donors work together to make sure there is no repeating/duplicating of efforts.
   
   E. The donor community regularly interacts with local members of the health profession to ensure that their programs are effective and meet actual needs.

2. The government works actively with the international community to find solutions that balance intellectual property rights issues with the health needs of the country.
   
   A. The government allows for the use of generic pharmaceuticals when available.
   
   B. The use of legal lower-cost generics is encouraged within the formal sector.
   
   C. Information on quality assurance standards and procedures for branded pharmaceuticals and the efficacy of generics are publicly available.
   
   D. Public and private sector providers are encouraged to
   
   E. The government allows for the donation of products from foreign entities.
   
   F. Health service providers, including doctors, nurses, midwives, traditional healers, as well as the general public receive regular updates on the status of patented pharmaceutical products and medical devices.

3. Adequate communication channels exist between the Ministry of Health, Distribution Centers, and other agencies to avoid "stovepiping" issues.
   
   A. All parties have access to information regarding supply chain movements.
   
   B. Parties share information regarding supply chain movements and plan for future contingencies.

4. The reliability and cost of goods delivery does not discriminate based on region, ethnicity, class, gender, other affiliation, or extent of morbidity.
   
   A. Differences are recognized and compensated for.
   
   B. The taxing of pharmaceuticals and medical goods is not a significant impairment to access by consumers

5. Intellectual property rights are enforced, and the government is seeking innovative, sustainable solutions to accessible medical devices for all citizens.
   
   A. The government recognizes that intellectual property rights enforcement must not be sacrificed as it is an unsustainable resolution to high drug prices.
   
   B. The government has created a multi-sectoral strategy body, engaging members of the private sector as well as public sector and civil society to identify innovative solutions for lower-cost drug acquisition and distribution methods.
   
   C. The government is coordinating the response of donor organizations to focus on sustainable infrastructure, workforce, and capacity investments in the regulation and delivery of medical goods.
   
   D. The government has reviewed local regulatory burdens to identify constraints that might be limiting private sector goods delivery within specific municipalities within the country.

6. The private sector is engaged by the government, and is seen within public health practitioners as a resource rather than a competitor.
A. Public health practitioners engage in a periodic discussion open to private sector stakeholders to discuss breakdowns within the drug supply chain and identify potential short and long-term solutions.

B. The public health sector engages the private sector in distribution of medical goods via concessions, procurements, and social marketing campaigns.

C. The public health sector does not seek to “crowd out” private sector participation, but instead seeks to encourage more users to seek private sector services.
## Developing Human Capacity

### Legal Framework

1. The source of authority for professional medical licenses, pharmaceutical licenses, nursing certifications, and all other prerequisites to practicing in a medical profession, is clear and accessible.

   - A. Medical registries have a mandate to issue, archive and monitor professional licenses.
   - B. The medical certification process (e.g. registration, testing & examination scores) is confidential and restricted to key personnel.
   - C. Qualification of medical professionals are standardized and verified regularly, using international standards and/or best practices.
   - D. Re-certification and continuing education standards are in place, using international standards.
   - E. Mechanisms to receive/review complaints, request investigations and conduct hearings are in place and are standardized, using international standards and/or best practices.
   - F. Governing bodies are in place to support operating systems of various medical committees (e.g. Medical Professional Boards and Advisory Committees).
   - G. Administrative staff provide support to Medical Professional Boards and Advisory Committees.
   - H. Roles and responsibilities are clearly delineated throughout tiers of medical professionals (physicians, nurses, midwives, etc.).
   - I. An accreditation process is clearly articulated for all tiers of medical professionals.

2. The legal framework pertaining to foreign medical professionals operating in the country is in place.

   - A. Policies are in place to enable the employment of foreign medical health workers in the country.
   - B. The Ministry of Labor, or other agency, has standard procedures for verifying work permit, visa and/or other authorizing documentation to practice.
   - C. The National High Commissioner, or other agency, implements standard procedures for verifying professionals qualifications from the relevant home country.
   - D. The Ministry of Health, or other agency, has standard procedures for medical professionals to pass national testing requirements for accreditation to practice.
   - E. Medical registries issue, archive and monitor professional licenses.
   - F. Functional language proficiency is standardized.
   - G. Foreign medical practitioners are able to establish a private practice according to a clear set of regulations.
   - H. National policies encourage the inflow of foreign medical practitioners into medical practice areas experiencing human capital shortages.

3. Laws and regulations pertaining to labor and employment are readily available, clearly drafted, and easy to use.

   - A. Print copies of labor and employment laws, occupational safety and health, wages, hours, social security, and employment in the health sector are readily available.
   - B. Data pertaining to qualifications, evaluation performance measures and malpractice are captured, evaluated and tracked.
   - C. Laws relating to wages and severance packages protect employees, but are not so punitive so as to discourage employers from employment termination.

4. The legal framework pertaining to the accreditation of medical academic institutions is in place.

   - B. Input of core curriculum includes the Ministry of Health, National Medical Council, or other agencies.
C. Input of competent medical professors includes the Ministry of Health, National Medical Council, or other agencies.
D. Bribes/Informal payments are not an issue for awarding accreditation to medical academic institutions.
E. Political influences are not an issue for awarding accreditation to medical academic institutions.
F. An accreditation process is clearly documented for academic institutions.
G. The laws associated with accrediting a medical academic institution are consistent with international best practices/standards.
H. The laws associated with accrediting a medical academic institution do not discriminate against foreign students.
I. The laws associated with accrediting a medical academic institution are widely available to all interested stakeholders; clearly drafted, well organized by subject, with proper indexing, and with article headings; and regularly updated by practical-minded experts.

5. The legal framework pertaining to paraprofessionals operating in the country is in place.

A. Health registries issue, archive and monitor paraprofessional licenses.
B. Certification are standardized and are in place, using international standards.
C. The Ministry of Health, or other agency, understands the need for paraprofessionals to complement the work of their medical professionals.
D. The Ministry of Health, or other agency, allocates resources to deploy paraprofessionals in under-served areas.

6. Policies to decentralize public sector human capacity decision-making processes are in place.

A. Health care managers have funds to carry out decisions necessary to address the local context.
B. Health care managers have decision-making authority to carry out important human resource functions (hiring, firing, staff structures) according to local context.
C. Decentralized decision-making does not result in significant variation in the quality and availability of medical personnel across the country.

7. National planning policies pertaining to the equitable distribution of public sector health staff are in place.

A. Staffing decisions are based on regional and demographic demand.
B. Staffing decisions are based on public/private complementarities.
C. Staffing decisions are based on allocative efficiency.
D. Staffing decisions made in collaboration with the Ministry of Education, Ministry of Health, and Labor Office.
E. Staffing decisions are made based upon regional and local need.

8. National policies pertaining to information availability on public sector staff expenditures (including salaries, allowances and other benefits) are in place.

A. Comprehensive information regarding employment cost data is available.
B. Donor agency subsidies are built into employment cost estimates.
C. Information is available to those making decisions on the allocation of salary and non-salary budgets.

9. National policies pertaining to pay and condition of service are in place.

A. The total value of rewards packages for public sector health worker benefits is known.
B. Retention strategies have been developed to address compensation disparities.
C. The use of pay incentives to attract workers to less desirable service areas is in place.
D. Staff are paid according to schedule.
E. Wage payment adjustments to account for performance bonuses or deductions for absenteeism are flexible.
F. The Ministry of Health, Labor, or other relevant agency permits "dual practice" by public sector medical personnel who are certified to hold a private practice outside of Government work hours.

Implementing Institutions

1. Medical registries or other national bodies that manage professional medical licensing and certifications within the health sector are well led, well organized, and endowed with sufficient resources to fulfill their mandates.
   A. Their head and management staff are non-political, and/or they view their role as ministerial.
   B. They have sufficient staff that are adequately trained.
   C. They have sufficient funding from a source that is not politically controlled.

2. Universities have adopted curricula using international standards to produce well qualified medical, public health/health policy/health management professionals.
   A. School curricula are up to date and are evidence-based.
   B. School curricula include adequate clinical training aligned with international standards.
   C. School curricula are developed based on current market demands.
   D. School curricula are adapted to meet the demands of regional environments (accounting for language needs) and demographic needs.
   E. Class schedules are tailored to the practical needs of the students, offering night classes or other practical solutions to promote accessibility.
   F. University and public libraries have current supplemental publications as references.
   G. Undergraduate and graduate research training opportunities are in place.
   H. Career development programs are established to encourage new professionals.
      I. Universities have opportunities to partner with 'sister' universities to share knowledge on curriculum development
      J. Universities have policies in place to ensure the pipeline of health professionals is adequate for the country's needs
      K. University professors contribute to national dialogue on health through research, publications, and symposia.
      L. There are enough places in teaching institutions to graduate as many doctors, nurses, and medical technicians as the local labor market demands.
   M. The Ministry of Health, or other agency, develops partners with foreign universities and hospitals to provide opportunities for further learning for medical professionals.

