Development of the National Minimum Standards for Healthcare Facilities in Ethiopia: A Milestone for Country Ownership and Sustainability of Best Practices

June 2014

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Development of the National Minimum Standards for Healthcare Facilities in Ethiopia: A Milestone for Country Ownership and Sustainability of Best Practices

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June 2014

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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

healthcare facilities national minimum standards, stakeholders engagement, standards for pharmaceutical services, quality and safety of healthcare practices

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ACRONYMS AND ABBREVIATIONS

BPR	business process reegineering
BSc	bachelor of science
DACA	Drug Administration and Control Authority
EFMHACA	Ethiopian Food, Medicines and Healthcare Administration and Control Authority
ENT	ear-nose-throat
ESA	Ethiopian Standards Agency
FMOH	Federal Ministry of Health
H.E.	His Excellency
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SPS	Strengthening Pharmaceutical Systems
TORs	terms of reference
TWG	technical working group
USAID/PHSP	United States Agency for International Development/Private Health Sector Program

EXECUTIVE SUMMARY

Licensing is a statutory mechanism by which a governmental authority grants permission to an individual practitioner to engage in an occupation or to a healthcare organization to operate and deliver services. Licensing allows governments to ensure basic public health and safety by controlling the entry of providers and facilities into the healthcare market and by establishing standards of conduct for maintaining that status.

A standard is a document that sets out requirements for a specific item, material, component, system, or service, or describes in detail a particular method or procedure. According to the European Standards Organizations, standards bring benefits to businesses and consumers in terms of reducing costs, enhancing performance, and improving safety. Standards are developed and defined through a process of sharing knowledge and building consensus among technical experts nominated by interested parties and other stakeholders—including businesses, consumers, and environmental groups, among others. It also defines a standard as a "document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context."

Based on its mandate to regulate health service provision in the country, the Ethiopian Food, Medicines and Health Care Administration and Control Authority (EFMHACA) established a national technical working group (TWG) having 30 members drawn from different federal institutions, hospitals, professional associations, private sector practitioner representatives, and partners. Expertise was provided by medical doctors of different specialties, public health specialists, pharmacists, lawyers, engineers, laboratory technologists, and nurses. The TWG developed 39 types of draft standards based on national and international best regulatory practices, and the draft standards were reviewed in 7 consultative meetings in the presence of experts from regional health bureaus, federal institutions, health professional associations, universities, partners, and different types of health facilities from the public and private sectors. The leadership of EFMHACA worked closely with this TWG and provided continued support and oversight during the course of the development process. After being thoroughly reviewed and approved by EFMHACA management, these standards were submitted to the Federal Ministry of Health (FMOH) for further enrichment and to make sure that the standards are in accordance with the country's health policy and development agendas. Following feedback and general guidance from FMOH, a final draft was prepared and submitted to the Ethiopian Standards Authority (ESA) for approval so as to make it the country's health service–governing regulatory tool for licensure and inspection. After a series of consultations with this agency, all 39 standards were endorsed on May 2, 2012, by the ESA board, which is authorized by law to endorse national standards.

The national minimum standards constitute licensure requirements, good governance practice standards, human resource management standards, service providers' and clients' rights and responsibilities, health service practice standards, premises standards, professionals' standards, product standards, and cross-cutting service standards for different types and levels of health facilities. All standards incorporated proven best practices in healthcare, including pharmaceutical services that should be instituted within all health facilities, whether operating in the public or private sector.

In Ethiopia, government and development partners are investing a huge amount of resources to improve the quality of health services and ensure their sustainability. However, there remain the serious challenges of accountability, ownership, and sustainability. Accordingly, governance is recognized as one of the key strategic interventions in the Health Sector Development Programme (HSDP) IV. It is also recognized by international development partners as a building block for health system strengthening. The development of these standards can be taken as a good governance intervention within the health system. These regulatory tools mandate that both practitioners and health institutions comply with a minimum set of requirements and update their licenses regularly to continue operating as a healthcare-providing institution. This way, best practices (adapted to the country's context) will easily be owned and sustained. On the other hand, the EFMHACA will develop and deploy standardized tools to execute inspection and licensing functions and ensure transparency and accountability in these processes.

During the course of the standards development process, stakeholders' engagement and participation were ensured; this is expected to facilitate a greater sense of ownership and increased sustainability. Close to 450 health professionals, policy makers, managers, consultants, and institutional delegates from governmental, nongovernmental, and private organizations, attended a number of consultative workshops and meetings and provided valuable feedback. Finally, it was recognized that the persistent commitment and leadership of senior management at EFMHACA, FMOH, and ESA made a tremendous contribution to the remarkable achievement and successful conclusion of this important work.

INTRODUCTION

In recent years, there is an increased interest in developing countries in ensuring that healthcare provision is safe and effective. Since countries face the problem of scarce resources for health, increasing attention is being given to how to achieve maximum results with such limited resources. Health sector reform processes have given further impetus to ensuring accountability in the health sector and developing the steering role of the Ministries of Health, particularly with respect to the government's role as steward and protector of the public's health.

Through regulatory approaches, governments establish expectations for the competence of healthcare providers and institutions and for the quality of services they provide. Regulators of quality may define specific standards and require that health providers comply, but they can also allow healthcare or professional organizations to prescribe their own rules. Regulators can simply specify that standards are to be used and that those standards be formulated and applied through an acceptable process. The degree of specificity of a quality regulation depends in large part on the perceived competence of provider institutions and on regulators' confidence that the desired ends of regulation will be achieved.

Licensing is a statutory mechanism by which a governmental authority grants permission to an individual practitioner to engage in an occupation or to a healthcare organization to operate and deliver services.[1] Licensing allows governments to ensure basic public health and safety by controlling the entry of healthcare providers and facilities into the healthcare market and by establishing standards of conduct for maintaining that status.[2] On the other hand, a standard is a document that sets out requirements for a specific item, material, component, system, or service, or that describes in detail a particular method or procedure. According to the European Standardization Organizations, standards bring benefits to businesses and consumers in terms of reducing costs, enhancing performance, and improving safety. Standards are developed and defined through a process of sharing knowledge and building consensus among technical experts nominated by interested parties and other stakeholders—including businesses, consumers, and environmental groups, among others. The formal definition of a standard is a "document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context."[3]

There are different types of standards. Basically, standards include requirements and/or recommendations in relation to products, systems, processes, or services. Standards can also be a way to describe a measurement or test method or to establish a common terminology within a specific sector. Standards are voluntary, which means that there is no automatic legal

[1] Zeribi, K. A., L. and Marquez. 2005. *Approaches to Healthcare Quality Regulation in Latin America and the Caribbean: Regional Experiences and Challenges.* LACHSR Report Number 63. Published for the U.S. Agency for International Development (USAID). Bethesda, MA: Quality Assurance Project.
[2] Zeribi, K. A., L. and Marquez. 2005. *Approaches to Healthcare Quality Regulation in Latin America and the Caribbean: Regional Experiences and Challenges.* LACHSR Report Number 63. Published for the U.S. Agency for International Development (USAID). Bethesda, MA: Quality Assurance Project.
[3] http://www.cencenelec.eu/standards/DefEN/Pages/default.aspx

obligation to apply them. However, laws and regulations may refer to standards and even make compliance with them compulsory.[4]

In the Ethiopian context, standards are documents that are ratified by the Board of Directors representing key line ministries and technical agencies that are authorized to approve national standards. The Ethiopian National Health Facilities Minimum Standards are obligatory, since health standards are categorized in the latter group.

