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1.0 Purpose

This document aims to standardize the implementation of the procedure for certification, licensure, and accreditation of hospitals and other health facilities to harmonize the licensing process nationwide.

2.0 Scope

This procedure starts with the receipt of **complete** application to the issuance of **CON, PTC, LTO/COA/ATO** by the HFSRB or the CHD-RLED.

3.0 References

R.A. 11032 also known as "Ease of Doing Business and Efficient Government Service Delivery Act of 2018"
DOH Quality Management System
Refer to Annex A "List of DOH Issuances and Pertinent Laws"

4.0 Definition of Terms

Authority to Operate (ATO)-a formal authorization issued by the Department of Health to blood station/ blood collecting unit upon meeting the licensing requirements.

Health Facilities and Services Regulatory Bureau (HFSRB) – The regulatory body of the Department of Health in charge of licensing and accreditation of hospital and other health facilities. The Bureau consists of the following divisions:

1. **Standards and Development Division (SDD)** - Task to formulate standards, requirements, and policies.
2. **Quality Assurance and Monitoring Division (QAMD)** - Responsible for the monitoring of compliance to standards of licensed facilities and surveillance of unlicensed facilities.
3. **Regulatory Compliance and Enforcement Division (RCED)**- Responsible for the issuance of license and accreditation of health facilities upon compliance to standards and technical requirements

Certificate of Need (CON) – an authorization required prior to the establishment of new hospital, conversion from special to general hospital, or conversion of *primary care facility* into a general hospital. It is a prerequisite to issuance of Permit to Construct


Certificate of Accreditation (COA) - a formal authorization issued by the Department of Health to an individual, partnership corporation or association to operate a hospital and other health facilities. Unlike licensing, Accreditation focuses on continuous improvements strategies, achievement of optimal quality standards, and on-going education and consultation; set at a minimum achievable level to stimulate improvement overtime.

Certificate of Compliance or Recommendation Letter (COC or RL) – Certification issued by the Food and Drug Administration (FDA) that the facility is compliant with the requirements for pharmacy and x-ray facility.

Client- constitutes the regulated facilities, stakeholders or members of the public.

Health Facility- a building or physical structure where healthcare is provided.

Hospital- a health facility for the diagnosis, treatment and care of individuals suffering from deformity, disease, illness or injury or in need of surgical, obstetrical, medical or nursing care. It is an

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institution where there are installed bassinets or beds for 24-hour use or longer by patients in the management of deformities, diseases, injuries, abnormal physical and mental conditions and maternity cases.

Inspection- actual visit to hospital and other health related facilities to verify compliance to standard minimum requirements as to service capability, physical plant, personnel, and equipment/ instrument.

License to Operate (LTO) - A formal authorization issued by the Department of Health to an individual, partnership corporation, or association to operate a hospital and other health facilities. Licensing focuses on adherence to minimum standards intended to assure public safety; set at a minimum level to ensure an environment with minimum risk to health and safety.

One-Stop-Shop Licensure System (OSS)- a strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other facilities including but not limited to, clinical laboratory, HIV testing, drinking water analysis and drug testing; blood bank, blood collection unit and blood station; dialysis clinic; ambulatory surgical clinic; pharmacy and medical X-ray facility.

Permit to Construct (PTC) – An authorization required before the construction of a new hospital or other health facility; with substantial alteration, expansion or renovation, change in classification, increase in bed capacity, transfer of site, or for add-on services. It is a prerequisite for a License to Operate or a Certificate of Accreditation.

Regulations, Licensing, and Enforcement Division (RLED) - A division at the Center for Health Development (CHD) responsible for the issuance of Certificate of Need, Permit to Construct, License to Operate/Authority to Operate, and the conduct monitoring of hospital and health facilities such as but not limited to the following: Infirmary, Birthing Homes, Laboratory for Drinking Water Analysis, Clinical Laboratory, Blood Station/ Blood Center Unit, Dental Laboratory

5.0 Responsibilities

CON Committee	Responsible for evaluating application for CON based on established criteria and recommends issuance/non-issuance of CON.
Director IV	responsible for final approval of License to Operate (LTO)/Certificate of Accreditation (COA)/Authority to Operate (ATO), Permit to Construct (PTC), Certificate of Need (CON), resolution on complaints and other regulatory actions such as issuances of Notice of Violations and Cease and Desist Order.
Division Chief	responsible for recommending the approval of License to Operate (LTO)/Certificate of Accreditation (COA)/Authority to Operate (ATO), Permit to Construct (PTC), Certificate of Need (CON), resolution on complaints and other regulatory actions such as issuances of Notice of Violations and Cease and Desist Order.
Health Facility Evaluation and Review Committee (HFERC).	Responsible for reviewing all applications of PTC with respect to compliance with planning and design guidelines.
Licensing Officers/OSS Team	responsible for inspection and evaluation of hospitals and other health related facilities as to four (4) major areas: service capability, physical plant, personnel, and equipment/ instruments



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Records Section

responsible for recording, safekeeping, and releasing the copies of CON/PTC/LTO/COA/ATO and other related records