3. Medical facilities have staffing plans appropriate to their staffing needs where all resources are focusing on their competitive advantage skills
   A. Medical professionals spend the majority of their time delivering health services.
   B. Facilities management spend their time on facility administration, reporting, and general management.
   C. Operational staff focus on the other processes required to keep the facility running effectively (e.g. janitorial duties, laundry, etc.)
   D. Accountability for staff absenteeism (i.e. illness, attend funeral, informal days off, etc.) are anticipated and circumvented.
   E. Paraprofessionals spend their time delivering basic health services (also play triage role).
   F. Task shifting is emphasized and procedures are in place for implementation.

4. Teaching hospitals exist where medical practitioners hone their skills.
   A. Mentorship programs established to facilitate learning for new professionals are in place.
   B. Adequate staff to train new professionals are in place.
   C. Adequate resources (medical and laboratory equipment) are available to practice skills.
   D. Opportunities exist for doctors to perform research with student help.
Admission is merit based.

5. Programs / Research Institutes exist in country (for medical practitioners) to focus on specific areas of need identified as resource-poor.
   A. Programs/Research Institutes complement health institutions to advance health promotion and disease prevention.
   B. Programs/Research Institutes are adequately staffed.
   C. Programs/Research Institutes staff are adequately trained.
   D. Programs/Research Institutes have management that is adequately staffed.
   E. Programs/Research Institutes have management that is adequately trained.
   F. Programs/Research Institutes have facilities to ensure that the quality of equipment are calibrated, per international standards.
   G. Programs/Research Institutes understand the supply chain for goods and manage it to ensure that service deliveries are met.
   H. Programs/Research Institutes have modern technology to conduct laboratory experiments.
   I. Programs/Research Institutes for pharmaceuticals/medical/laboratory supplies carry out regular inventories, per international standards.
   J. Programs/Research Institutes for pharmaceuticals/medical/laboratories supplies are audited periodically, per international standards.
   K. Programs/Research Institutes for pharmaceuticals/medical/laboratory supplies have adequate security to protect against theft.
   L. Its head and management staff are non-political and/or they view their role as administrative and ministerial.
   M. Programs/Research Institutes have sufficient funding (through regional or national budget, fees for registration or other services, or both.
   N. Research/experimental findings are peer reviewed to maintain professional standards.
   O. Research/experimental findings are disseminated to the professional community.
   P. International research resources for knowledge management and development of human capital are accessible.

6. University facilities and services are in place to support the development of competent health professionals.
   A. Libraries are up to date with journals, books, and web access.
   B. Laboratories have adequate facilities to facilitate learning.
   C. Career development services are adequate.
   D. A dedicated budget is allocated to ensure upkeep of health resource facilities and services
   E. Medical/Health professionals are trained to teach students, using international standards (or best practices).
   F. Facility resources are adequate.
   G. Support systems in teaching and career counseling skills are available for lecturers and tutors.
   H. Medical schools are adequately funded, with faculties, facilities and other resources that are sufficient to build a well trained and sufficiently competent cadre of doctors and nurses.

7. University curricula include courses in support of business skills and legal skills training that support private medical sector service providers.
   A. Medical students are offered electives in basic team and financial management skills to prepare to manage a private practice.
   B. Attorneys at law schools are trained in Health law and advocacy within the health field.
   C. Hospital administrator professionals have specialized degrees within medical school or business school curricula.

8. Universities are innovating to produce paraprofessionals that can handle more routine healthcare tasks that do not require a doctor or nurse.
A. Curriculum is tailored and adequate for medical technicians (and other paraprofessionals), using international standards (or best practices).
B. Clinical practicum training conforms with international best practices.
C. Clinical practicum training processes are objectively evaluated to ensure quality standards and training effectiveness.
D. Clinical practicum trainees are held to a rigorous and objective testing standard.
E. Licensing practices are formalized and adhere to international standards.
F. Recruitment and retention measures are in place.
G. The medical technicians and other paraprofessionals are educated as to when referrals should be given.
H. Universities have opportunities to partner with ‘sister’ universities to share knowledge tailored for paraprofessional development.
I. Universities have harmonized training programs for producing medical technicians.
J. The curriculum for paraprofessionals focuses on primary care training vs. specialized care training.

9. The Ministry of Health and other agencies actively engage in human capital planning for the country’s public sector medical personnel.

A. The Ministry of Health manages a multi-year human capital planning process for medical personnel.
B. The Ministry of Health collaborates with the Ministries of Labor, Finance, Education and other stakeholders to develop a human capital plan which includes annual staffing targets.
C. The Ministry of Education, or other agency, partners with NGOs, hospitals and other health institutions to conduct career fairs or other networking opportunities to engage students in medical sciences.
D. The human capital planning process includes the Ministry of Finance and is reflected in the budget process.
E. The planning process includes statistics and projections from the private sector.
F. The planning process includes statistics and projections regarding the international movement of medical professionals both into and out of the country.
G. In the instance of a decentralized health system, the planning process includes local government decision makers.
H. The planning process includes regular meetings of stakeholders, action plans, and performance metrics.

Supporting Institutions

1. The Bureau of Statistics, in collaboration with the Ministry of Health, collects and synthesizes data associated with human capacity.

A. Staff resources and budgets are designated for the specific collection and management of health data supporting MOH policy objectives.
B. Standard statistics and procedures for collection are set by the Ministry of Health.
C. Statistics collected are consistent with international best practice.
D. Mechanisms for data collection and reporting are automated.
E. Local analysis (i.e. health facility or distribution center level) is conducted for process improvement at the local level.
F. Macro analysis is conducted by the Bureau of Statistics with reporting to the Ministry of Health to evaluate the national level of human capacity.
G. Human capacity is also evaluated at the regional and local levels to ensure gaps are known and addressed.
H. Enrollment, graduation, and general capacity figures from medical schools are analyzed to understand the potential for new professionals.
I. Data pertaining to the issue of competing jobs are captured and evaluated to assess impact on work performance and work fatigue (i.e. medical doctors also working as researchers).
Score

J. Data pertaining to the issue of gender-based work schedules (e.g. leave day differentials).
K. Data collected are analyzed, reported and disseminated to MOH and accessible to the public.
L. Data sharing policies are in place, giving researchers access to data sets immediately following data processing and validation exercises.
M. Data collected are relevant to MOH policy objectives.
N. Research institutions are involved in survey development and analysis efforts.
O. Statistics collected include the usage of private and public facilities, traditional health care facilities, etc.
P. Statistics are used by MoH in the development of strategies for the public and private health sector.
Q. Private sector statistics are incorporated into human capacity data.

2. Medical associations/unions play an active role in promoting the interests of medical professionals within the country.

A. Established Medical/Nursing Boards meet periodically to discuss how health and disease (both chronic and infectious) shapes practice.
B. Recruitment and retention mechanisms of medical professionals are established.
C. Community health committees allow community representation in health services.
D. Community health committees are used to identify training needs and service offering gaps.
E. Medical associations/unions are involved in strategic planning processes at the national policy level.
F. Medical associations/unions are involved in the development of university curriculum.
G. Community health committees discuss local health problems to allow curricula to incorporate local context.
H. Medical associations/unions are involved in advocacy efforts on behalf of medical personnel.

3. The public health communication system is in place to build the health knowledge base within the population.

A. The Ministry of Health or other agency builds capacity by training lay persons (and/or local celebrities) to become spokespersons about health-related issues.
B. School curriculum focus on health-related topics.
C. Clinics have sufficient health materials (written and visual) to distribute to attendees.
D. Partner with civil society, faith-based, and non-governmental organizations to spread health knowledge throughout the population.

4. NGOs and other civil society organizations coordinate foreign medical professionals to practice in the country for a period of time, either for particular experience, or service.

A. The Ministry of Labor, or other agency standardizes recruitment policies and statement of work of foreign medical professionals to practice in the country for a particular experience, or service.
B. Human capacity is evaluated at regional and local levels to leverage unique skills sets or competencies acquired from foreign medical and laboratory professionals.
C. Macro analysis is conducted by the Bureau of Statistics with reporting to the Ministry of Health to evaluate the national level of human capacity.
D. Foreign medical professionals are strategically placed to complement labor resource requirements and build human capital capacity.

Social Dynamics

1. The admittance of students into medical programs (i.e. medical school, nursing school, etc.) is merit based.

A. Student qualification is merit based.
B. Qualified students are not turned away do to lack of resources.
C. Qualified students are not considered ineligible due to regional, local and/or tribal affiliation.
D. Qualified students are not considered ineligible due to gender and class.
E. Bribes/informal payments are not an issue for admittance to medical programs.
F. Political influences are not an issue for admittance to medical programs.

2. The awarding of medical degrees is objective and merit based.
   A. Competencies of course curriculum are met, using international standards (or best practices).
   B. Bribes/informal payments are not used for awarding medical degrees.
   C. Competencies of course curriculum are met, using international standards.
   D. Political influences are not an issue for awarding medical degrees.