During the health sector reform, it was learned that there was a huge gap in delivery of safe and quality health services. Lack of transparent and accountable health service regulation was found to be the major contributor to this gap. There was also a double standard in the sense that the existing licensure and inspection requirements didn't apply to government-owned (public) health facilities and were implemented to regulate practice in the private sector. EFMHACA, which has been evolved from what was the Drug Administration and Control Authority (DACA) during the reform process to uphold the vision of "Quality Health Services and Products to all Ethiopians," recognized this gap and made it an important priority. EFMHACA defined its mission as to "promote and protect the public health by ensuring safety and quality of products and health service through registration, licensing and inspection of health professionals, pharmaceuticals, food and health facilities and provision of up-to-date regulatory information while promoting rational medicine use."[5] The objective of regulatory process optimization in accordance with the BPR (business process reengineering) principle was to establish and maintain an efficient and responsive health regulatory system that can bring about dramatic results at minimum cost and time to safeguard public health.

As part of achieving the above, EFMHACA made the decision to develop national minimum standards applicable for all types of health facilities. Consistent with this government priority, the USAID Ethiopia Country Development Cooperation Strategy (2011–2015) also states that "by strengthening regulatory systems, USAID will:

- Promote safety in the delivery of health services, products and practices;
- Improve professionalism among health workers;
- Implement regulations concerning institutional waste; and
- Create a conducive environment to expand the role of the private sector and civil society in the health sector."

In June 2009, EFMHACA requested assistance from its stakeholders and partners to develop these standards. SPS provided a positive response to this request, as part of technical assistance in pharmaceutical sector good governance, and the follow-on program, SIAPS, continued providing the support necessary to develop and finalize the standards.

Good governance in public health requires up-to-date, well-informed, and transparent policies, laws, and regulations plus mechanisms that allow for checks and balances throughout the process of exercising authority. The United Nations Development Programme

[4] http://www.cencenelec.eu/standards/DefEN/Pages/default.aspx

[5] Federal Democratic Republic of Ethiopia, Ministry of Health (FMOH). 2008. *Business Process Reengineering, Health and Health Related Services and Products Quality Regulation Core Process.* Addis Ababa: FMOH.

has defined the characteristics of good governance in societal terms, and these characteristics have been linked to good governance in pharmaceutical systems.[6]

Within the framework of the Management Sciences for Health (MSH) Center for Pharmaceutical Management approach to governance, SPS and SIAPS continuously supported the development of standards as part of developing policies and legislations that govern pharmaceutical services and incorporating good governance practices into systems and processes. The development of the health facility standards envisaged by EFMHACA also included pharmaceutical service standards at different tiers of the healthcare system (primary up to tertiary healthcare levels) of the country.

Then a senior expert was seconded to EFMHACA to assist in this important undertaking, which took more than three years to complete. SIAPS served as member of the core team for technical leadership of the development process from inception up to endorsement. Accordingly, EFMHACA, with the participation of key stakeholders and in close consultation with FMOH and the Ethiopian Standards Agency (ESA), led the development and approval of the health facility standards.

[6] Center for Pharmaceutical Management/Management Sciences for Health (CPM/MSH). 2011. Center for Pharmaceutical Management: *Technical Frameworks, Approaches, and Results.* Arlington, VA: CPM.

PRINCIPLES AND OBJECTIVES

Before EFMHACA began developing the standards, the following fundamental principles were agreed on:

- Regulatory standards shall be prepared for all health facilities according to the new healthcare tier system.

- All public and private healthcare delivery facilities shall be treated by uniform standards to avoid double standards in the health sector. Every type of health facility, whether it is public or privately owned, will be governed by the specific approved standards applicable to the respective levels.

- The service provided by the health facilities should be quantitatively and qualitatively standardized so as to enable informed decision making with regard to what, where, when, and how services are to be provided.

- Regulatory standards will serve as a tool for ensuring safe and quality healthcare services in both the public and private sectors.

- Stakeholders shall be engaged throughout the regulatory standards development and implementation processes.

- The new standards will help promote investment in health and bring fair competition to the health industry, which helps improve access to quality health services.

In line with these principles, EFMHACA set the following objectives:

- Ensure quality and safety of healthcare services

- Provide guidance on healthcare regulation

- Provide a standardized tool for licensing and inspection of health facilities

- Standardize requirements for provision of health services across the public and private sectors

- Establish transparent processes and ensure accountability in regulating the health sector

PREPARATORY PHASE AND DRAFT DEVELOPMENT

The preparatory and drafting phases of developing health facility standards followed the following important steps.

Establishing the Core Team

EFMHACA established a core team comprised of experts from different specialties and institutions. The team worked closely with the TWG, the management of EFMHACA, and the Standard Setting and Information Delivery Directorate. In general, the team was represented by full-time employees drawn from the EFMHACA Standard Setting Team, SIAPS, USAID/PHSP, and other partners, some of which participated intermittently. SPS and its follow-on program, SIAPS, were represented with one senior advisor from inception up to completion of standards development. The team was tasked with producing draft standards based on local and international experiences using the specialized expertise of individual TWG members and sharing the draft with the all TWG members for further consultation and consensus. In addition, this team was responsible for presenting or explaining the work to EFMHACA management and FMOH executives on behalf of the TWG. Overall, the team was responsible for technical management of the standards development process based on the health sector governing laws and regulations. The permanent core team members were Mrs. Yeshialem Bekele, Mr. Kidanemariam Gebremichael, and Mr. Zelalem Melesse from EFMHACA, Mr. Edmealem Ejigu from SPS and SIAPS, Dr. Petros Mitiku from USAID/PHSP, and intermittent members from Tulane University.

Establishment of Technical Working Group

A technical working group comprised of medical specialists, public health specialists, pharmacists, laboratory technologists, a nurse professional, a lawyer, and an engineer was drawn from FMOH, EFMHACA, university hospitals, professional associations, and development partners, in addition to the core team. The TWG was mandated to make a preliminary evaluation of draft standards and make recommendations to area-specific specialists and core team members, who drafted the standards. The core team and area-specific specialists prepared a final draft and presented it to the TWG for approval and submission to EFMHACA senior management. Feedback from different stakeholders, including EFMHACA management, was managed by the core team with the knowledge of the TWG. The TWG had defined terms of reference (TORs). Members of the TWG were Dr. Getahun Mengistu, Dr. Kidane Melles, Ato Yohannes Jorge, Dr. Adefris Debalke, Dr. Wondwossen Fantaye, Dr. Faris Hussein, Dr. Petros Mitiku, Dr, David A. Conteh, Dr. Ruth Lawson, Dr. Birna Abdosh, Ato Liyusew Solomon, Ato Edmealem Egjigu, Dr. Solomon Tessema, Dr. Endale Tefera, Ato Yihalem Tamiru, Dr. Abyou Kiflie, Ato K/mariam G/Michael, Ato Wondie Alemu, W/t Raey Yohannes, Ato Ayalew Adinew, Dr. Zegeye Hailemariam, Dr. Tassew Tadesse, Dr. Alem Michael, Dr. Aynalem Abraha, Dr. Mehrtu W/yes, Ato Zelalem Mesele, Ato Salehunae, Dr. Daniel Admassie, and Dr. Tekle-ab Zaid.