6.0 Procedure

Ref No.	Key Activities	Responsibilities	Reference Document/record	
6.1	<div style="text-align: center; border: 1px solid black; border-radius: 50%; width: 150px; height: 150px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <p style="margin: 0;">Receipt of Application for (CON/PTC)/LTO COA/ ATO</p> </div> <div style="text-align: center; margin-top: 10px;">↓</div>	<ol style="list-style-type: none"> 1. Receipt and checking of completeness of required documents 2. Issuance of order of payment 3. Endorse complete application to CON Comm./HFERC/ Inspection Team 	<p>Administrative Staff (AS) or Licensing Officer (LO)</p>	<ul style="list-style-type: none"> • Accomplished Application Form for CON/ PTC /LTO COA/ ATO • Logbook/Log Sheet • Order of payment • Official Receipt • Proof of Compliance (for renewal) • COC/RL from FDA • Refer to applicable references
6.2	<div style="text-align: center; border: 1px solid black; width: 150px; height: 100px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <p style="margin: 0;">Processing of application for CON/PTC/ LTO/COA/ ATO</p> </div> <div style="text-align: center; margin-top: 10px;">↓</div>	<ol style="list-style-type: none"> 1. Evaluation of application for CON/PTC/ LTO/COA/ ATO as to compliance to requirements 2. Inspection visit (<i>applies only to initial LTO, COA, and ATO</i>) 3. Review findings and make recommendations 	<p>CON Committee/ HFERC/ Inspection Team</p> <p>Inspection Team</p> <p>Inspection Team</p>	<ul style="list-style-type: none"> • Accomplished CON Evaluation Report • Accomplished Checklist Review of Floor Plan for HF • Accomplished Application Form for CON/PTC/LTO/ COA/ATO • Accomplished HF Assessment Tool • Refer to applicable references
6.3	<div style="text-align: center; border: 1px solid black; border-radius: 50%; width: 150px; height: 100px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> <p style="margin: 0;">Issuance or non-issuance of CON/PTC/ LTO/COA/ATO</p> </div>	<ol style="list-style-type: none"> 1. Approval/ disapproval 2. Release CON/PTC/ LTO/COA/ATO 	<p>HFSRB/RLED</p>	<ul style="list-style-type: none"> • CON /PTC /LTO/ COA/ATO • Letter of Disapproval



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Procedure Details:

6.1 The Administrative Staff (AS)/Licensing Officer (LO) receives Client application for CON/PTC/LTO/COA/ATO.

- 6.1.1 The AS/LO reviews submitted application for completeness of application/documents. If incomplete, notify client of lacking requirements, *including payment of application fee*, in writing or in electronic format for mailed applications. *For walk-in clients, in case the document is incomplete, return it to the client.*
- 6.1.2. If complete, issues order of payment to client. Client submits proof of payment to the receiving AS/LO.
- 6.1.3. The AS/LO forwards complete application to CON/HFERC Committee/Inspection Team for evaluation. RLED endorses all PTC applications to HFSRB for approval/ disapproval except for HFEP Projects, Birthing Home, Psychiatric Care Facilities, Infirmary, and Level 1 Hospital including add-on services.

Note: All clients are required to register and file their application online at the One Stop Shop Online Licensing System website or at www.olrs.doh.gov.ph when the online system becomes available.

6.2 CON Committee/ HFERC/Inspection Team evaluates the application as to compliance to the set criteria/requirements.

- 6.2.1, The Committee/Team recommends approval/disapproval to the Director if the application is compliant. If not, notify client of lacking requirements in writing or in electronic format. If no compliance is received within 30 days, application shall be disapproved and payment forfeited.

For renewal of license, authorization is renewed upon submission of complete requirements. Incomplete submission of requirements may result to the disapproval of application.


6.2.2 Team Leader refers to the list of applications and sets the schedule of the inspection visit.

6.2.2.1 Pre-inspection Activities

- 6.2.2.1.1 The team notifies the owner/medical director of the date of visit;
- 6.2.2.1.2 Prepares Office Order;
- 6.2.2.1.3 Prepares assessment tools;
- 6.2.2.1.4 Arranges for transport

6.2.2.2 Inspection Activities

- 6.2.2.2.1 Team leader conducts pre-conference with concerned staff
- 6.2.2.2.2 Inspection team performs ocular inspection through observation, interview, and facility tour and evaluate facility in terms of service capability personnel, physical plant, equipment/instruments.
- 6.2.2.2.3 Inspection team deliberates and consolidates findings.
- 6.2.2.2.4 The inspection team conducts exit conference with the concerned staff and provide copy of the assessment tool to the facility

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If with deficiencies noted, the team recommends submission of proof of compliance from the facility within 30 days. Failure of the facility to comply within the given period will result to the disapproval of the application and the application fee forfeited.

6.2.3 If complied or with no deficiency, the Committee/division chief recommends issuance of CON/PTC/LTO/COA/ATO. Validity date of initial LTO/COA starts on the day of full compliance of the deficiency/ies.

6.3 AS/LO prints certificate/permit/license and drafts letter of approval/disapproval

6.3.1 Director approves/disapprove CON/PTC/LTO/COA/ATO

6.3.2 AS/LO forwards approved/disapproved certificate/permit/license to Record Section for release to the owner through letter or email.

6.3.3 RLED submits list of approved CON/LTO/COA to HFSRB.

Appendix A. Specific Requirements for Certificate of Need for New General Hospital

1. Application form and Acknowledgement (Notarized)
2. Certification from Provincial Planning and Development Office that the Proposed Hospital is part of the duly approved Provincial Hospital/Health Care Delivery Plan (if available)

Appendix B. Specific Requirements for Permit to Construct for a Health Facility

A. For new health facility:
1. Certificate of Need from the DOH-Regional Office (for hospital below 100 Authorized Bed Capacity)
2. Proof of Registration of Name of facility:
2.1.1. DTI/SEC Registration including Articles of Incorporation and By-Laws (for private health facility)
2.1.2. Enabling Act/Board Resolution (for government health facility)
2.1.3. Cooperative Development Authority Registration including Articles of Cooperation and By-Laws
3. Three (3) Sets of Site Development Plans and Architectural Floor Plans (in blue print 20" x 30") or in white print with scale 1:100 meters
B. For expansion/renovation of existing health facility:
1. Latest DOH Approved Permit to Construct and Approved Floor Plan
2. Floor Plan indicating proposed changes
C. Feasibility Study (for non-hospital based dialysis clinic only)
D. Copy of O.R. for application fee

Appendix C. Specific Requirements for Application for Health Facility

	Hospital/ PCF (OSS)	Clinical Lab	BSF	LDWA	DL
Duly accomplished Application Form & Acknowledgement	✓	✓	✓	✓	✓
Copy of OR for application fee	✓	✓	✓	✓	✓
Filled out self-	✓	✓	✓	✓	✓