3. The majority of medical students expect to practice in country when receiving their degrees
   A. Incentives exist to retain talent
   B. Hospital and other medical/laboratory institutions partner with medical (and paraprofessional) schools to facilitate fellowship programs for entry-level medical professionals.
   C. The Ministry of Health has data on the salary differentials locally, regionally and overseas.
   D. Information/Studies are available on the salary differentials locally, regionally and overseas.
   E. Scholarship grants are awarded to support students with cost of medical education in exchange for years of service after graduation in country.

4. The degree to which traditional medicine is practiced, and demanded, is fully understood by the Ministry of Health.
   A. Traditional providers are educated as to when referrals should be given.
   B. The demand for traditional medicine is understood, whether cultural or cost-based.
   C. Public Health initiatives to improve health are disseminated in rural and urban communities.
   D. Traditional providers have a voice in local community health decisions.
   E. Traditional providers are targeted when starting community health programs.
   F. Information is available on the prevalence and use of traditional practitioners.

5. The issue of brain drain in the country is understood by the Ministry of Health.
   A. The Ministries of Health and Labor have programs in place to support retention.
   B. The Ministry of Health fully understands the salary differentials locally, regionally, and overseas.
   C. The Ministry of Health understands the issues of intra-country brain drain.
   D. The Ministry of Education, or other agency, fully understands the issue of seeking education abroad.
   E. The Ministry of Health, or other agency, understands issues of medical professionals with multiple jobs (i.e. medical physicians also working as research study physicians)
   F. Data pertaining to student satisfaction to pursue a medical career are captured and evaluated to mitigate disinterest.

6. Medical professionals with experience abroad are acclimated into the health sector.
   A. The Ministry of Health, or other agency, has standard recruitment and retention processes in place for returning medical professionals.
   B. The Ministry of Health, or other agency, understands issues for returning medical professionals and seeks opportunities to leverage their unique competencies.

7. The issue of human capacity differentials across the country are addressed.
   A. Urban and rural capacity differentials are understood and plans are in place to ensure adequate provision to all citizens.
   B. Regional capacity differentials are understood and plans are in place to ensure adequate provision to all citizens.
C. Professional discipline differentials (e.g. proportion of nurses to medical doctors) are understood and plans are in place to ensure adequate provision to all citizens.
D. Data pertaining to human capacity needs are evaluated to identify gaps.
E. The Ministry of Health, or other agency, understands issues of health disparities among all citizens seeking health care services.
F. Programs for rural/urban exchange of human resources exist.

8. The issue of language barriers is understood and programs are in place to mitigate this issue.
   A. The Ministry of Education, or other agency, partners with schools to mitigate language barriers.
   B. The Ministry of Education, or other agency, fully understands the issue of intra-country language barriers.

9. No restrictions on citizens ability to pursue and practice medicine is in place based on gender, region, ethnic, or other characteristic.
   A. The Ministry of Labor, or other agency policies are standardized that enforce no restrictions on citizens ability to pursue and practice medicine.
   B. Qualified citizens are not considered ineligible due to regional, local and tribal affiliation.
   C. Qualified citizens are not considered ineligible due to gender and class.

10. Gender, region, ethnic or other differences between patient and care giver do not cause problems for service delivery.
   A. Qualified medical professionals are not discouraged to practice in patient service delivery.
   B. The Ministry of Health understands the issue of gender differences between the patient and the caregiver and their interactions.
   C. The Ministry of Health understands the issue of ethnic or tribal differences between the patient and the caregiver.
   D. Services provided are culturally and ethically acceptable to patients.

11. Adequate communication channels exist between the Ministry of Health, universities, other agencies, and the private sector to avoid "stovepiping" issues.
   A. National policies outline strategic measures to provide infrastructure for medical professionals and medical facilities.
   B. The Ministry of Health and other institutions and agencies understand national, regional and local health needs.
   C. National, regional and local human capacity differentials are understood and plans are in place for established infrastructure to support needs.
   D. Executive Committee Boards across health institutions understands need for collaboration and consensus on mitigating disease and strengthening health promotion.
   E. Quarterly and annual progress reports of institutions activities are made available and disseminated across health institutions.
   F. Formal communication channels exist to share information between the Ministry of Health, universities, other agencies, and the private sector.
Accessing Finance

Legal Framework

1. Laws have been enacted that provide a legal framework for direct investment in the health sector, including special provisions for foreign direct investment.
   
   A. The legal regime for investment does not discriminate in favor of foreign investors against local investors.
   B. Investment laws support the principal of "open admission" to foreign investors.
   C. There is no unduly complicated or cumbersome admission requirements for investment.
   D. No special treatments are afforded foreign investors OR local investors regarding protection of person or property.
   E. Business licenses, import and export permits, and employment authorizations are provided on the basis of non-discrimination.
   F. There is no requirement of local participation in the ownership of companies or property, except in areas reserved to the state, if any.

2. The legal framework includes international best practices in investment protection.
   
   A. The country has a bilateral investment treaty in force with the European Union, the United States, neighboring countries, and other key trading partners.
   B. The International Center for the Settlement of Investment Disputes (ICSID) Convention has been ratified.
   C. The Multilateral Investment Guarantee Agency (MIGA) Convention has been ratified.
   D. An Overseas Private Investment Corporation (OPIC) program is in operation in country, hedging against political and currency risk.

3. There is a law on secured transactions, and it is readily available, clearly drafted, and easy to use.

   A. There is a law on secured transactions that specifically allows for the use of movable property as collateral to secure a loan.
   B. The types of property that can be used as collateral are clearly outlined in the law and include medical property, machines, and inventories of drugs and/or medical equipment.
   C. The law is current and is consistent with international best practice.
   D. The law allows for financing leases on medical equipment.
   E. The law allows the securitization of inventories.
   F. Print copies of law pertaining to secured transactions are readily available to members of the legal profession, the business community, and the health sector.

4. The law on secured transactions enables quick, inexpensive, and simple creation of a proprietary security right without depriving the person giving the security of the use of his or her assets.
   
   A. The framework law facilitates the creation of multiple kinds of relationships regarding secured interests, including direct personal guarantees, third-party guarantees, bank guarantees, etc.
   B. The framework law provides for adequate legal remedies for breach of a secured transactions contract as well as clear measures for calculating monetary damages if possession of the secured property is not reasonably possible.
   C. The law allows for non-possessory pledges in a variety of tangible and intangible property interests, including pledges of after-acquired property, values expressed in foreign currency, inventory, equipment, warehouse receipts, and other property.
   D. A general rather than specific description of assets is permitted in collateral agreements.
   E. A general rather than specific description of debt is permitted in collateral agreements.
   F. Any legal or natural person may grant or take security in the property.
G. The law recognizes that ownership or title is not necessary for a borrower to seek creation of a secured interest, instead recognizing that lawful possession can allow for the creation of such interest.

H. The law establishes that courts have a clear mandate, which is understood and accepted by the other bodies of the state, to interpret, apply, and enforce secured transactions law.

5. There is a clear and accessible body of supporting regulations for all law pertaining to secured transactions.

A. The law and related regulations create clear and easily understandable rules and procedures for registering a security interest and outline the consequences for registration and non-registration of such interests.

B. The fees associated with the registration of a secured interest do not discourage parties from registering such interests with the registry.

C. Collateral registries operate under clear and accessible rules of procedure, including unambiguous rules pertaining to administrative fees and costs.

D. Notaries and other officials involved in the creation of security interests operate under clear and accessible rules of procedure, including unambiguous rules pertaining to administrative fees and costs.

6. The legal framework provides for clear ownership and easy transfer of ownership rights.

A. An owner may transfer ownership to any other domestic or foreign individual or legal entity, without permission from the government or a government official.

B. Registration of real property is simple and inexpensive.

C. Sales and leases are commonly executed at freely negotiated prices and other terms and in the “normal course” of business.

D. Transaction costs such as appraisal, survey, notarial and registry fees, and lawyers’ fees do not represent an excessive part of the transaction value, and do not preclude or discourage deals.

E. The law provides for registration of land, buildings and fixtures together (unified registry).

F. The law provides for an official document to be issued to a land owner which certifies his registered legal rights.

G. The law guarantees public access to the registry records.

7. There is a legal framework pertaining to debt dispute resolution, and it is both efficient and effective.

A. There is an enforcement mechanism in place that requires patients to repay consumer debts to health service providers.

B. Copies of the law pertaining to creditors’ rights and debt dispute resolution are readily available to members of the legal profession, the business community and the general public, including in rural areas.

C. New laws are published according to a uniform, timely and consistently implemented procedure (such as through regular publication of an Official Gazette) and the law is published in all official languages of the country.

D. The procedures for court enforcement of a judgment are clearly outlined in the relevant law or in court procedure.

E. The institution responsible for enforcing court judgments, often the “Bailiff's office,” is vested with clear authority for enforcing court judgments.

F. The law clearly defines specific procedures for attachment of cash, accounts, intangibles, movable property, and real property.

G. The law adequately defines the roles of bailiffs (or similar judicial officers) in the enforcement process.

H. The law provides for the use of self-enforcing judgment orders instead of new and separate actions for enforcement.

I. The framework laws establish a system of sanctions for delays and failure to comply with procedure, rules or court orders, which, if applied, provide sufficient disincentives to discourage inappropriate behavior by parties and their attorneys.
8. The legal framework provides for the formation of well governed bank and non-bank institutions that foster financial intermediation and that give the medical sector broad access to financial services.