Review of Local and International Experience

TWG members reviewed healthcare standard–related materials and experiences from local and international sources. These documents included:

- Mississippi Department of Health, Health Facilities Licensure and Certification Standards (U.S.)
- Mississippi Department of Health, Minimum Hospital Standards (Supplement 1989) (U.S.)
- Florida Department of Health, Florida Board of Nursing, Nurse Practice Act, 2006 (U.S.)
- Florida Department of Health, Control of Radiation Hazard Regulations, 2009 (U.S.)
- Florida Department of Health, Emergency Medical Services, 2008 (U.S.)
- Florida Department of Health Standards for Onsite Sewage Treatment and Disposal System, 2009 (U.S.)
- Standards for Egyptian Hospital Accreditation Program, Sixth Edition, May 2005
- South Africa Good Pharmacy Practice Manual, Second Edition, 2006
- Jordan, Health Care Accreditation Council Hospital Accreditation Standards
- Experience-sharing visit to Jordan hospitals, Healthcare Accreditation Council of Jordan and Jordan Royal Medical Services
- Joint Commission International Hospital Accreditation Standards, Second Edition
- Joint Commission International Hospital Accreditation Standards for Clinical Laboratory, Second Edition
- Federal Democratic Republic of Ethiopia, Proclamation No 513/2007: Solid Waste Management
- Federal Democratic Republic of Ethiopia, Proclamation No. 300/2002: Environmental Pollution Control
- Federal Democratic Republic of Ethiopia, Proclamation No. 661/2009: Food, Medicine and Health Care Administration and Control Proclamation
- Ethiopian Building Code Standards
- FMOH: Various licensure standards for private health facilities in Ethiopia
- FMOH, Ethiopian Hospital Reform Implementation Guidelines, 2010

Defining the Type, Scope, and Structure of the Standards

During initiation of the drafting process, the hospital (three levels—primary, secondary, and tertiary), health center, and health post were the primary focus. However, as the work progressed, it was found to be necessary to cover different types of health facilities within the tier system. Therefore, it was determined to be important to assess the types of health facilities operating at the time of the drafting. Accordingly, the core team identified a number of different types of health facilities under the same tier system, as shown in Figure 1. Depending on the type of diagnostic facility and level of specialty, the specialty centers and advanced medical laboratories were categorized under either secondary or tertiary level of care. It was agreed among the TWG and EFMHACA management that the higher clinics operating at the time will no longer be part of a recognized health institution. Instead, higher clinics will have the opportunity to apply for specialty clinic or specialty center status, under the new categorization. Although new types of health facilities might emerge with time, the TWG and EFMHACA management defined the structure of the standards (for those identified as priority health facilities in need of standardization) as follows:

- General
- Licensure
- Governance
- Patient Rights and Responsibilities
- Human Resource Management
- Health Service Standards
- Cross-cutting Services Standards
- Physical Facility Standards

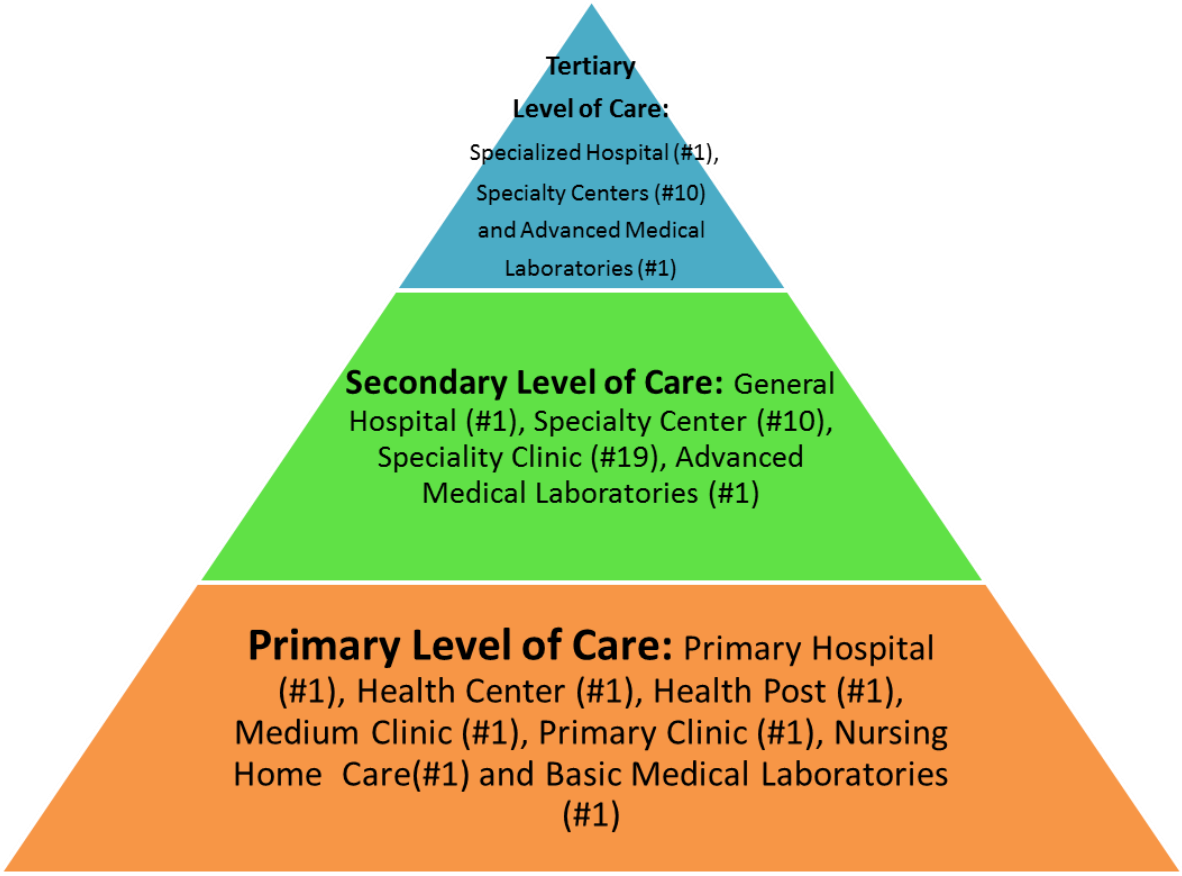

Figure 1. Number and classification of 39 standards by level of care

Development of Zero Draft

The different components of a health facility standard were divided among the various experts who were members of the TWG with the facilitation of the core team so as to draft the standards based on the international experiences and local contexts. The resulting draft was finally presented to the whole 30-member TWG. The governance and licensure components were drafted by a lawyer and regulatory expert, respectively, different specialty services components by the respective medical specialists, the laboratory section by a senior medical laboratory expert, the pharmacy section by a senior pharmacist, the physical premises standards by an engineer specializing in healthcare facility construction, nursing care standards by a senior professional nurse, and so on. Once an individual component was finalized, the core team combined all the sections and produced a draft health facility standards document; this was shared with the TWG for technical recommendations. This way, all standards were reviewed and the first draft was made ready for consultation with relevant stakeholders. Completing the first draft of all standards (which are more complex and numerous than initially anticipated by EFMHACA, as stated in the TORs), took more than two years.