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assessment tool					
*SEC/DTI Registration/ Board Resolution	✓	✓	✓	✓	✓
Duly accomplished FDA application form for x-ray and pharmacy (for endorsement to FDA)	✓				


**Not required for renewal of authorization*

7.0 Attachments

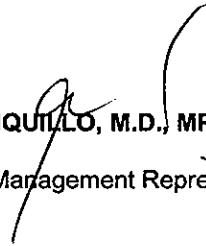
- Assessment Tool
- Templates of CON/PTC/LTO/COA/ATO
- Authority to Travel
- Itinerary of Travel
- Annex A

8.0 Approval


Prepared by:


ATTY. RODEL C. FLORES
 Regulatory Compliance and
 Enforcement Division,
 Health Facilities and Services
 Regulatory Bureau

Reviewed by:


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 Director IV
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ATTY. NICOLAS B. LUTERO III, CESO III
 Director IV, HFSRB



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ANNEX A

LIST OF DOH ADMINISTRATIVE ISSUANCES AND OTHER PERTINENT LAWS

Ambulatory Surgical Clinics

A.O. No. 2008-0027 dtd June 25, 2008 - **One-Stop Shop System** for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics and Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services (with OSS Application Form and attachment)

A.O. No. 183 s., 2004- dtd Nov. 16, 2004 – Rules and Regulations Governing the Licensure and Regulations of the Ambulatory Surgical Clinics

Birthing Home

A.O. No. 2012-0012 - "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facility in the Philippines." (Annex C of A.O. No. 2012-0012)

Dept. Circular 2015-0392 dated 12/12/2015 "Additional Clarification in the Requirement of License to Operate a Birthing Facility Pursuant to AO No. 2012-0012"

Department Memorandum 2014-0277 dtd. Sept. 15, 2014 Permit to Construct of HFEP Projects

Blood Service Facility

R.A. 7719 National Blood Service Act of 1994 dtd. May 5, 1994 - **Implementing Rules and Regulations and Amendments to Sections 26-32 and Section 35**

A.O. No. 2008-0008-A dated Aug. 22, 2011- "Amendment to Administrative Order No. 2008-0008 Rules and Regulations Governing the Regulation of Blood Service Facilities."

A.O. No. 2008-0008 dated May 2, 2008- Rules and Regulations Governing the Regulation of Blood Service Facilities."


A.O. No. 2005-0002 dtd. Jan. 10, 2005 - Rules and Regulations for the Establishment of the Phil. National Blood Services Amending Pertinent Provisions of A.O. No. 9 s., 1995 (Rules and Regulations Implementing R.A. 7719 Otherwise Known as The National Blood Services Act of 1994)

A.O. No. 101-A s., 2003 dtd. October 14, 2003 - Rules and Regulations Governing Authorization of Blood Collection Unit and Blood Station (Part of National Voluntary Blood Services Program)

A.O. No. 17-A s., 1998 dtd. May 12, 1998 - Amendment to Sections 26 to 32 of A.O. No. 9 s., 1995 to be known as Requirements and Procedures for a License to Operate a Blood Bank/ Blood Center in the Philippines

A.O. No. 9 s., 1995 dtd. April 28, 1995 - Rules and Regulations Implementing RA 7719 otherwise known as "The National Blood Service Act of 1994"

A.O. No. 291 s., 1976 dtd. Aug. 9, 1976 - Amending Sec. 7 and Sec. 13 subsection (a) of A.O. 156 s., 1971 – Concerning Requirements for a Blood Bank and/or Blood Processing Laboratory.

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Clinical Laboratory

R.A. No. 4688 Clinical Laboratory Act of 1966 dtd. June 18, 1966 - An Act Regulating the Operation and Maintenance of Clinical Laboratories and Requiring the Registration of the Same with the Department of Health, Providing Penalty for the Violation Thereof, and for Other Purposes

A.O. 2008-0007 dtd. March 14, 2008 – Schedule of Fees for the "Licensure of General Clinical Laboratories and the Registration of Special Clinical Laboratories."

A.O. 2007-0027 dtd. Aug. 22, 2007- Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines (revised minimum standard for CL)

Dental Laboratory

RA 9484 dtd. Dec. 14, 2007- Phil. Dental Act of 2007 (issued by PRC)-An Act to Regulate the Practice of Dentistry, Dental Hygiene, and Dental Technology in the Philippines.

Presidential Decree No. 1542 dtd. 1978- Providing For the Registration and Licensing of Dental Prosthetic Laboratories

A.O. 2008- 0019 dtd. June 18, 2008- Revised Schedule of Fees for the Registration and Licensure of Dental Laboratories in the Philippines

A.O. 2008- 0010 dtd. May 7, 2008- Revised Rules and Regulations Governing the Registration and Licensure of Dental Laboratories in the Philippines.

Dialysis Clinic

A.O No. 2013-0003 dtd. Feb. 5, 2013- Implementing Guidelines in the Analysis, Monitoring and Maintenance of Water Used in Dialysis Facilities Pursuant to Administrative Order No. 2012-001 known as "New Rules and Regulations Governing the Licensure and Regulation of Dialysis Facilities in the Philippines."

A.O. No. 2012 – 0001 dtd. Jan. 26, 2012- "New Rules and Regulations Governing the Licensure and Regulation of Dialysis Facilities in the Philippines"

A.O. No. 2008-0027 dtd. June 25, 2008 – One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics and Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services


Drug Testing Laboratory

RA 9165 dtd. June 7, 2002 – Comprehensive Dangerous Drugs Act of 2002
An Act instituting the comprehensive Dangerous Drugs Act of 2002, Repealing RA No. 6425, otherwise known as the "Dangerous Drugs Act of 1972, as Amended Providing Funds Therefore, and for Other Purposes."