   A. There are laws allowing for the formation and operations of various financial institutions, including:
   B. (a) commercial banks
   C. (b) savings banks, including rural banks
   D. (c) credit unions or cooperatives
   E. (d) microfinance institutions
   F. (e) leasing companies
   G. (f) factoring companies
   H. (g) insurance companies
   I. Laws pertaining to the above institutions are current and regularly updated by practical-minded experts.
   J. Laws pertaining to the above institutions provide clear guidance pertaining to their internal governance that is consistent with international standards.
   K. The laws allow for multiple suppliers of the same financial products and services.
   L. The laws do not artificially restrict competition among various suppliers of financial products and services.
   M. The legislative framework clearly defines the process for entry and exit of banks and non-bank financial institutions, as well as minimum capital requirements, prudential regulations, and reporting obligations.
   N. There is a legal distinction between a microfinance institution and a commercial bank or cooperative.
   O. The laws provide for exceptions or exemptions for intermediaries operating below established minimum capital, or other thresholds, where activities present limited risk to financial sector stability.

9. The legal framework empowers banking and financial sector regulators to maintain stability through reasonable regulation and enforcement.

   A. The law clearly identifies the financial system regulators, their powers, and the scope of their authority as the supervising agency.
   B. The law clarifies the roles and responsibilities of different agencies involved in financial sector supervision.
   C. The law specifies a clear and consistent process for the issuance of financial-sector regulations and guidance.
   D. The law authorizes the necessary tools and resources to verify compliance with regulations.
   E. The law provides the regulators with sufficient authority to take action to remedy and enforce compliance with regulations.
   F. The law provides authority to suspend or terminate the operating license with due process.

10. At least a basic system of credit reporting exists.

    A. There is at least one credit bureau, and most banks use it regularly.
    B. Credit bureau staff are sufficient and adequately trained to ensure strong customer service.
    C. Credit bureau management and directors are adequately trained for their roles and are not just political figures.
    D. The information contained in a credit bureau is secure and reliable both as a result of the integrity of the bureau staff as well as the quality of the IT systems.
    E. There is a process for review of a negative, adverse, or erroneous credit report, and it is accessible, understandable, transparent and can be completed in a reasonable amount of time.
    F. Credit reports are provided in a reasonable amount of time for a reasonable fee through a straightforward process.
11. Health care providers are generally confident of reasonably swift and simple reimbursement for services

A. If a system of medical insurance exists, it provides for rapid reimbursement of outlays
B. Insurance-related disputes can usually be resolved quickly, whether in court, by ADR, or by some other means.
C. Factoring companies assist drug suppliers in accessing business credit within one week of selling goods to retail pharmacies

12. The legal framework for finance is friendly to innovation and flexibility.

A. Laws do not set interest rate caps or create other unnecessary obstacles to serving high-cost clients.
B. The development of financial sector law and policy is mindful of the beneficial aspects of accessible new technologies, such as cell phones and internet-based services.
C. Laws enable access to funds from remote locations, such as through the use of cell phones and other electronic services.
D. The legal framework adequately addresses electronic transactions of all kinds, including electronic signatures of contracts, to allow for use of those transactions to complete secured transactions.
E. There are modern leasing and factoring laws which support the creation of secured interests using those assets for security.
F. There is a law on franchising agreements that is in-line with international best practices.

Implementing Institutions

1. Commercial banks, rural banks, credit unions, microfinance institutions and other formal lending institutions are capable of efficiently and transparently executing loans to health private sector organizations based on moveable property.

A. Banks and other financial institutions only require a general description of moveable property to be used as collateral.
B. Banks and other financial institutions only require a general description of moveable property to be used as collateral.
C. Banks and other financial institutions provide clear and consistent information to borrowers about their obligations, the mechanics of repayment, and the consequences of default.
D. Banks and other financial institutions provide clear and consistent information to borrowers about their obligations, the mechanics of repayment, and the consequences of default.
E. SMEs, including rural healthcare facilities, have relatively equal access to loans in comparison to large companies and multinationals.
F. Loans to SMEs, including rural healthcare facilities, entrepreneurial medical professionals and local retail pharmacies, are issued at reasonable rates.

2. The courts are regarded as an appropriate institution for resolving disputes related to financing, where self-help or informal means of enforcement are not successful or available.

A. Lawyers and commercial actors report that, if they go to court, they can expect to receive a just decision, grounded on published laws, regulations and standards, in a timely manner.
B. Court fees for commencing a lawsuit regarding debt collection are relatively inexpensive and do not act as a disincentive for parties to use the courts for contract disputes.

3. The government has a fair and effective process for adopting and revising policy and law pertaining to the flow of credit and funding into the medical sector.

A. There is a well understood health sector policy development process, which includes access to finance as a policy goal.
B. A Public Private Partnership dialogue exists which provides financial incentives to increased private sector participation, including low-credit access to finance, tax incentives, and other similarly designed incentives.

C. The government (through a specialized unit or formal committee structure) has the technical capacity to draft laws and regulations that are needed for effective financial flows within a modern health sector.

4. There is a competitive, functioning commercial banking sector with services that meet the needs of different segments within the health sector.

   A. Banks operate within a clear regulatory framework.
   B. There is significant breadth within the banking sector that enables competition for the provision of services to the private sector.
   C. The banking sector is predominantly privately owned.
   D. Banking services are available in all regions of the country, including urban, suburban, and rural areas.
   E. Banks are an integral part of an efficiently functioning payment system.
   F. Where there is a significant Muslim population, banks offer loans and other services that are Shari'ah-compliant.
   G. Small, uncollateralized, or less-than-normally collateralized loans are available and accessible to rural providers of health services, such as midwives, small-scale local drug distributors and pharmacies.

B. Accessing Finance

5. Banks and other financial institutions offer adequate and varied services to pharmaceutical and medical goods importers, medical device importers, and other health sector firms typically engaged in international trade.

   A. Financial institutions offer trade finance to domestic importers and exporters on reasonable terms.
   B. Traders exporting out of the country consider trade finance services to be:
      C. sufficient in quantity.
      D. professionally competent.
      E. reasonably priced.
   F. Traders importing into the country consider trade finance services to be:
      G. sufficient in quantity.
      H. professionally competent.
      I. reasonably priced.

6. Private sector financial institutions:

   A. offer letters of credit.
   B. facilitate access to foreign credit information.
   C. facilitate the availability of information on credit insurance to their clients.
   D. provide advice to exporters, in particular new exporters, for adequate use of credit insurance in light of the method of payment of the commercial transaction and potential risk.
   E. are prepared to advise clients on the pre-shipment financing facilities available in their country or region.
   F. facilitate access to export factoring services for their export clients.
   G. are able to refer clients to qualified counter trade brokers and financial institutions which specialize in facilitating countertrade transactions.
   H. Their staff are trained in laws governing financial exchange and overseas trade, and in facilitating overseas trading transactions

7. Banks provide the health sector with savings and investment instruments.

   A. Banks, credit unions, and micro-finance institutions provide financial services including credit, savings, and insurance to rural healthcare facilities, entrepreneurial medical professionals, local retail pharmacies and distributors.
B. Banks and financial institutions are willing to provide loans to medical and nursing school graduates who seek to open practices in underserved areas.

8. The private sector engages with entrepreneurial medical professional to help establish medical facilities.

A. Rural institutions, including rural banks and cooperatives, provide rural health providers, drug distributors and pharmacies with relevant information about credit opportunities.
B. Trade, medical and pharmaceutical associations have affiliations with international trade organizations and are involved in the harmonization of contract and commercial law and practice with international standards.
C. Trade, medical and pharmaceutical associations provide lists of attorneys or law firms that can provide assistance to their members with respect to credit.
D. Trade, medical and pharmaceutical associations effectively represent the private sector in public debate over monetary policy and overall sector development.
E. Trade, medical and pharmaceutical associations help their members find credit.

9. Regulators of banks and other financial sector institutions are well organized, well led, and endowed with sufficient resources to fulfill their mandates.

A. Regulators and supervisory agencies have clearly defined policies and execute them with consistency.
B. Regulators and supervisory agencies have sufficient authority under the law and support from the government to execute it.
C. Regulators and supervisory agencies have competent and well trained staff.
D. Sector performance results are published on regular schedules.

10. Access to banking and other financial services is universally available.

A. Financial service providers do not discriminate against women, ethnic or religious minorities.
B. Bank accounts, loans and other financial products and services are freely available irrespective of gender, ethnic or religious affiliation.
C. Equal access to financial products and services is legally protected under the law and there are no patterns of systematic discrimination.
D. Financial services are available throughout metropolitan, urban and rural regions.
E. Financial service providers are utilizing contemporary product and service delivery methods to reach traditionally underserved population groups.
F. Non-bank financial intermediaries are an integral part of the financial services sector.

Supporting Institutions

1. Accountants and auditors are available in sufficient number and level of expertise to support broad-based access to credit.