STAKEHOLDERS' ENGAGEMENT AND PARTICIPATION

The health facility standards are intended to serve as a licensure and inspection tool for both federal and regional regulatory bodies. In addition, any institution providing health services is expected to be aware of these standards before any new investment, as any change in premises, services, professionals, or products may have an implication for licensing. The standards will affect not only health institutions but also professionals who provide health services. Therefore, for the successful implementation of the standards, relevant stakeholders' engagement and participation in the development process was important. Accordingly, one national and six regional consultation workshops were organized to review the draft standards in the presence of relevant stakeholders. During the consultation process, the general public was represented by the different level health administration offices, whose function is to ensure the health of the population. A summary of the two levels of consultation is presented below.

National Consultative Workshop

The national consultative workshop was officially opened by His Excellency (H.E.) the State Minister of the Federal Ministry of Health of Ethiopia on February 8, 2010. Draft standards for health post, health center, primary hospital, general hospital, and the different types of specialized hospitals were presented at this national workshop. About 150 participants drawn from different stakeholder and partner organizations participated. The workshop was conducted February 8–12, 2010, at the Management Institute, Debrezeit. It was expected that the workshop would help in creating consensus and facilitate ownership among participants. In addition, a variety of technical inputs were expected from participants. The consultation process achieved these expectations.

The national consultative workshop was attended by experts of diverse specialties who contributed their experience and valuable feedback. The draft documents were reviewed in five groups; following the group work a plenary session was held in which the findings and recommendations of each group were presented to the general audience. Participation during the group work and general assembly was extremely constructive, informative, and encouraging to the organizers and made a huge contribution in terms of creating clarity, a common understanding, and consensus on the contents and intent of the standards.

Standards for Public Health Institutions: Regarding the health post, health center, primary hospital, general hospital, and specialized hospitals, workshop participants made a number of recommendations, comments, and suggestions for inclusion, deletion, clarification, and further work. It was noted that the private sector is free to invest in and establish such facilities. Among the key issues forwarded to the organizers for due consideration were:

- Feasibility of a three-year grace period for existing health facilities to fulfill these regulatory standards

- Availability of specialists in 30 minutes upon call during off-hours, which is not feasible in the Ethiopian context

- Number of beds for different types of hospitals

- Mandated overlap between EFMHACA and the Ethiopian Radiation Protection Authority
- Clarity on the roles and responsibilities of Chief Executive Officer and Chief Clinical Officer
- Nurses' prescribing privileges
- Human resource requirements for certain disciplines
- Merging laboratory and pathology services
- The need to have ambulance service at the general hospital level

Standards for Ambulatory Care: The question of whether to develop ambulatory patient care regulatory standards was one of the issues discussed thoroughly. It had been agreed that ambulatory patient care should have the following structure. However, with a series of consultations, changes have been made to this recommendation.

- Office practice: later, this component was omitted
- Level I (existing lower clinic)
- Level II (existing midlevel clinic)
- Level III (specialty clinics and polyclinics): later, it was decided to categorize these clinics into specialty clinics and specialty centers
- Level IV (medical center): later, this standard was omitted because the services and functions of a medical center overlaps with those of a general hospital
- Stand-alone imaging and laboratory diagnostic service
- Nursing home centers
- Mobile medical service: suspended due to priority
- Dietary counseling service: suspended due to priority

The key issues that were controversial and forwarded to the attention of the organizers and plenary by the small-group participants were:

- Who is the appropriate health personnel to manage a medium clinic? It is known that health officers are the best fit. Can a BSc (bachelor of science) nurse manage this type of clinic?
- Average length of stay for patients admitted in the medical center. Two options had been proposed by the group: "5–7 days based on physician judgment" or "no limitation."

Physical Facility Standards: A team of experts from engineering and regulatory standards was assigned to work on physical facility standards. They made a number of recommendations and suggestions to improve the draft document to the level of an acceptable standard by the organizers. In addition, the group had forwarded the following issues to the attention of the plenary:

- Service standards are not dealt with equally. Some describe the premises requirements in detail and others do not. Can we take this as final and continue our design work?

- Communal spaces like reception and recreational places are not well addressed. Are they to be regulated or only the specialty areas?

- Most specialty clinics are large with attached with offices. This will increase space requirements, as well as traveling time from one unit to other, and it has to be noted that it will change the design of the existing hospital.

- International experience has to be considered in determining regulatory standards for physical facilities.

- This team or expert who works on premises needs the support of other health professionals, and this must be facilitated.

- The country's building code standards and health facility standards must be reconciled.

Plenary Session: At the end of the workshop, participants were given the chance to express their views about the development process for the regulatory standards. Among others, the following were reflections of the general audience:

- They appreciated the efforts of the EFMHACA and they expect these standards will bring change in the quality and safety of healthcare services. They also said it that the authority's development of these standards is overdue.

- The issue of organizing EFMHACA as an independent institution needs attention.

- The EFMHACA should develop regulatory standards for health facilities such as physiotherapy center, stand-alone medical laboratory, traditional medicine, dietary counseling service, nursing home, and others.

- The scope of practice for each healthcare professional must be developed.

- Duplication of efforts and quality of training in health teaching institutions must be revisited (in relation to BSc nurses and health officers).

- Uniformity in style of presentation among different sections (of the standards) must be respected.

- Application of one standard for public and private health facilities is greatly appreciated.

Regional Consultative Workshops

Following the same fashion, the core team and TWG developed the first draft of regulatory standards for specialty centers, specialty clinics, medium clinics, primary clinics, nursing homes, office practices (canceled at latter stage), and different levels of laboratory and diagnostic facilities for stakeholders' consultation. Following the completion of these standards, 6 rounds of regional consultative workshops were conducted, in Bahir Dar, Debrezeit, Dire Dawa, Hawassa, Jimma, and Mekelle, with a total of more than 300 participants. The following general comments were provided:

- Implementation should consider the real situation of the country.
- For specialists, work experience should be exempted. Others said two years of relevant work experience should be mandatory for head physicians, nurses, and laboratory and pharmacy personnel.
- Availability of radiologists and anesthesiologists was of great concern in most of the consultative workshops.
- On-call service should be within 60 minutes instead of 30 minutes.
- Health-professionals-to-inpatients ratio should be converted to health professionals-to-inpatient-beds. Accordingly, these ratios should be respected: nurse (1:6), general physician (1:15), and specialist (1:30).
- There must be clear direction on merging maternal and child health/pediatric center, neurology and neurosurgery, urology and renal surgery, and other internal medicine components.
- Standards should also be prepared for gynecology/obstetrics, psychiatry with rehabilitation, pathology, ear-nose-throat (ENT), trauma, plastic surgery, infectious disease management center, ophthalmology center, maxillofacial surgery center, and others.
- All premises and professionals should be briefly defined under each specialty.
- Inconsistencies in laboratory premises across all specialty centers should be avoided.
- Outsourcing of kitchen, laundry, cleaning, and security should be allowed but not of laboratory service.
- Toilet with hand washing basin should be included in the premises of all types of centers.
- The private sector shall be represented in the board of directors of the appropriate regulatory body.
- Human resource was identified as a concern.