A.O No. 2010-0024 dtd July 19, 2010- Requirement of Permit to Construct in the Establishment of Free Standing Screening Drug Testing Laboratories Nationwide

Department Memorandum No. 2010-0226 dtd Sept. 14, 2010 – Paperless Online Renewal of 2011 Certificate of Accreditation for Drug Testing Facility

Department Memorandum No. 2010-0025 dtd Sept. 14, 2010 - Non Inclusion of Drug Testing Laboratories in the Health facilities covered by the One-Stop-Shop Strategy for Hospitals and OFW Clinics.

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Bureau Memorandum No. 01 s., 2009 dtd. Jan. 8, 2009- Guidelines on the Issuance of Cease and Desist Orders for Drug Testing Laboratories during the Conduct of Inspection and Monitoring Visits

A.O. No. 2008-0025 DTD. July 29, 2008- Guidelines on the Implementation of the Integrated Drug Testing Operations and Management Information System (IDTOMIS) for Screening and Confirmatory Drug Test Laboratory Operation

Department Circular No. 2008-0119 dtd. May 28, 2008- Prescribing Drug Test Fee for Government-Owned and Private Drug Testing Laboratories Accredited by the Department of Health

Bureau Circular No. 9 s., 2004 dtd. Sept. 2, 2004- Guidelines for Remote Collection of Drug Testing Specimen

Bureau Circular No. 04 s. 2004 dtd. April 21, 2004- Drug Test Operation and Management Information System (IDTOMIS) Requirement for Accreditation.

Bureau Circular No. 03 s. 2004 dtd. March 26, 2004- Prescribing Drug Test Fee for Government-Owned and Private Drug Testing Laboratories Accredited by the Department of Health

Bureau Circular No. 02 s. 2004 dtd. February 6, 2004- Reiteration of Bureau Circular No. 1 s., 1990

Bureau Circular No. 01 s. 2004 dtd. January 12, 2004- Submission of the Name of Confirmatory Drug Testing Laboratory to Which a Screening Drug Testing Laboratory Refers Positive Results.

Bureau Circular No. 08 s. 2003 dtd. September 30, 2003- Connection with the Department of Health's Drug Testing Operations Management Information System

Bureau Circular No. 3 s. 2003 dtd. March 13, 2003- Moratorium on the Issuance of Permit to Construct and License to Operate Free Standing Clinical Laboratories Nationwide.

Drug Abuse Treatment and Rehabilitation Center

RA 9165 dtd. June 7, 2002 – Comprehensive Dangerous Drugs Act of 2002
An Act instituting the comprehensive Dangerous Drugs Act of 2002, Repealing RA No. 6425, otherwise known as the "Dangerous Drugs Act of 1972, as Amended Providing Funds Therefore, and for Other Purposes."


DDB Board Regulation No. 5 s., 2013 – Amendment of Board Regulation No. 4 series of 2003 entitled "Implementing Rules and Regulations Governing Accreditation of Drug Abuse Treatment and Rehabilitation Centers and Accreditation of Center Personnel"

DDB Board Regulation No. 4 s., 2013 – "Implementing Rules and Regulations Governing Accreditation of Drug Abuse Treatment and Rehabilitation Centers and Accreditation of Center Personnel"

Hospital

R.A. 4226 - (Hospital Licensure Act) "An Act Requiring the Licensure of All Hospitals in the Philippines and Authorizing the Bureau of Medical Services to Serve as the Licensing Agency"

R.A. 8344 - An Act Penalizing the Refusal of Hospitals and Medical Clinics to Administer Appropriate Initial Medical Treatment and Support in Emergency or Serious Cases, Amending for the Purpose Batas Pambansa Bilang 702, otherwise known As "An Act Prohibiting the Demand of Deposits or Advance Payments for the Confinement or Treatment of Patients in Hospitals and Medical Clinics in Certain Cases"

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R.A. 9439 - An Act Prohibiting the Detention of Patients in Hospitals and Medical Clinics on Grounds of Nonpayment of Hospital Bills or Medical Expenses

A.O. No. 2012-0012 - "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

A.O. No. 2012-0012-A "Amendment Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

A.O. No. 2012-0012-B "Amendment to Section 13. Transitory Provisions of A.O. No. 2012-0012-A entitled "Amendment Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

Department Memorandum 2014-0277 dtd. Sept. 15, 2014 Permit to Construct of HFEP Projects

A.O. No. 2016-0042- Guidelines in the Application for Department of Health Permit to Construct

A.O. 2006-0004-C dtd. March 22, 2013 – Amendment of A.O. No. 2006-0004-A as Amended, Hereby Requiring Only the Certificate of Need (CON) to New Government Hospitals and Providing Additional Requirements for New General Hospital.

A.O. 2006-0004-B dtd. Nov. 18, 2008 – Amendment to Certain Provisions of A.O. No. 2006-0004-A on the Guidelines for the Issuance of Certificate of Need to Establish a New Hospital

A.O. 2008-0021 dtd. July 30, 2008 – Gradual Phasing Out of Mercury Content

A.O. 2008-0001 dtd. Jan. 7, 2008 - Implementing Rules and Regulations of RA 9439 " An Act Prohibiting the Detention of Patients in Hospitals and Medical Clinics on Grounds of Non-Payment of Hospital Bills or Medical Expenses." (with copy of RA 9439)

A.O. 2007-0041 dtd. Nov. 7, 2007- Guidelines on the Mandatory Allocation of a Certain Percentage of the ABC as Charity Beds in Private Hospitals- (Gov't. hosp. are mandated to operate with not less than 90% of its bed capacity as free or charity beds)

A.O. 2007-0024 dtd. June 6, 2007- Guidelines for the Licensure of DOH Hospitals

A.O. 2007-0023 dtd. June 6, 2007- Schedule of Fees for the One-Stop-Shop Licensure System for Hospitals


A.O. 2007-0022 dtd. June 6, 2007- Violation under the One-Stop-Shop Licensure System for Hospitals