A. There is an adequate number of accountants who have expertise and practical experience in audit and financial aspects of public and private health facilities, drug distributors and pharmacies.
B. Most health sector actors that are incorporated produce annual independently audited financial statements.
C. Accountants and appraisal firms apply generally accepted accounting principles (GAAP) or other internationally recognized standards and norms to asset valuations.
D. There is an association of accountants that effectively represents its members’ interests with respect to sound governance, best practice dissemination, education and innovation, and prudent sector development.
E. There is an association of auditors that effectively represents its members’ interests with respect to sound governance, best practice dissemination, education and innovation, and prudent sector development.
2. Medical sector investors consider lawyers who can assist with matters related to their investment and businesses to be:

   A. sufficient in quantity;
   B. professionally competent; and
   C. reasonably priced.

3. Health professionals are generally willing to seek and implement legal advice with respect to commercial transactions, securing credit and enforcing the collection of debts.

   A. State institutions, including arms of the Government and State-Owned Enterprises, generally will help medical institutions collect debts.

4. Debt collection services:

   A. are available through the private sector; and
   B. do not resort to extra-legal enforcement mechanisms (e.g., thuggery).

5. Civil society organizations promote and support access to credit for the private health sector.

   A. Trade, medical and pharmaceutical associations are informed of developments in finance and credit-related laws and have advocated new commercial practices and reforms to existing law to accommodate changes (e.g. electronic commerce).
   B. Consumer groups adequately represent the interests of banking consumers and contribute positively to the national discussion on monetary policy and financial sector development.
   C. Education, training, and research institutions contribute the required knowledge and skills necessary for a society to support broad-based access to credit for the health sector.
   D. There is a professional association of doctors.
   E. There is a professional association of pharmacists.
   F. There is an association of retail drugstores and/or drug distributors.
   G. One or more established foreign investors’ associations actively seek improvements in the investment environment.

Social Dynamics

1. The private health sector trusts and possesses a high level of confidence in the financial sector's service and product providers.

   A. The population willingly chooses to store assets with depository institutions.
   B. The private sector entrusts its investable assets in the formal banking and financial system.
   C. The formal financial sector is the primary source of financial intermediation.
   D. Shocks to the financial system, if they have occurred, have not substantially undermined the credibility of the financial sector.

2. A stable macroeconomic environment is creating the conditions for health sector development.

   A. Unstable macroeconomic conditions are not distorting health sector policy development.
   B. Macroeconomic conditions are not creating disincentives to lending to the health sector.
   C. Macroeconomic conditions are providing incentives for foreign investment in healthcare facilities.
   D. The extent and nature of the informal economy is known.
   E. The government is taking effective steps to address the problem of informality, which may include efforts at law or regulatory reform, improvement and streamlining of registry or other agency procedures at the local level, work with specific industry segments, etc.
   F. The business and professional community is taking effective steps to cure the problem, which may include assisting in law reform, lobbying for regulatory improvement, advising clients of the law and of the benefits from exiting the underground economy, etc.
3. **Within the private sector, there is an appropriate sense of urgency and the will for improvement of access to health services**

   A. The business community exhibits an awareness of funding needs in the health sector
   B. Banks and other financial institutions demonstrate a commitment to access to health services
   C. Large NGOs demonstrate a commitment to access to health services.
   D. The academic community demonstrates a commitment to access to health services.

4. **Professional associations in the medical sector:**

   A. have specialized sections or committees dedicated to business issues such as foreign investment, IPR, and/or access to finance.
   B. have established formal mechanisms with policy makers for providing input and feedback on business-related issues
   C. regularly provide substantive input and feedback (including studies, statistics, policy documents, etc.) to policymakers on business-related issues;
   D. conduct programs and events for their members and the general public to promote better understanding of business-related issues in the medical sector.

5. **Trade and special interest groups in the medical sector:**

   A. have specialized sections or committees dedicated to business issues such as foreign investment, IPR, and/or access to finance.
   B. have established formal mechanisms with policy makers for providing input and feedback on business-related issues
   C. regularly provide substantive input and feedback (including studies, statistics, policy documents, etc.) to policymakers on business-related issues;
   D. conduct programs and events for their members and the general public to promote better understanding of business-related issues in the medical sector.

6. **Formal mechanisms for soliciting input from the medical community regarding formulation and amendment of business and financial policy:**

   A. have been established by the government;
   B. are actively used by the government; and
   C. according to sector investors, generally satisfy private sector demand for providing input.

7. **There is, in general, political will and an appropriate sense of urgency for improvement of access to financing for the private health sector, and concrete steps are being taken.**

   A. At the government level, important officials are knowledgeable and active in this area.
   B. There is an effective law reform process that carries a clear a mandate to address issues related to access to credit reform, including drafting of new laws or amendments.
   C. A formal mechanism exists for reviewing the performance of the company registry on a regular basis, and the director of the Registry is committed to improving its performance and effectiveness.
   D. The government is open and welcoming to private-sector participation and has formal mechanisms for soliciting input from the health sector’s business and professional community.
   E. Business and professional communities are aware of issues regarding access to credit and have access to relevant officials to suggest reforms.
### Providing Facilities

#### Legal Framework

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<td>1. The company law applies to companies owning or operating private medical facilities, and is readily available, clearly drafted, and easy to use.</td>
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|   | A. Private medical facilities are subject to the country's company law.  
|   | B. Copies of the company law, which govern the establishment of companies managing or operating private medical facilities, are freely available to the public.  
|   | C. The law (or laws) cover all subjects that a modern company law should include.  
|   | D. The law is user-friendly—clearly drafted and well organized.  
|   | E. The law is published in all official languages of the country and there is an official English translation.  
|   | F. The law is current and is regularly updated by practical-minded experts.  
|   | G. The law does not discriminate against foreign ownership or management of medical facilities.  
|   | H. The law does not discriminate against ownership or management of medical facilities by gender, ethnicity or tribal affiliation. |   |
| 2. The company law or accompanying regulations clearly define the role and responsibilities of the institution charged with registering companies. |   |
|   | A. There is a single governmental body which has clear and comprehensive authority for registering medical companies.  
|   | B. Its authority includes maintaining publicly available data regarding registered companies, including companies managing private medical facilities.  
|   | C. If it has regulatory powers, those powers are limited and are not arbitrarily exercised or abused. |   |
| 3. The laws and procedures regulating medical facility start-up are readily available, clearly drafted, and easy to apply. |   |
|   | A. The procedures and licensing requirements for starting a medical facility are clear, accessible to the public, and found in practitioners' offices (facility managers, site operations managers, etc).  
|   | B. The procedures and licensing requirements for starting a medical facility are not used for improper purposes such as managing competition.  
|   | C. The process of setting up a medical facility can be completed without a lawyer, notary, facilitator or other paid third party. |   |
| 4. Certificates of need or other market entry barriers for facilities support a strong health sector, and are not viewed as burdensome to market entry. |   |
|   | A. The regulations outlining the basis for certificates of need or other similar market entry barrier are based upon specific market data.  
|   | B. Certificates of need are decided in a public forum, and final decisions are appealable to a judicial forum  
|   | C. Facility owners may apply for certificates of need simultaneously with their business license application.  
|   | D. The decisionmaking process for certificates of need is transparent, and final decisions are timely, and appealable. |   |
| 5. The registration process for foreign ownership or management of medical facilities is simple, quick, and inexpensive. |   |
|   | A. The law enumerates all steps which foreign investors must undertake to own and operate a private medical facility.  
|   | B. The steps for foreign registration are simple and objective and are not subject to “interpretation” or “discretion.” |   |
C. The steps are few in number, they may be taken concurrently, and the law mandates that the entire process takes at most a few days.
D. In general, the registration rules encourage—or at least do not discourage—foreign investment in the health care sector.

6. Licensing and accreditation regulations for medical facilities are transparent, fairly applied, and are not overly burdensome.

A. An accreditation process is clearly documented for both public and private medical facilities.
B. The laws associated with accrediting a medical facility are widely available to all interested stakeholders; clearly drafted, well organized by subject, with proper indexing, and with article headings; and regularly updated by practical-minded experts.
C. The laws and regulations clearly delineate the responsibilities of inspectors.
D. The laws associated with accrediting a medical facility do not discriminate against foreign investors.
E. The laws associated with starting a medical facility do not discriminate against persons by gender, ethnicity and tribal affiliation.
F. The laws associated with accrediting a medical facility are consistent with international best practices/standards.
G. The laws associated with accrediting a medical facility are based upon

7. The legal framework clearly defines the jurisdiction and responsibilities of administrative agencies charged with regulating health facilities.

A. Administrative agencies are empowered to regulate/audit health facilities according to clear standards/criteria.
B. The auditing schedule and level of detail provide adequate oversight of health facilities.

8. The law on public private partnerships authorizes concessions or some other form of private and private partnership in the health sector.

A. The law establishes sufficient authority on public sector entities to engage in contracts with the private sectors.
B. Public private partnerships are engaged through open, public tender opportunities that are available to the public.
C. A sound regulatory framework exists to monitor and evaluate performance and ensure compliance with contract terms.
D. A government unit is tasked with monitoring public private partnerships to minimize waste, theft, fraud, and graft.