- A concern was raised about the implementation capacity of the standards.
- Supplies are not available on the market as per the standard.
- Setting complex premises requirements for healthcare facilities will make getting an operating license a challenge.
- Corruption has been raised as a serious concern within the regulatory system. Corruption is reported as becoming a "legitimate" means to get the required service from regulatory authorities.
- There is a need to substitute the term "license" with "professional license."

Once feedback was collected, the core team and the TWG had a series of consultations to incorporate appropriate comments. When an issue was beyond the capacity of the core team and TWG to decide, it was presented to the management of EFMHACA for a final decision.

After completion of the stakeholders' consultation process, the draft standards were tested at selected health facilities in different parts of the country. The lesson learned from the field test was that the standards developed are achievable but that this requires the commitment of all parties concerned.

LEADERSHIP INVOLVEMENT IN THE DEVELOPMENT PROCESS

The enforcement of these standards is expected to have substantial implications on access to and quality of healthcare services in Ethiopia. As a result, the senior management of the relevant government institutions had given utmost emphasis to following up the entire standards development process, from drafting to approval. Their persistent leadership during the preparation/development, alignment, and process validation/endorsement phases played a key role in successful conclusion of the task.

Preparation/Development Phase

The EFMHACA management successfully led the development process by organizing a core team and TWG composed of experts of the highest professional qualification and experience in the health sector of the country. The management was able to effectively secure the active involvement of different stakeholders, including professional associations, regional health bureaus, regional regulatory bodies, federal institutions, selected health facilities, and partners. In addition, the management had several meetings with the core team and TWG to get clarification and resolve ambiguities at each step of the process, and provided important directions and oversight to the group and its work. After finalization of the draft standards from a regulatory perspective, the EFMHACA management arranged a consultative meeting with the FMOH Executive Committee, presented the standards, and ensured that overall consensus was achieved on key issues.

Alignment Phase

The FMOH Executive Committee, which comprises the Minister and State Ministers and Agency Directors, dedicated adequate time to review the standards to make sure that their contents are in line with the Health Sector Development Programme and the country's health and drug policies and legislations. After a detailed briefing about the development process by EFMHACA on September 30, 2011, the executive committee pinpointed those controversial and policy issues raised during the development process. Based on the explanations made by the core team members and EFMHACA management, the executives took appropriate decisions on some of the key issues. After two days of thorough discussion with EFMHACA management and core team members, the Executive Committee recommended the finalization of the draft standards as per the directions and feedback and submission to the ESA for approval.

Process Validation/Endorsement Phase

The concerted effort of the EFMHACA management and core team in close consultation with the TWG members finally produced the final draft standards as per the format provided by the ESA. Then EFMHACA submitted them to ESA for review and approval. ESA has its own internal process for the approval of such mandatory standards. After close consultation with EFMHACA management and the core team, ESA learned that EFMHACA developed the draft standards through a series of consultations using a bottom-up approach (from practitioners up to FMOH executives and other relevant external stakeholders), which is a mandatory procedure for the setting of national standards. With this understanding, ESA submitted the draft to the Board of Directors, which is the final legitimate body, to endorse the national standards. The board approved all standards on May 2, 2012.

INAUGURATION AND POPULARIZATION OF STANDARDS

There was consensus among federal and regional government bodies to provide a one-year grace period to launch the implementation of these standards. One year after their approval by ESA, the Ethiopian Health Facilities Minimum Regulatory Standards, the first of their kind in the country, was launched at a workshop held in Hawassa on May 17, 2013. The Minster of Health, H.E. Dr. Kessetebirhan Admassu, inaugurated the new standards in the presence of H.E. Dr. Kebede Worku, State Minister of Health; H.E. Mr. Yosef, Deputy Chair of the House of Representatives' Social Sector Standing Committee and member of Parliament; a delegation from the ESA; members of professional associations and development partners; Heads of the Regional Health Bureaus; the EFMHACA; PFSA senior management members; and invited guests from government and nongovernmental organizations. (See photo 1.)

Photo 1. H.E. Dr. Kessetebirhan Admassu during inaugural speech

During the inaugural ceremony, the Minister indicated that the health sector is now restructured into three pillars: Service Provider, Service Purchaser, and Service Regulator. He emphasized the important contributions of the new standards in achieving the objectives of the health sector by helping the EFMHACA to ensure the safety and quality of health services. The delegate of the ESA, Mr. Legesse, Head of the Standard Development Division, noted that the process of developing these standards is an exemplary work for the country, as the engagement of concerned stakeholders was prominent, ensuring their ownership of the process. He announced that the one-year grace period for adhering to these standards has expired and that responsible government institutions now must enforce health facilities'

compliance with the standards. He also added that health facilities should work hard to meet the requirements defined by the new standards.

After several remarks made by delegates of different institutions, the Minister acknowledged all institutions, partners, and TWGs involved in standards development. Institutions and partners have received certificates of appreciation and members of TWGs (photo 2) have been awarded medals and certificates of appreciation directly from the Minister of Health and State Minister of Health.

Photo 2. Some members of the technical working group

The total number of health facility standards (photo 3) that were ready for inauguration was 39, encompassing health post and nursing home standards at the primary level of care to comprehensive specialized hospitals at the tertiary level of care.