A.O. 2007-0021 dtd. June 6, 2007- Establishment of One-Stop-Shop Licensure System for Hospital- Decentralization of the Licensing Process (with Reporting Forms – Hospital Application form, PTC form, CHD Report Form)

A.O. 2006-0004 A dtd. Jan. 15, 2007 -Amendment of Guidelines for the Issuance of Certificate of Need (CON) (with Form- 2 pages)

A.O. 2007-0001 dtd. Jan. 5, 2007 –Revised Schedule of Fees for Certain Services Rendered by BHFS and CHDs in Relation to the Regulation of Health Facilities and Services and Validity Period of License to Operate, Accreditation, Authority to Operate and Clearance to Operate for Certain health Facilities and Services

A.O. 2006-0004 dtd. March 13, 2006 - Guidelines for the Issuance of Certificate of Need (CON)

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Infirmary

A.O. No. 2012-0012 - "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

A.O. No. 2012-0012-A- Amendment to "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

Kidney Transplant Facility

A.O No. 2010-0019 dtd June 23, 2010- Establishment of a National Program for Sharing of Organs from Deceased Donors

A.O. No. 2010-0018 dtd. June 23, 2010- Revised National Policy on Living Non-Related Donation and Transplantation and its Implementing Structure Amending for the Purpose Administrative Order No. 2008-0004-A

A.O. No. 2008 – 0034 dtd. Nov. 13, 2008 – Revised Rules and Regulations Governing Accreditation of Hospitals Engaged in Kidney Transplantation

A.O. No. 2008-0004-A dtd. May 29, 2008- Amendment to AO 2008-0004 on Revised National Policy on Living Non-Related Organ Donation and Transplantation and its Implementing Structure (NCDPC-DOH issuance)

A.O. No. 2008-0004 dtd. March 3, 2008 - Revised National Policy on Living Non-Related Organ Donation and Transplantation and its Implementing Structure (NCDPC-DOH issuance)

A.O. No. 81 s., 2003 dtd. Sept. 1, 2003- Rules and Regulations Governing Accreditation of Hospitals Engaged in the Conduct of Kidney Transplantation

Laboratory for Drinking Water Analysis

A.O. 2006- 0024 s., 2006 dtd. May 10, 2006- Rules and Regulations Governing the Accreditation of Laboratories for Drinking Water Analysis

Medical Facility for Overseas Workers and Seafarers


Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995 as Amended by Republic Act No. 10022 (July 8, 2010)

R.A. No. 10022 dtd March 8, 2010-an Act Amending R.A No. 8042 Otherwise known as "The Migrant Workers and Overseas Filipinos Act of 1995, as Amended, further Improving the Standard of Protection and Promotion of the Welfare of Migrant Workers, their Families and Overseas Filipinos in Distress, and for other Purposes."

R.A. No. 10029- An Act to Regulate the Practice of Psychological Creating for the Purpose A Professional Regulatory Board of Psychology, Appropriating Funds thereof and for Other Purposes

Department Circular No. 2014-0383 dated Sept. 17, 2014- "Clarification on the Implementation of the Integrated Clinical Laboratory Test Management Information System (I-Clinical lab) Pursuant to Administrative Order (AO) No. 2013-0006 known as Guidelines to Rule XI: Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995, as Amended by Republic Act No. 10022."

A.O. No. 2013-0006-A "Amendment to A.O # 2013-0006 entitled Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995, as amended by Republic Act 10022"

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A.O. No. 2013-0006 "Guidelines to Rule XI: Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995, as amended by Republic Act 10022"

A.O No. 2010-0022-B dtd. Feb. 15, 2011- Suspension of AO No. 2010-0022. Otherwise known as the Policies in the Conduct of Psychological Examinations for Overseas Work Applicants and BHFS Bureau Circular No. 1s. 2010

A.O. No. 2009-0002 dtd Feb. 28, 2009- Addendum to AO No. 1 s. 2003 "Operational of Guidelines in the Conduct of Pre-Employment Medical Examination for Overseas Workers and Seafarers"

A.O. No. 2008-0027 dtd. June 25, 2008- One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics and Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services

A.O. 2005-0024 dtd. Sept. 13, 2005-Amendment to AO No. 181 s., 2004 on the Revised Rules and Regulations Governing Accreditation of Medical Facility for Overseas Workers and Seafarers (Annex A)

A.O. 2005-0024 dtd. Sept. 13, 2005-Amendment to AO No. 181 s., 2004 on the Revised Rules and Regulations Governing Accreditation of Medical Facility for Overseas Workers and Seafarers (Annex A)

A.O. No. 181 s., 2004 dtd. Sept. 9, 2004 – Revised Rules and Regulations Governing Accreditation of Medical Facilities for Overseas Workers and Seafarers (with Annex A-Technical Requirements)

A.O. 124 s. 1992, AO 35 s. 1994 Medical X-ray Facility

A.O. 2008-0027 **A.O. No. 7 s., 1993** dtd. Jan. 18, 1993-Amendment to Sec. 8-4 Subsection 1 of A.O. No. 85- A s., 1990- Revised Rules and Regulations Governing Accreditation of Medical Clinics - Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services

Department Order No. 190-C s., 1993 dtd. June 1, 1993-Lifting of the Ban in Metro Manila on Regular Accreditation of Medical Clinics and Hospital to Conduct Medical Exam. of Overseas Workers and Seafarers

A.O. No. 9 s., 1993 dtd. Feb. 18, 1993-Authority of the Maritime Industry Authority (MARINA) from the DOH to Authenticate Medical Certificates of Seafarers


A.O. No. 7 s., 1993 dtd. Jan. 18, 1993-Amendment to Sec. 8-4 Subsection 1 of A.O. No. 85-A s., 1990- Revised Rules and Regulations Governing Accreditation of Medical Clinics

Newborn Screening Center

RA 9288 dtd. April 7, 2004 "Newborn Screening Act of 2004" An Act Promulgating a Comprehensive Policy and a National System for Ensuring Newborn Screening.