Implementing Institutions

1. The company registry is well organized, well-led, and endowed with sufficient resources to fulfill its mandate.

A. Its head and management staff are non-political, and/or they view their role as ministerial.
B. It has sufficient staff.
C. It has sufficient funding.
D. Its physical facilities are accessible, and there are branch or regional offices throughout the country.

2. The administrative agencies charged with regulating public health facilities listed below are well organized, well led, and endowed with sufficient resources to fulfill their mandates.

A. Drug Regulatory Administration
B. Ministry of Health
C. Ministry of Sanitation
D. Ministry of Labor (sometimes responsible for health and safety)
E. Ministry of Local Government (often responsible for local facilities)
F. It has sufficient staff and funding.
G. The staff know the relevant law, forms and procedures.
H. Salaries are adequate to attract and retain qualified staff.
I. The agencies have formal and informal staff training programs in place.
J. The agencies have the authority and means to hire additional expertise on an as-need basis (e.g., industry experts, academics, consultants, advisors).
K. The agencies draw on the experience of other countries and international organizations.
L. The agencies have an adequate library.
M. The agencies have adequate communications and information technology.
N. The agencies have a written operating manual.
O. The agencies’ priorities are clearly spelled out and are made public.

3. The agencies responsible for regulating private medical facilities are well organized, well led, and endowed with sufficient resources to fulfill their mandates.

A. Relevant agencies regulate private facilities to ensure standardization of care across the private sector.
B. Processes exist for addressing under-performing medical facilities.
C. The relevant agencies have sufficient staff and funding.
D. The staff know the relevant law, forms and procedures.
E. Salaries are adequate to attract and retain qualified staff.
F. The agencies have formal and informal staff training programs in place.
G. The agencies have the authority and means to hire additional expertise on an as-need basis (e.g., industry experts, academics, consultants, advisors).
H. The agencies draw on the experience of other countries and international organizations.
I. The agencies have an adequate library.
J. The agencies have adequate communications and information technology.
K. The agencies have a written operating manual.
L. The agencies’ priorities are clearly spelled out and are made public.

4. The licensing and accreditation agencies for medical facilities are well organized, well led, and endowed with sufficient resources to fulfill their mandates.

A. Agencies have sufficient, trained staff and funding
B. Agencies meet international standards.
C. The staff know the relevant law, forms and procedures.
D. Salaries are adequate to attract and retain qualified staff.
E. The agencies have formal and informal staff training programs in place.
F. The agencies have the authority and means to hire additional expertise on an as-need basis (e.g., industry experts, academics, consultants, advisors).
G. The agencies draw on the experience of other countries and international organizations.
H. The agencies have an adequate library.
I. The agencies have adequate communications and information technology.
J. The agencies have a written operating manual.
K. The agencies’ priorities are clearly spelled out and are made public.

5. The agency charged with registering and supporting private medical clinics is well organized, well led, and endowed with sufficient resources to fulfill its mandate.

A. Its head and management staff are non-political and/or they view their role as administrative and ministerial.
B. It has sufficient staff.
C. It has sufficient funding (through direct state budget, fees for registration or other services, or both.)
D. Its physical facilities are accessible and welcoming, and there are branch or regional offices throughout the country offering easy access to services for both rural and urban populations.
E. It issues official forms (which may or may not be mandatory) for registrations; the forms are available free or at minimal cost from the registry or bookstores; the forms cover all types of registrations; and there is a handbook or other instructions.
F. It has adequate, formally issued internal regulations and operating procedures.
G. The registration experience is efficient and user friendly.

6. The bodies that grant approvals and licenses to medical facilities are efficient and business-friendly

A. It is easily ascertainable what approvals, permits, licenses, and procedures are needed for start up and continuing operation of a medical facility.
B. The bodies/persons are non-political and view their role as technical and business-friendly.
C. In the case of a start up of a medical facility, all necessary permits and licenses are completed within the few-day time period required for registration.
D. There is a “one stop shop” procedure under which registration, permits, licenses are sought concurrently.
E. The process is transparent and inexpensive.
F. The bodies perform adequately their regulatory obligations and their duty to serve and protect the public safety and welfare.

7. The agency charged with registering foreign investments is well organized, well led, and endowed with sufficient resources to fulfill its mandate.

A. Its head and management staff are non-political and/or they view their role as administrative and ministerial.
B. It has sufficient staff.
C. It has sufficient funding (through direct state budget, fees for registration or other services, or both.)
D. Its physical facilities are accessible and welcoming, and there are branch or regional offices throughout the country offering easy access to services for both rural and urban populations.
E. It issues official forms (which may or may not be mandatory) for registrations; the forms are available free or at minimal cost from the registry or bookstores; the forms cover all types of registrations; and there is a handbook or other instructions.
F. It has adequate, formally issued regulations and operating procedures.
G. It has a website which is easy to use and regularly updated, and which contains the company law and relevant Registry regulations, instructions and forms for registration, fee schedules, data on individual companies, and other useful information.
H. Registration can be done remotely on the internet or by computer at the registry office.

8. Administrative systems for creating, updating, and reviewing health regulations are clear, open, and free of corruption.

A. A formal system is in place for meaningful contributions by the business community to the development and updating of health regulations.
B. Persons charged with drafting health regulations have adequate resources and training.
C. The process of creating or revising health regulations involves pre-enactment activities that serve to inform and educate the stakeholding community.
D. Notice and comment are part of the regulatory process.
E. Individuals and institutions that participate in the regulatory development process report that their views are given fair consideration.

9. The health care facilities in the country are of the right scale to handle the population's needs.
A. Where capacity is too low (not enough beds, lab facilities, etc), plans are in place to expand capacity.
B. Where capacity is under utilized, plans are in place to share services to benefit from economies of scale.
C. The MoH has a strategy for deciding number and distribution of public health facilities.
D. All geographic regions are serviced by local health facilities, taking private facilities into account (the distribution of health facilities reflects the population distribution)

10. Health facilities are adequately staffed with individuals trained to handle their responsibilities.
   A. Management staff is in place to handle the administration of the facility: maintenance, finance, human resources, technology, other non-medical services.
   B. Medical staff focus the overwhelming majority of their time on health service delivery.
   C. Non-medical staff focus the overwhelming majority of their time on operational service delivery (laundry, food, janitorial duties, etc.).
   D. Facility staff have clearly delineated roles and responsibilities and job descriptions.
   E. Facility staff have undergone a training program prior to undertaking their positions.
   F. Medical staff are trained to address sensitive health topics.

11. The management of health facilities is endowed with the processes and technology to allow for efficiency.
   A. Human resources management processes and systems are in place on par with international standards.
   B. Inventory management processes and systems are in place on par with international standards.
   C. Records management processes and systems are in place on par with international standards.
   D. Sanitation management processes and systems are in place on par with international standards.
   E. Facility staff are trained on the processes and technology in place.

12. Health facilities procure and receive pharmaceutical and medical supplies in a timely fashion.
   A. Facilities engage in a process of forecasting to ensure the appropriate level and type of stock.
   B. Facilities consistently hold sufficient stock.
   C. Contingency plans exist in case of stock outs.
   D. Facilities have clear service level agreements with suppliers/distributors (Central Medical Stores, private entities, etc).

13. The facilities across the public and private health systems are endowed with the appropriate equipment to deliver the services required.
   A. Medical devices, whether new or refurbished, are maintained to be in proper working order (e.g. properly calibrated).
   B. Medical devices, whether new or refurbished, are maintained to be validated for use (e.g. expired and/or recalled equipment).

14. Security at health facilities is appropriate and in line with international standards.
   A. Access to facilities is controlled.
   B. Pharmaceuticals and other hazardous agents are controlled
   C. Records and other confidential documents are controlled.
   D. Money, financial reports and other confidential documents are controlled.

Supporting Institutions
1. The Bureau of Statistics, in concert with the Ministry of Health, supports data collection associated with both public and private facilities.
   A. Standard statistics and procedures for collection are set by the Ministry of Health.
   B. Statistics collected are consistent with international best practice.
   C. Mechanisms for data collection and reporting are automated.
   D. Local analysis (i.e. health facility or distribution center level) is conducted for process improvement at the local level.
   E. Macro analysis is conducted by the Bureau of Statistics with reporting to the Ministry of Health to evaluate the national facilities capacity/quality.
   F. Facility capacity/quality is also evaluated at the regional and local levels to ensure gaps are known and addressed.
   G. Statistics collected include the usage of private and public facilities, traditional health care facilities, etc.
   H. Statistics are broken down into primary care, tertiary care, etc.
   I. Statistics are used by MoH in the development of strategies for the public and private health sector.

2. Medical associations/unions have a voice in policy decisions regarding the management and oversight of health facilities.
   A. Medical associations/unions have an open line of communication and constructive dialogue with all government oversight agencies.
   B. Medical association/union members actively participate in advocacy efforts.

3. An insurance market is in place to protect against asset loss of potential new investors.
   A. Public domestic and/or international financial institutions provide assistance in obtaining insurance.
   B. The quantity and quality of insurance, bonds, etc. are sufficient.
   C. The cost of insurance, bonds is reasonable.