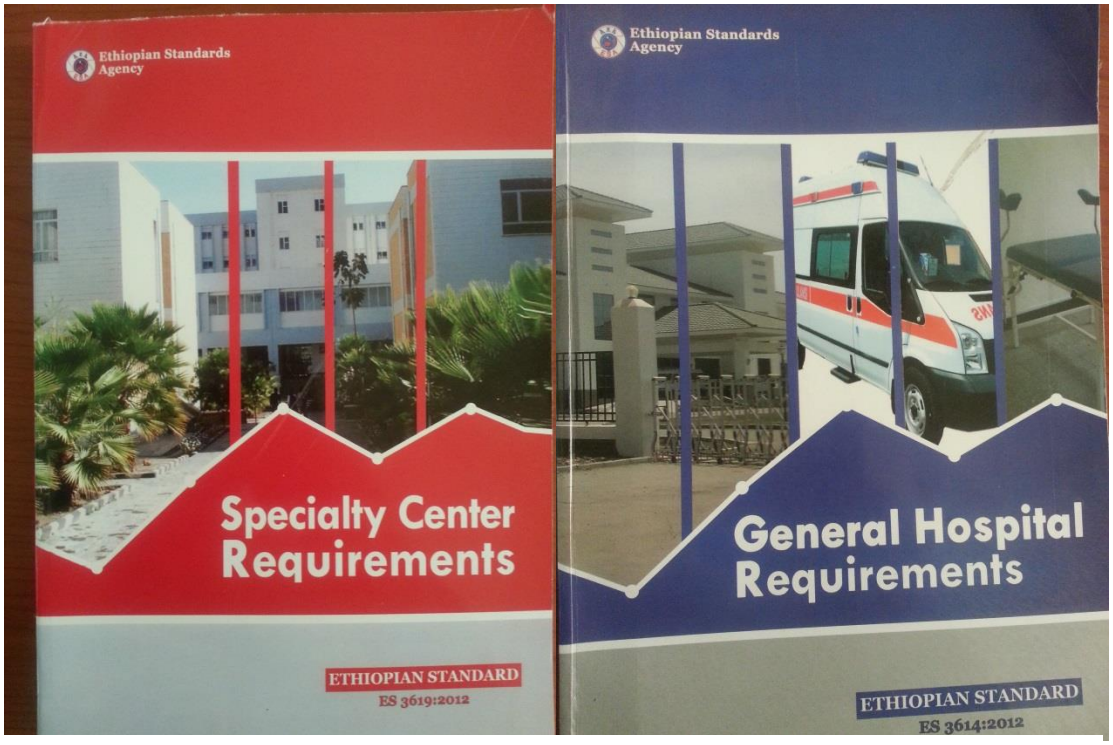

Photo 3. Selected printed health facility standards

LIST OF NEW NATIONAL MINIMUM STANDARDS

Category		Standards	
I.	**Health Posts**	1.	Health Post Standards
II.	**Nursing Home Care**	2.	Nursing Home Care Standards
III.	**Primary Clinics**	3.	Primary Clinic Standards
IV.	**Medium Clinics**	4.	Medium Clinic Standards
V.	**Laboratories**	5.	Basic Medical Laboratory Standards
		6.	Advanced Medical Laboratory Standards
VI.	**Specialty Clinics**	7.	Eye/Ophthalmology Specialty Clinic
		8.	Specialty Dental Clinic
		9.	Medium Dental Clinic
		10.	Dental Laboratory
		11.	Obstetrics & Gynecology Clinic
		12.	Pediatric Specialty Clinic
		13.	Dermatology Clinic
		14.	Psychiatry Clinic/Mental Health Clinic
		15.	Oto-Rhino-Laryngo (ORL)/Ear-Nose-Throat (ENT) Specialty Clinic
		16.	Surgery Specialty Clinic
		17.	Orthopedic Specialty Clinic
		18.	Internal Medicine Specialty Clinic
		19.	Neurology Specialty Clinic
		20.	Cardiovascular Specialty Clinic
		21.	Gastroenterology Specialty Clinic
		22.	Rheumatology Specialty Clinic
		23.	Nephrology Specialty Clinic
		24.	Chest Specialty Clinic
		25.	Physiotherapy Clinic
VII.	**Specialty Centers**	26.	Maternal and Child Health Specialty Center
		27.	Pediatric Specialty Center
		28.	Surgery Specialty Center
		29.	Internal Medicine Specialty Center
		30.	Orthopedic Specialty Center
		31.	Cardiac Specialty Center
		32.	Oncology Specialty Center
		33.	Neurology Specialty Center
		34.	Gastroenterology Specialty Center
		35.	Renal Specialty Center
VIII.	**Primary Hospitals**	36.	Primary Hospital Standards
IX.	**Health Centers**	37.	Health Centers Standards
X.	**General Hospitals**	38.	General Hospital Standards
XI.	**Comprehensive Specialized Hospitals**	39.	Comprehensive Specialized Hospital Standards

SNAPSHOTS OF PHARMACEUTICAL SERVICE STANDARDS

Health facilities that have inpatient care are allowed and expected to establish inpatient, outpatient, and emergency pharmacies. Health facilities that provide ambulatory patient care only are not allowed to establish any of these pharmacies. In health facilities that are allowed to establish a pharmacy within their premises, the standard of pharmaceutical services is organized as practice, premises, professional, and product/facility standards. The practice standards are extensive, and just to give an overview, they are grouped into these 12 categories:

- Dispensing and Medication Use Counseling
- Control of Drug Abuse, Toxic or Dangerous Drugs
- Hospital-Based Pharmaceutical Preparations
- Clinical Pharmacy Services
- Emergency Pharmacy Services
- Adverse Drug Reactions/Pharmacovigilance
- Pharmaceutical Supply and Management
- Drug Information Services
- Medicines Waste Management and Disposal
- Recording and Reporting
- Billing Patients
- Pharmacy Organization Management and Quality Improvement

The application of these 12 categories of practice standards varies from one health facility to another based on the level of care in the tier system. For instance, clinical pharmacy services and hospital-based pharmaceutical preparations are mandatory for specialized hospitals but not for primary hospitals or health centers. The premises standards define the premises requirements for patient-oriented pharmacy services in outpatient and inpatient settings and for medicines supply management operations. Again, the requirements vary based on the type of health facility. The same approach had been followed in defining the professional and product/facility requirements.

In health facilities, such as ambulatory clinics, that are not allowed to establish a pharmacy within their premises, the standard of pharmaceutical services is organized in a different way. These facilities are required to abide by some restrictions in the delivery of medicines to their patients. They are allowed to avail only emergency medicines used to manage emergency cases. Standards for the appropriate management of these emergency medicines are defined. The responsibility to execute these standards is given to the medical staff of the clinics; therefore, they are not allowed to recruit pharmacy professionals. In addition, the premises and products/facilities requirement they are supposed to fulfill are limited to the types of emergency medicines they are allowed to manage.

IMPLEMENTATION STATUS, CHALLENGES, AND THE WAY FORWARD

EFMHACA, in collaboration with SIAPS and PHSP, has taken the lead in printing adequate copies of these standards and distributing them to all stakeholders and customers of the regulators at different levels. SIAPS has provided support for printing most of the standards (specialty clinic, specialty center, primary hospital, and specialized hospital categories), both technically and financially. EFMHACA has provided training of trainers for its own and regional regulatory bodies' inspection and licensing officers. As a result of this training, a number of regional-level trainings have been conducted to familiarize the implementers with the new standards. Cascading to the lower level, regional regulatory bodies are conducting training on health facility inspection and licensing as per the new standards. Addis Ababa City Administration, Amhara Regional, Southern Nations, and Nationalities Regional States are among the pioneer regions implementing the standards; others are following same path.

These new standards are part and parcel of the country's health legislation, with which compliance is mandatory. As is stated in the licensure part of the standard, penalties for violation of regulations are serious: "The appropriate organ may deny, suspend or revoke a license or order closure of a service or unit within the health facility, cease admissions to a hospital, order removal of patients from a hospital, or impose a financial penalty where it finds that there has been a substantial failure to comply with these standards." However, there are limitations in the implementation process of these new standards, as discussed below:

- Although introduction of these standards is a huge transformation in the country's healthcare regulation, there is no written, agreed-upon strategy for how to effectively implement these standards in all public and private health facilities. The new standards are expected to increase the budget allocation for health services, as the requirements oblige health institutions to improve the four Ps: Practices, Premises, Professional, and Products. The implication of these standards for the resources required, with particular attention to the landscape of the healthcare budget, should be properly forecasted in a strategic document.