A.O. No. 2008-0026-A dtd. Nov. 20, 2008 – Amendment to the A.O. No. 2008-0026 on Addendum to the Rules and Regulations Implementing Republic Act No. 9288, Otherwise Known as the "Newborn Screening Act of 2004."

A.O. No. 2008-0026 dtd. Aug. 8, 2008 – Addendum to the Rules and Regulations Implementing Republic Act No. 9288, Otherwise Known as the "Newborn Screening Act of 2004"

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Occupational Establishment Dental Clinics

Private School Dental Clinics RA 951 "An Act to Amend RA 124, Approved June 20, 1953 Amended Section 1 of RA 951" (refer to Section 2 for mandate of HFSRB)

R.A. 3814 – An Act creating the Bureau of Dental Health Services (as amended by RA 5211)

A.O. No. 4 s., 1998 dtd. Feb. 4, 1998 Revised Rules and Regulations and Standards Requirements for Private School Dental Services in the Philippines - BHFS mandate

A.O. No. 3 s., 1998 dtd. Feb. 4, 1998- "Revised Rules and Regulations and Standard Requirements for Occupational Dental Services in the Philippines"

A.O. 44 s., 1996 dtd. Dec. 27, 1996 – Revised Standards Individual Patient Dental Health Record (DHS Form 1) – BDHS-DOH

Psychiatric Care Facility

A.O. No. 2012-0012 "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines

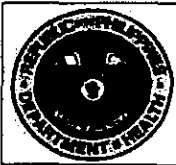
Bureau Circular No. 002 s., 2005 dtd. June 3, 2005- Licensure Standards for Psychiatric Care Facilities

Stem Cell Facility

A.O. No. 2013-0012" dtd January 18, 2013 Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell Based or Cellular Therapies in the Philippines"

Schedule of Fees

A.O. 2007-0001 dtd. Jan. 5, 2007 – Revised Schedule of Fees for Certain Services Rendered by BHFS and CHDs in Relation to the Regulation of Health Facilities and Services and Validity Period of License to Operate, Accreditation, Authority to Operate and Clearance to Operate for Certain Health Facilities and Services



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1.0 Purpose

This document aims to standardize the implementation of licensing, certification, and accreditation of health facilities to ensure quality and safe health care services.

2.0 Scope

This procedure starts with the receipt of application to the issuance of LTO/COA/ATO by the BHFS and the Regional Offices.

3.0 References

Ambulatory Surgical Clinics

A.O. No. 2008-0027 dtd June 25, 2008 - **One-Stop Shop System** for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics and Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services (with OSS Application Form and attachment)

A.O. No. 183 s., 2004- dtd Nov. 16, 2004 – Rules and Regulations Governing the Licensure and Regulations of the Ambulatory Surgical Clinics

Birthing Home

A.O. No. 2012-0012 - "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facility in the Philippines." (Annex C of A.O. No. 2012-0012)

Department Memorandum 2014-0277 dtd. Sept. 15, 2014 Permit to Construct of HFEP Projects

Blood Service Facility

R.A. 7719 National Blood Service Act of 1994 dtd. May 5, 1994 - Implementing Rules and Regulations and Amendments to Sections 26-32 and Section 35

A.O. No. 2008-0008-A dated Aug. 22, 2011- "Amendment to Administrative Order No. 2008-0008 Rules and Regulations Governing the Regulation of Blood Service Facilities."

A.O. No. 2008-0008 dated May 2, 2008- Rules and Regulations Governing the Regulation of Blood Service Facilities."

A.O. No. 2005-0002 dtd. Jan. 10, 2005 - Rules and Regulations for the Establishment of the Phil. National Blood Services Amending Pertinent Provisions of A.O. No. 9s., 1995 (Rules and Regulations Implementing R.A. 7719 Otherwise Known as The National Blood Services Act of 1994)

A.O. No. 101-A s., 2003 dtd. October 14, 2003 - Rules and Regulations Governing Authorization of Blood Collection Unit and Blood Station (Part of National Voluntary Blood Services Program)


A.O. No. 17-A s., 1998 dtd. May 12, 1998 - Amendment to Sections 26 to 32 of A.O. No. 9 s., 1995 to be known as Requirements and Procedures for a License to Operate a Blood Bank/ Blood Center in the Philippines

A.O. No. 9 s., 1995 dtd. April 28, 1995 - Rules and Regulations Implementing RA 7719 otherwise known as "The National Blood Service Act of 1994"

A.O. No. 291 s., 1976 dtd. Aug. 9, 1976 - Amending Sec. 7 and Sec. 13 subsection (a) of A.O. 156 s., 1971 – Concerning Requirements for a Blood Bank and/or Blood Processing Laboratory.



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Clinical Laboratory

R.A. No. 4688 Clinical Laboratory Act of 1966 dtd. June 18, 1966 - An Act Regulating the Operation and Maintenance of Clinical Laboratories and Requiring the Registration of the Same with the Department of Health, Providing Penalty for the Violation Thereof, and for Other Purposes

A.O. 2008-0007 dtd. March 14, 2008 – Schedule of Fees for the "Licensure of General Clinical Laboratories and the Registration of Special Clinical Laboratories."

A.O. 2007-0027 dtd. Aug. 22, 2007- Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines (revised minimum standard for CL)

Dental Laboratory

RA 9484 dtd. Dec. 14, 2007- Phil. Dental Act of 2007 (issued by PRC)-An Act to Regulate the Practice of Dentistry, Dental Hygiene, and Dental Technology in the Philippines.

Presidential Decree No. 1542 dtd. 1978- Providing For the Registration and Licensing of Dental Prosthetic Laboratories

A.O. 2008- 0019 dtd. June 18, 2008- Revised Schedule of Fees for the Registration and Licensure of Dental Laboratories in the Philippines

A.O. 2008- 0010 dtd. May 7, 2008- Revised Rules and Regulations Governing the Registration and Licensure of Dental Laboratories in the Philippines.