4. Health facilities provided at the worksite by the private sector are monitored and encouraged.
   A. Where successful, these interventions are considered for replication on a larger level.

Social Dynamics

1. Bribes/informal payments are not an issue for facilitating licensing, inspections, or accreditation.
   A. The Ministry of Health enforces penalties for offering and accepting bribes/informal payments.
   B. Bribes/informal payments are both criminalized, and also stigmatized.
   C. The framework for facilitating licensing, inspections or accreditation is transparent.
   D. Political influences are not an issue for awarding accreditation to facilities.

2. Bribes/informal payments are not an issue for accessing services at health facilities.
   A. The Ministry of Health enforces penalties for offering and accepting bribes/informal payments.
   B. The framework for accessing services at health facilities is transparent.

3. Where informal health facilities exist, the government seeks to take steps to address services provided through formal means.
   A. Regional and local human capacity differentials are understood that drive supply and demand that provide adequate provision to citizens in informal health facilities.
   B. Cost analysis of inventory management processes, systems and goods are in place.
C. Providers are educated on up-to-date and evidence-based practices within scope of services provided.
D. Regional and local organizations, or other informal networks that are linked to the supply chain of service goods are understood.
E. Local vendors that are linked to the supply chain of service goods are understood.

4. The state’s role in the health sector, both as regulator of facilities and provider of facilities, promotes private sector participation and increases urban and rural access to healthcare.
A. The national government is perceived to support public and private cooperation and collaboration in rural healthcare facility initiatives.
B. Health sector facility providers actively seek better laws and regulations to promote their interests.
C. National and local political figures express support for private sector participation, and do not favor public sector facilities over private sector facilities.
D. Public sector facilities are not perceived to “crowd out” private sector facilities from the local marketplace.

5. The Government and political leadership support a culture of competition.
A. Leading political figures publicly advocate competition as a means to improve the health sector.
B. Government officials look to and draw from other countries’ experiences enacting and enforcing competition.
C. The overall legal framework does not create or permit unnecessary licensing or market entry restrictions favoring incumbents.

6. Access to facilities is not based on region, ethnicity, class, gender, economic status, or other affiliation.
A. Persons seeking access are not considered ineligible due to regional, local and tribal affiliation.
B. Persons seeking access are not considered ineligible due to gender and class.
C. Bribes/informal payments are not an issue to access facilities.
D. Political influences are not an issue to access facilities.

7. Adequate communication channels exist between the Ministry of Health, medical facilities, and other agencies to avoid “stovepiping” issues.
A. National policies outline strategic measures to provide infrastructure for medical facilities.
B. The Ministry of Health and other institutions and agencies understand national, regional and local infrastructure needed to support health needs and service delivery.
C. National, regional and local human capacity differentials are understood and plans are in place for established infrastructure to support needs.
D. Formal mechanisms (working groups, regular mtgs etc) exist in order to facilitate collaboration among these stakeholders.

8. Facilities support governmental public health initiatives.
A. Facilities promote public health agendas through treatment, prescription of drugs, etc.
B. Facility staff are trained to address medical problems with sensitivity.

9. The media report regularly, freely, and accurately on matters related to health facilities.
A. The media has sufficient access to all appropriate sources of information concerning health terms and conditions.
B. The media can report freely on issues pertaining to health without fear of government reprisal.
C. The private sector, workers, and government consider media coverage of health issues to be sufficient, accurate and fair.
D. Independent media exist and are free to report on governmental issues.
E. Audits and reports of health facilities are publicly available.
Governing the System

Legal Framework

1. A national health plan exists that outlines strategy in both the healthcare and public health sectors over the next 3-7 years.
   - A. Input includes government, private sector, international agencies, NGOs, and civil society.
   - B. The plan formulates funding needs and sources.
   - C. The plan enables innovation through pilot projects and provides a framework to document lessons learned and recommendations.
   - D. The plan seeks to monitor projects by NGOs and CSO groups and scale up those projects that are being effective.
   - E. The plan takes into account varying demographics due to changing policies.
   - F. The plan considers changing behaviors due to changing policies.
   - G. The plan quantifies human capacity needs due to staffing and training of medical professionals.
   - H. The plan dictates quantifies human capacity needs due to staffing and training of foreign medical professionals.
   - I. The plan addresses gaps in health service delivery and provides short, medium, and long-term recommendations to close those gaps.
   - J. The plan includes a section on public health and public health surveillance which creates an epidemiological framework for statistics.
   - K. The plan includes metrics which will allow the nation to determine how successful their public health and healthcare efforts are.
   - L. The plan seeks to minimize transaction costs through donor coordination and harmonization.
   - M. The plan takes account of existing and future capabilities of the private and NGO sectors.

2. The legal framework pertaining to developing the budget for healthcare delivery is in place.
   - A. The budget factors in the needs of varying stakeholders.
   - B. The budget factors in the needs for medical professionals and their research projects.
   - C. The budget factors in the needs for paraprofessionals.
   - D. The budget factors in the needs for facilities management.
   - E. The budget factors in the needs for operational staff.
   - F. The budget factors in medical education and sustainability.
   - G. The budget factors in the needs for medical logisticians and bio-medical repair technicians.
   - H. Budget allocations are based on a number of different factors including mortality, morbidity, disease surveillance, and needs of community.
   - I. The budget factors in but does rely on official development aid.

3. The legal framework pertaining to developing the budget for healthcare is transparent
   - A. The legislative/political supporters and detractors of the final budget are not granted anonymity.
   - B. Historical budget data is available to allow for comparisons.
   - C. The national government takes the lead in working with local communities, facilities, NGOs in developing a national budget.
   - D. The final draft of the budget is vetted by both local and international health economists to determine its feasibility.

4. The legal framework pertaining to developing the budget for healthcare takes into account the needs at the local level, as well as national priorities.
   - A. The legal framework takes into account the local political influences on healthcare.
   - B. The legal framework takes into account the local economic influences on healthcare.
   - C. The legal framework takes into account the regional political influences on healthcare.
D. The legal framework takes into account the regional economic influences on healthcare.
E. The legal framework takes into account the national political influences on healthcare.
F. The legal framework takes into account the national economic influences on healthcare.
G. The legal framework takes into account the international political influences on healthcare.
H. The legal framework takes into account the international economic influences on healthcare.
I. The legal framework takes into account the funding that is provided through government taxes and what is provided through outside donors.

5. Health policy makers have an open communication channel to executive and legislative branches of government.

A. Health policy makers are informed about any deviations from strategic plans.
B. Input includes health policy makers for new or changed health legislation.
C. Forums exist for discussing health policy directly with government leaders.
D. The public has ready access to national healthcare data through the Ministry of Health within the country.
E. The influence of health statistics on changes in health policy are transparent.

6. The legal framework allows for flows from NGOs, aid from other governments, and aid from multi-lateral institutions to flow into the budget process.

A. Funds from outside the government go through the government structure, rather than external programs.
B. The reporting burden for outside funds is reasonable and can be primarily met through established reporting.
C. External and internal funds and programs are coordinated through the Ministry of Health and the national health plan.
D. External and internal donors are asked to provide quarterly reports in order to establish a system of accountability.
E. Outside funds and programs are coordinated through the Ministry of Health and the national health plan.

7. The legal framework pertaining to the roles and responsibilities of various agencies (e.g. Ministry of Sanitation, Ministry of Agriculture, etc.) is in place.

A. Amendments to the said roles and responsibilities are possible.
B. Changes in agency funding priorities are visible.
C. Changes in agency funding priorities are data driven.
D. Channels of communication exist between the various agencies.
E. Memorandums of Understanding (MOUs) between the government ministries are necessary to outline roles and responsibilities.
F. If the individual agencies do not follow the roles and responsibilities that they agreed on, the executive branch of government can take action.
G. A Senior Executive Committee should be created to generate annual strategic plans for each ministry.

8. The laws and regulations governing the health system are readily available, clearly drafted, and easy to use.

A. Copies of all laws and regulations that comprise the country's regime pertaining to the health system are widely available to all interested stakeholders.
B. The legal framework pertaining to the health system is user-friendly -- clearly drafted, well organized by subject, with proper indexing, and with article headings.
C. The legal framework pertaining to the health system is published in all official languages of the country and there is a good English translation.
D. The legal framework pertaining to the health system is current and is regularly updated by practical-minded experts.
9. The processes of budget formulation, government rulemaking, and Health standards creation are transparent, accessible, and accountable to the public
   
   A. The process for agency rulemaking provides adequate notice to the public for proposed rule changes, and provides a forum for feedback from private and public sector participants.
   B. Comments received from private and public sector participants are meaningfully addressed during agency rulemaking processes.

Implementing Institutions

1. The Ministry of Health assesses annually the funding needs based on health outcomes, facility performance levels, facility-based input and national priorities
   
   A. The Ministry of Health has adequate data to evaluate needs by region, city, gender, ethnic group, or health issue area.
   B. The Ministry of Health, or other agency/ministry, has adequate data to evaluate health needs and/or disease by incidence, prevalence, morbidity rates and mortality rates in the country.
   C. The Ministry of Health considers cross-border and transnational health outcomes when determining funding needs.