- There is a lack of sufficient advocacy for the standards to health facility owners and executives. Private health facilities are complaining that the new standards don't consider the realities of the country. They are demanding an extended grace period and changes in some of the standards. The implementation needs effective public-private partnership.

- The capacity of regulatory bodies at regional levels is still in its infancy, as the decentralization of regulatory functions to regions is a recent occurrence. The decentralization was made after the enactment of proclamation 661/2009. These regional bodies have limited capacity in terms of resources, trained and experienced human resources, and well-functioning systems.

To effectively implement and achieve quality- and safety-related objectives, the government should develop a long-term strategy, provide adequate resources, and lead the implementation process through effective collaboration with the private sector, civil society organizations, and development partners.

Terms of Reference for Healthcare Facilities Standards Development

Regulatory Standards–Setting Team of the Ethiopian Food, Medicines & Healthcare Administration and Control Authority

June 2009

1. Introduction

The Ministry of Health is responsible for the quality of health service throughout the country. Although a number of special programs have been operational, in the last few years, the Primary Health Care quality still requires due attention. Various challenges, assumptions, and bureaucratic hurdles have been hampering the steady progress in quality health care delivery system.

It has been recognized that decision making processes have not been fully decentralized. The public health care system is underdeveloped and only able to provide basic service to a small number of the population. Most of the population has little access to modern and standardized health care. This is because of the inability of the health care delivery system to respond both quantitatively and qualitatively to the health needs of the people. The Federal Government and the regional authorities are trying to recognize health services into a more cost-effective and efficient system better able to meet the needs of its citizens and contribute to the overall socio-economic development effort of the country.

The Ministry hence initiated business process reengineering (BPR) in order to establish an efficient and effective system to standardize the whole health system of the country at all levels of the health sector. It is believed that the whole health sector is committed to bring a dramatic result on the health services of the country by fundamentally re-thinking and radical redesign. As a result of the business process reengineering the health sector services are organized into health service **providers, purchasers, and regulators**.

Based on the health sector service classification, the Ministry expressed its commitment to fully decentralize and redesign the health care regulatory system to meet the needs and expectations of customers/stakeholders. From the analysis of the findings observed from customer/stakeholder studies, problems and their cause and effect relationship, it is found that the health care delivery should require standardization.

The re-designing of the health care delivery core process of the health sector indicates there is a five-tier health care delivery system. The provision of complete health service by each level of health care tier necessitates the availability of standards required for quality health care service. The five-tier system has a pyramidal structure which consists of health posts at the base, followed by health centers, primary hospitals, general hospitals, and specialized hospitals going up the pyramid.

2. Problem of Statements

- There were double standards.
- The previous health care delivery tier system is changed.
- Non-standardized health care facilities exist.

3. Rationale

According to the BPR of the health sector, all the public and private health care delivery facilities will be treated by uniform standards. This avoids double standards in the health sectors. There will not be different standards in the same country.

To achieve a standardized health service in the country it is not enough to avail health services available. But it should also address safety and quality. The service provided by the health facilities should be quantitatively and qualitatively standardized so that the public

could be an informed decision maker for itself in terms of where, what, when, and how to be served.

The business process re-engineering of the health care provision of the health sector shows the need for standards. According to the new-tier health care delivery system there should be a standard for each health care facility (hospitals, health centers and health posts).

Furthermore, based on the legal framework of our country, Ethiopia, standards are to be developed at the federal level and implementation will be throughout the country. Accordingly, in our case the regions are expecting regulatory standards from the federal regulatory authority (EFMHACA).

Therefore, the EFMHACA has planned to develop health care standards (for hospitals, health centers, and health posts) so that the public will have access to standardized health services.

4. Objective

4.1 *General Objective*

The general objective of this project is to develop healthcare facility (for specialized hospitals, general hospitals, primary hospitals, health centers, and health posts) standards according to the new-tier health care delivery system throughout the country.

4.2 *Specific Objectives*

The specific objectives of the project are:

- To promote quality of health care service in the standardized health care facilities
- To design a mechanism for assessing the quality of care provided in the health care facility
- To ensure the quality of health delivery service provided in the health care facilities
- To control their compliance with the available standards
- To enforce the health care facilities who do not comply with contemporary health care facility standards
- To provide licenses for the newly established health care facilities
- To regulate and control qualitative and quantitative performance of health delivery service in the health care facilities
- To achieve customer satisfaction
- To create an informed citizen/public and to make the citizens/public a decision-maker about the services given
- To help the public know where to be served
- To guide service providers and owners about the norms of practice

5. Scope of the Working Group

The scope of the working group is:

- To conduct need assessments, if found to be necessary
- To develop health care facilities (specialized hospitals, general hospitals, primary hospitals, health centers, and health posts) standards

6. Roles and Responsibilities of the Working Group

The working group has the following roles and responsibilities:

- Develop proposed checklist for need assessment, if required
- Conduct need assessment, if required
- Compile, analyze, and interpret the collected data, if required
- Report the assessment result, if required
- Develop the required standards through this process:
    - Collect resource materials and relevant information
    - Develop the zero draft
    - Organize consultative meeting
    - Finalize or enrich the draft document
    - Organize national workshop on the document
    - Finalize and print the standards
    - Carry out familiarization and dissemination of the standards
- Send the information to the regulatory information delivery service

7. Qualifications of the Members of the Working Group

The working group shall have the following members:

- Pharmacist
- Sanitarian
- Public health officer
- Laboratory technologist
- Medical practitioners (gynecologist, or specialist, internal medicine specialist, etc.)

8. Resource Budget

- Government
- NGOs (Clinton Foundation, MSH/SPS, Tulane University, PEPFAR, etc.)

9. Terms of the Working Group

The working group is limited to completing its objectives of development of the standards with in **2 months**

Se.No	Activities to Be Performed	Time Limit
1	Collection of information (benchmarked standards)	Prior to May 20, 2009
2	Writing invitation letter for stakeholders and sending	
3	Formulating working group	June 1–3, 2009
4	Sensitizing the working group about the task	June 3, 2009
5	Task division/sharing assignment	June 3, 2009
6	Developing the zero draft standards	June 3–26, 2009
7	Regular meeting with working group	Weekly, Saturday a.m.
8	Mini workshop	June 29–30, 2009
9	Enrichment of the draft document from the mini workshop	July 1–8, 2009
10	General consultative workshop	July 9–14, 2009
11	Finalizing the document (standards)	July 15–30, 2009
12	Finalizing and printing the standards	
13	Familiarization and dissemination of the standards	

10. Output of This TOR

- Health care facility standards

11. Template for Healthcare Facilities Standards (Hospitals Standards According to the Health Tier System)

General Provision:

- The standards or rules should apply for licensing of new healthcare facilities and for regulation and control of each licensed facility that renders services to the public. They are intended for use in inspection process and ensuring enforcement actions.
- These standards should contain specifications, requirements, minimum components of quality of care and standards of practice.
- The standards should be designed according to the type of healthcare facility level.
- The standards should be applicable for profit or nonprofit (i.e., government or private) facilities. There will not be a double standard at the national level. The standards should treat both the government and private hospitals equally according to the health tier system.