Dialysis Clinic

A.O No. 2013-0003 dtd. Feb. 5, 2013- Implementing Guidelines in the Analysis, Monitoring and Maintenance of Water Used in Dialysis Facilities Pursuant to Administrative Order No. 2012-001 known as "New Rules and Regulations Governing the Licensure and Regulation of Dialysis Facilities in the Philippines."

A.O. No. 2012 – 0001 dtd. Jan. 26, 2012- "New Rules and Regulations Governing the Licensure and Regulation of Dialysis Facilities in the Philippines"

A.O. No. 2008-0027 dtd. June 25, 2008 – One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics and Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services

Drug Testing Laboratory

RA 9165 dtd. June 7, 2002 – Comprehensive Dangerous Drugs Act of 2002
An Act instituting the comprehensive Dangerous Drugs Act of 2002, Repealing RA No. 6425, otherwise known as the "Dangerous Drugs Act of 1972, as Amended Providing Funds Therefore, and for Other Purposes."


A.O No. 2010-0024 dtd July 19, 2010- Requirement of Permit to Construct in the Establishment of Free Standing Screening Drug Testing Laboratories Nationwide

Department Memorandum No. 2010-0226 dtd Sept. 14, 2010 – Paperless Online Renewal of 2011 Certificate of Accreditation for Drug Testing Facility

Department Memorandum No. 2010-0025 dtd Sept. 14, 2010 - Non Inclusion of Drug Testing Laboratories in the Health facilities covered by the One-Stop-Shop Strategy for Hospitals and OFW Clinics.



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Bureau Memorandum No. 01 s., 2009 dtd. Jan. 8, 2009- Guidelines on the Issuance of Cease and Desist Orders for Drug Testing Laboratories during the Conduct of Inspection and Monitoring Visits

A.O. No. 2008-0025 DTD. July 29, 2008- Guidelines on the Implementation of the Integrated Drug Testing Operations and Management Information System (IDTOMIS) for Screening and Confirmatory Drug Test Laboratory Operation

Department Circular No. 2008-0119 dtd. May 28, 2008- Prescribing Drug Test Fee for Government-Owned and Private Drug Testing Laboratories Accredited by the Department of Health

Bureau Circular No. 9 s., 2004 dtd. Sept. 2, 2004- Guidelines for Remote Collection of Drug Testing Specimen

Bureau Circular No. 04 s. 2004 dtd. April 21, 2004- Drug Test Operation and Management Information System (IDTOMIS) Requirement for Accreditation.

Bureau Circular No. 03 s. 2004 dtd. March 26, 2004- Prescribing Drug Test Fee for Government-Owned and Private Drug Testing Laboratories Accredited by the Department of Health

Bureau Circular No. 02 s. 2004 dtd. February 6, 2004- Reiteration of Bureau Circular No. 1 s., 1990

Bureau Circular No. 01 s. 2004 dtd. January 12, 2004- Submission of the Name of Confirmatory Drug Testing Laboratory to Which a Screening Drug Testing Laboratory Refers Positive Results.

Bureau Circular No. 08 s. 2003 dtd. September 30, 2003- Connection with the Department of Health's Drug Testing Operations Management Information System

Bureau Circular No. 3 s. 2003 dtd. March 13, 2003- Moratorium on the Issuance of Permit to Construct and License to Operate Free Standing Clinical Laboratories Nationwide.

Drug Abuse Treatment and Rehabilitation Center


RA 9165 dtd. June 7, 2002 – Comprehensive Dangerous Drugs Act of 2002
An Act instituting the comprehensive Dangerous Drugs Act of 2002, Repealing RA No. 6425, otherwise known as the "Dangerous Drugs Act of 1972, as Amended Providing Funds Therefore, and for Other Purposes."

DDB Board Regulation No. 5 s., 2013 – Amendment of Board Regulation No. 4 series of 2003 entitled "Implementing Rules and Regulations Governing Accreditation of Drug Abuse Treatment and Rehabilitation Centers and Accreditation of Center Personnel"

DDB Board Regulation No. 4 s., 2013 – "Implementing Rules and Regulations Governing Accreditation of Drug Abuse Treatment and Rehabilitation Centers and Accreditation of Center Personnel"



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Hospital

R.A. 4226 - (Hospital Licensure Act) An Act Requiring The Licensure of All Hospitals in the Philippines and Authorizing the Bureau of Medical Services to Serve as the Licensing Agency

R.A. 8344 - An Act Penalizing the Refusal of Hospitals and Medical Clinics to Administer Appropriate Initial Medical Treatment and Support in Emergency or Serious Cases, Amending for the Purpose Batas Pambansa Bilang 702, Otherwise known As "An Act Prohibiting The Demand of Deposits or Advance Payments for the Confinement or Treatment of Patients in Hospitals and Medical Clinics in Certain Cases"

R.A. 9439 - An Act Prohibiting The Detention of Patients in Hospitals and Medical Clinics on Grounds of Nonpayment of Hospital Bills or Medical Expenses

Department Memorandum 2014-0277 dtd. Sept. 15, 2014 Permit to Construct of HFEP Projects

A.O. 2006-0004-C dtd. March 22, 2013 – Amendment of A.O. No. 2006-0004-A as Amended, Hereby Requiring Only the Certificate of Need (CON) to New Government Hospitals and Providing Additional Requirements for New General Hospital.