2. The Ministry of Health budget takes into account national, and international, targets to improve national health levels (e.g. MDGs)
   
   A. The Ministry of Health understands the metrics to improve national health levels.
   B. The Ministry of Health understands the derailers that hinder optimal health outcomes (i.e. health disparities, health perception among the poor, gender access discrimination).
   C. The Ministry of Health considers strategic health plans of countries with similar demographics to create their strategic plan.
   D. The Minister of Health meets with his counterparts throughout the world to assist with developing goals and objectives that can be met.
   E. The Ministry of Health bases their strategic metrics on the Millennium Development Goals (MDGs).
   F. The Ministry of Health has adequate technical capacity to properly forecast and manage needs.
   G. The Ministry of Health has health economists and business managers on staff to complement staff with technical medical expertise.

3. Local service delivery points submit on a periodic basis their needs for funding and/or goods to the Ministry of Health for planning purposes
   
   A. Local service delivery vendors work orders are organized, clear and transparent.
   B. Quarterly or annual progress reports are submitted to outline work processes, activities and outcomes.
   C. Local service delivery vendors have mechanisms in place to obtain and organize data.
   D. The Ministry of Health works to create a Medical Depot system where medical supplies, pharmaceuticals and healthcare vehicles are stored.
   E. Local service delivery vendors have support to build capacity to produce necessary information for the MoH.

4. The Ministry of Health assesses the needs of schools training medical professionals during the budgeting process.
   
   A. The Ministry of Health considers the cost of medical education and continued education.
   B. The Ministry of Health considers the cost of not supporting/underwriting medical education.
   C. The Ministry of Health considers the barriers to training medical professionals.
   D. The Ministry of Health strategizes about retaining locally educated medical professionals.
   E. The Ministry of Health takes into account the labor needs of private health-care providers in budgeting for medical education.
5. Coordination of external participation in the health sector is efficient and facilitates achieving the strategic goals of the country.

A. Non-governmental funds flow through formal channels rather than establishing parallel or vertical programs.
B. Vertical programs are minimal so as not to build redundant systems.
C. Programs established by NGOs, foreign donors, the private sector, and contractors for foreign donors work with the government in order to build the capacity of the national health system.
D. The donor community regularly interacts with local members of the health profession to ensure that their programs are effective and meet actual needs.
E. Coordination of donor activities relating to improving the health environment is considered by both local actors and donors to be adequate and effective.
F. Donor activities pertaining to the health environment are regularly subject to monitoring and evaluation and prove responsive to suggestions for change and improvement.

6. The use of performance management mechanisms exist in the health system.

A. Performance management framework is based on the achievement of strategic objectives.
B. Mechanisms based on supervision, appraisal, reward, skill development or discipline are in place.
C. The performance management system is integrated.
D. There are perceptions at different organizational levels that performance matters and is used as a management tool.
E. Evidence on the use of performance management for improvement exists and is accessible.
F. Managers at different levels accept responsibility for levels of performance achieved.
G. Performance management is linked to staff professional development plans.
H. External checks on staff performance take place.
I. Action is taken to resolve performance issues.

Supporting Institutions

1. The Bureau of Statistics collects statistical data on health outcomes, risks, and service delivery which are readily available and taken into account for planning.

A. Data must be easily disaggregated by region/district/locality to allow for evaluation of local needs.
B. Existing reporting structures meet the basic reporting needs of outside donors.
C. Household level national demographic and health surveys are completed on a periodic basis to provide policy makers information to assess the health needs of the country.
D. Facility level surveys are completed periodically to assess outcomes by facility, as well as capacity and quality of the infrastructure.
E. Patient surveys are completed periodically to assess outcomes and perceptions by facility, region, etc.
F. Monitoring periodically throughout the supply chain for delivering goods provides the information necessary on the efficiency of the infrastructure.
G. Data are easily disaggregated by region/district/locality to allow for evaluation of local needs.
H. Existing reporting structures meet the basic reporting needs of outside donors.
I. Reporting to the Ministry of Health and elected government officials occurs on a periodic basis.
J. Monitoring and evaluation reports by donor projects and programs are completed on a regular basis.
K. Data are readily available to all. If there is a fee charged for use of the data, it is the same for public and private requestors.

2. Audit mechanisms are in place to ensure that funds reach those to whom they are allocated

A. Incentives are in place to ensure that audit and reporting are transparent and conducted without interference.
Score

Governing the System

3. Medical Associations and local service delivery points collectively have a voice in the budgeting process.
   A. The voices of medical and paramedical associations are given equal weight.
   B. Fora are available for these groups to interact and establish a unified voice.

4. Schools training medical professionals have a voice in the budgeting process.
   A. Funds may be allocated to providing incentives to students to continue their education.
   B. Schools and students' prospective employers (healthcare institutions) communicate openly about mutual needs, standards, and expectations.

5. Civil Society and the Private Sector have a voice in the budgeting process.
   A. Actual or virtual town hall meetings are convened to capture the needs of community members.
   B. Feedback regarding suppliers' expectations is welcomed.
   C. Civil society and private sector participants monitor and have the capacity to advocate within executive agencies and legislative committees on behalf of their interests.

6. Provider payment mechanisms are in place, where allocations from a national authority, or user fees do not cover the cost of treatment.
   A. The mechanisms are automated and efficient.
   B. Stakeholders understand and adhere to privacy laws.
   C. Forums for payment disputes exist.
   D. Mechanisms are in place to spread awareness and combat corruption in this area.

Social Dynamics

1. The issue of leakage of funds due to management issues, bureaucratic needs, or corruption, are well understood.
   A. Performance metrics indicate the percentage of funds allocated to and received by the service delivery point.
   B. Variance in the allocation and received amount is understood and held accountable.
   C. Corruption is punished by law, and the organizations where corruption exists are informed of it.
   D. Annual audits are completed which allow for accountability but also help to determine the percentage of funds which were actually spent on specific funding projects.

2. It is acceptable socially to take into account performance levels when allocating funds to create incentives.
   A. Performance measures are publicly accessible.
   B. Corruption does not influence performance measures.
   C. Methodology for allocation of funds is clearly articulated.
   D. Key objectives and outcomes must be defined in order to hold the key ministries and outside healthcare organizations accountable to reaching those objectives.
   E. Meetings between key stakeholders are held regularly to monitor performance levels from a national, regional and local basis.

3. Budget allocations do not discriminate on the needs of region, ethnicity, class, gender, or other affiliation.
   A. Population distinctions are recognized, but do not affect quality nor quantity of care.
4. Budget allocations reflect the needs of both urban and rural populations.
   A. Differences in transportation costs are balanced by differences in costs due to population size.

5. Adequate communication channels exist between the Ministry of Health, service delivery points, and other agencies to avoid "stovepiping" issues.
   A. Cross-sector exchanges in staff take place on a visiting basis.
   B. Cross-sector meetings take place on a periodic basis to discuss updates, progress in healthcare delivery and sustainability.

6. Global health campaigns receive adequate funding, and help to combat stigma around certain health issues.
   A. Global health advocates reach out to local and regional community leaders to discuss stigma, stereotypes and prejudice.
   B. Local and regional communities have methods for reaching out to global health advocates.
   C. Global health advocates partner with the media (television, newspaper & radio).

7. Individuals expect to pay for some, or all, of their health needs (depending on country health policy)
   A. These fees are official and expected
   B. Fees are not unreasonable and consider cost of living.
   C. The amount of money that patients pay is based on a sliding-scale system.
   D. Some medicines, like ARVs, are discounted, free, or substituted by generics.

8. Individuals use health insurance to cover needs unaccounted for by the national health system.
   A. Health insurance is available and affordable.
   B. The economic market favors competition in the private insurance industry.
   C. The health insurance system implemented is realistic for the environment.

9. One or more high-level government officials champion the cause of improving healthcare as a development strategy.
   A. Government officials are knowledgeable about and propose changes to laws and/or institutional processes affecting healthcare.
   B. At least one high-level government official seeks to reform inter governmental coordination processes that govern healthcare.
   C. At least one high-level government officials seeks to institute programs educating the private sector and civil society about healthcare.
   D. At least one high-level official is known to educate other government officials on the importance of healthcare, the agreements governing it and how best to use it as a tool for development.
   E. At least one high-level official sees private sector providers as important partners of public services.

10. The media reports on health issues in an informed manner
    A. The media report on health issues as something appropriately addressed by both public and private sectors.
    B. The media perceive over-regulation of private health services and barriers to entry as undesirable.

11. Legislative systems for creating, updating, and reviewing laws relating to delivering healthcare goods are clear, open, and free of corruption.
    A. Within the legislature, a system is in place for meaningful contributions by the private sector, NGOs, and appropriate government officials to develop and update laws impacting the delivery of healthcare goods.
B. Persons charged with drafting laws impacting the delivery of healthcare goods have adequate resources and funding.
C. Public hearings are part of the legislative process.