Objective of the Standards

a) To provide license for those newly established health care facilities
b) To regulate and control qualitative and quantitative performance of health delivery services in the health care facilities

The health care facility standards should encompass at least the following:

1) Licensure procedure
   - General provisions
   - Standards of compliance
   - License requirements
   - Certificates required
   - Initial licensure
   - License renewal
   - Denial, suspension, and revocation of a healthcare facility license
   - Hospital location (offsite location(s))
   - Type of hospital (description of facility)
   - Accreditation status
   - Bed capacity
   - Type of service delivery wards
   - Services to be provided
   - Staffing

2) Service requirements and specifications
   - Administration
   - Pharmaceutical services
   - Nuclear medicine services
   - Radiological services
   - Internal medicine
   - Laboratory services
   - Dermatological services
   - Optometric services
   - Infection control
   - Surgical services
   - Intensive care services
   - Anesthesia services
   - Cardiac services
   - Gynecology and obstetrics care services
   - Mental healthcare services

- Blood bank services
- ENT services
- Dentistry services
- Pediatrics services
- Outpatient services
- Nursing services
- Emergency services
- Ambulatory services
- Rehabilitation services
- Food and dietary services
- Staff requirements (medical staff, nursing staff, and other mandatory staff)
- Employee health requirements
- Patient flow
- Patient rights
- Patient care and treatment
- Discharge planning
- Record keeping requirements
- Physical plant standards (construction standards environment, building systems, site requirements)
- Housekeeping, laundry, and maintenance
- Sanitation requirements (waste disposal service, sewerage system….)

The standards should be ***qualitatively and quantitatively measurable***. Here, the management system, working manuals, and standards of hospitals should be clearly separated. In addition, the standards should vividly show ***"Do this, do not do that" and/or "Have this, do not have that."***

For example, some requirements concerning the physical plant of the health care facilities:

1. Selecting the site:
   - Size of the site
   - Topography
   - Drainage
   - Soil condition
   - Utilities availability
   - Natural nature
   - Infrastructure
   - Climatic condition
2. Construction or building condition
3. Conditions about the immediate surroundings of the health facility (sanitation, amount of light, sounding condition, etc.)
4.

12. List of Health Facility Standards to Be Developed

The standards to be developed may be built-in with parts or sections or chapters or volumes, etc. Here is a proposed framework for the standards.

Title 1: Health care facilities standards

Chapter 1: Minimum standards for specialized hospitals
- Section 1: Licensure procedure
- Section 2: Service standards
- Section 3: Plant standards
- Section 4: Administration and governing board

Chapter 2: Minimum standards for general hospitals
- Section 1: Licensure procedure
- Section 2: Service standards
- Section 3: Plant standards
- Section 4: Administration and governing board

Chapter 3: Minimum standards for primary hospitals
- Section 1: Licensure procedure
- Section 2: Service standards
- Section 3: Plant standards
- Section 4: Administration and governing board

Chapter 4: Minimum standards for health centers
- Section 1: Licensure procedure
- Section 2: Service standards
- Section 3: Plant standards
- Section 4: Administration and governing board

Chapter 5: Minimum standards for health posts
- Section 1: Licensure procedure
- Section 2: Service standards
- Section 3: Plant standards
- Section 4: Administration and governing board

NB: In each section there are sub-sections.

13. Classifications of healthcare services and facility requirements between the healthcare facilities

Services Required	**Specialized Hospital**	**General Hospital**	**Primary Hospital**	**Health Center**	**Health Post**
Administration	√	√	√	√	√
Pharmaceutical service	√	√	√	√	√
Nuclear medicine service	√	√			
Radiological service	√	√			
Chemo therapy	√				
Internal medicine	√	√	√		
Laboratory service	√	√	√	√	√
Blood bank service	√	√			
Infection control	√	√	√	√	√
Surgical service	√	√	√	√	
Intensive care service	√	√			
Anesthesia service	√	√	√	√	
Cardiac service	√	√			
Dermatological service	√	√	√	√	
Optometry service	√	√	√		
Gynecology and obstetrics care service	√	√	√	√	
Mental health care service	√	√	√	√	
ENT service	√	√	√		
Dentistry service	√	√	√		
Pediatrics	√	√	√	√	√
Outpatient service	√	√	√	√	√
Nursing service	√	√	√	√	√
Emergency service	√	√	√	√	√

Services Required	**Specialized Hospital**	**General Hospital**	**Primary Hospital**	**Health Center**	**Health Post**
Ambulatory service	√	√	√	√	
Rehabilitation service	√	√	√	√	
Food and dietary service	√	√	√	√	√
Staff requirements (medical staff, nursing staff, other mandatory staff)	√	√	√	√	√
Employee health requirement	√	√	√	√	√
Patient flow	√	√	√	√	√
Patient care and treatment	√	√	√	√	√
Discharge planning	√	√	√	√	√
Record keeping requirement	√	√	√	√	√
Physical plant standards - Construction standards - Environment - Building systems - Site selection requirements)	√	√	√	√	√
Housekeeping, laundry, and maintenance	√	√	√	√	√
Sanitation requirements (waste disposal, sewage system)	√	√	√	√	√

NB: The different services available in each facility may vary in their **extent** or **intensity** of service provision.

ANNEX B. EFMHACA (DACA) LETTER OF REQUEST

THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA
DRUG ADMINISTRATION AND CONTROL AUTHORITY OF ETHIOPIA

07/14.2/50
20 MAY 2009

To MSH/SPS

Addis Ababa

Subject: Request for Assistance

Dear Sirs,

The health sector Business Process Re-engineering (BPR) implementation has been initiated and the regulatory authority has been given some additional mandates so as to bring similar and related activities together and better serve customers.
We understand and appreciate that your office has made unreserved effort to assist the health sector in general and the regulatory in particular in the area of preparation of proclamation, regulations and human resource incentive strategy. We would like to inform you that our current critical gap is in skilled medical professionals mainly in the area of standard setting for health facilities (hospitals, health centers)

Therefore, we kindly request your good office to extend the assistance by assigning 2 pharmacy/health professionals with adequate experience in the area of developing standards for health facilities.

Sincerely yours,

Yehulu Denekew Alameneh
Director General

C/C.

- Deputy D/ General, Standards and Licensing
- Regulatory Standards setting and Information Delivery Directorate

EFMHACA

Dr Negussu
Ato Emoalem is temporarily assigned to represent DF until final decision made

ANNEX C. CERTIFICATE OF APPRECIATION

CERTIFICATE OF APPRECIATION

PRESENTED TO: USAID | SIAPS

IN RECOGNITION OF THE VALUABLE CONTRIBUTION TO THE DEVELOPMENT OF HEALTH FACILITY REGULATORY STANDARDS BY THE ETHIOPIAN FOOD MEDICINE & HEALTHCARE ADMINISTRATION & CONTROL AUTHORITY (EFMHACA)

MAY 2013, HAWASSA

ETHIOPIA

H.E DR. KESETEBIRHAN ADMASU
MINISTER, FEDERAL MINISTRY OF HEALTH

ATO YEHULU DENEKEW
DIRECTOR GENERAL, EFMHACA