A.O. No. 2012-0012 - "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

A.O. 2006-0004-B dtd. Nov. 18, 2008 – Amendment to Certain Provisions of A.O. No. 2006-0004-A on the Guidelines for the Issuance of Certificate of Need to Establish a New Hospital

A.O. 2008-0021 dtd. July 30, 2008 – Gradual Phasing Out of Mercury Content

A.O. 2008-0001 dtd. Jan. 7, 2008 - Implementing Rules and Regulations of RA 9439 " An Act Prohibiting the Detention of Patients in Hospitals and Medical Clinics on Grounds of Non-Payment of Hospital Bills or Medical Expenses." (with copy of RA 9439)

A.O. 2007-0041 dtd. Nov. 7, 2007- Guidelines on the Mandatory Allocation of a Certain Percentage of the ABC as Charity Beds in Private Hospitals- (Gov't. hosp. are mandated to operate with not less than 90% of its bed capacity as free or charity beds)

A.O. 2007-0024 dtd. June 6, 2007- Guidelines for the Licensure of DOH Hospitals

A.O. 2007-0023 dtd. June 6, 2007- Schedule of Fees for the One-Stop-Shop Licensure System for Hospitals

A.O. 2007-0022 dtd. June 6, 2007- Violation under the One-Stop-Shop Licensure System for Hospitals

A.O. 2007-0021 dtd. June 6, 2007- Establishment of One-Stop-Shop Licensure System for Hospital- Decentralization of the Licensing Process (with Reporting Forms – Hospital Application form, PTC form, CHD Report Form)

A.O. 2006-0004 A dtd. Jan. 15, 2007 -Amendment of Guidelines for the Issuance of Certificate of Need (CON) (with Form- 2 pages)

A.O. 2007-0001 dtd. Jan. 5, 2007 –Revised Schedule of Fees for Certain Services Rendered by BHFS and CHDs in Relation to the Regulation of Health Facilities and Services and Validity Period of License to Operate, Accreditation, Authority to Operate and Clearance to Operate for Certain health Facilities and Services



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A.O. 2006-0004 dtd. March 13, 2006 - Guidelines for the Issuance of Certificate of Need (CON)

Infirmary

A.O. No. 2012-0012 - "Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines."

Kidney Transplant Facility

A.O. No. 2010-0019 dtd June 23, 2010- Establishment of a National Program for Sharing of Organs from Deceased Donors

A.O. No. 2010-0018 dtd. June 23, 2010- Revised National Policy on Living Non-Related Donation and Transplantation and its Implementing Structure Amending for the Purpose Administrative Order No. 2008-0004-A

A.O. No. 2008 – 0034 dtd. Nov. 13, 2008 – Revised Rules and Regulations Governing Accreditation of Hospitals Engaged in Kidney Transplantation

A.O. No. 2008-0004-A dtd. May 29, 2008- Amendment to AO 2008-0004 on Revised National Policy on Living Non-Related Organ Donation and Transplantation and its Implementing Structure (NCDPC-DOH issuance)

A.O. No. 2008-0004 dtd. March 3, 2008 - Revised National Policy on Living Non-Related Organ Donation and Transplantation and its Implementing Structure (NCDPC-DOH issuance)

A.O. No. 81 s., 2003 dtd. Sept. 1, 2003- Rules and Regulations Governing Accreditation of Hospitals Engaged in the Conduct of Kidney Transplantation

Laboratory for Drinking Water Analysis

A.O. 2006- 0024 s., 2006 dtd. May 10, 2006- Rules and Regulations Governing the Accreditation of Laboratories for Drinking Water Analysis

Medical Facility for Overseas Workers and Seafarers

Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995 as Amended by Republic Act No. 10022 (July 8, 2010)

R.A. No. 10022 dtd March 8, 2010-an Act Amending R.A No. 8042 Otherwise known as "The Migrant Workers and Overseas Filipinos Act of 1995, as Amended, further Improving the Standard of Protection and Promotion of the Welfare of Migrant Workers, their Families and Overseas Filipinos in Distress, and for other Purposes."


R.A. No. 10029- An Act to Regulate the Practice of Psychological Creating for the Purpose A Professional Regulatory Board of Psychology, Appropriating Funds thereof and for Other Purposes

Department Circular No. 2014-0383 dated Sept. 17, 2014- "Clarification on the Implementation of the Integrated Clinical Laboratory Test Management Information System (I-Clinical lab) Pursuant to Administrative Order (AO) No. 2013-0006 known as Guidelines to Rule XI: Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995, as Amended by Republic Act No. 10022."

A.O. No. 2013-0006-A "Amendment to A.O # 2013-0006 entitled Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995, as amended by Republic Act 10022"



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A.O. No. 2013-0006 "Guidelines to Rule XI: Role of DOH in the Omnibus Rules and Regulations Implementing the Migrant Workers and Overseas Filipinos Act of 1995, as amended by Republic Act 10022"

A.O. No. 2010-0022-B dtd. Feb. 15, 2011- Suspension of AO No. 2010-0022. Otherwise known as the Policies in the Conduct of Psychological Examinations for Overseas Work Applicants and BHFS Bureau Circular No. 1s. 2010

A.O. No. 2009-0002 dtd Feb. 28, 2009- Addendum to AO No. 1 s. 2003 " Operational of Guidelines in the Conduct of Pre-Employment Medical Examination for Overseas Workers and Seafarers"

A.O. No. 2008-0027 dtd. June 25, 2008- One-Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital Based Dialysis Clinics and Non-Hospital Based Ambulatory Surgical Clinics with Ancillary Services

A.O. 2005-0024 dtd. Sept. 13, 2005-Amendment to AO No. 181 s., 2004 on the Revised Rules and Regulations Governing Accreditation of Medical Facility for Overseas Workers and Seafarers (Annex A)

A.O. 2005-0024 dtd. Sept. 13, 2005-Amendment to AO No. 181 s., 2004 on the Revised Rules and Regulations Governing Accreditation of Medical Facility for Overseas Workers and Seafarers (Annex A)

A.O. No. 181 s., 2004 dtd. Sept. 9, 2004 – Revised Rules and Regulations Governing Accreditation of Medical Facilities for Overseas Workers and Seafarers (with Annex A-Technical Requirements)

A.O. 124 s. 1992, AO 35 s. 1994 Medical X-ray Facility

A.O. 2008-0027 A.O. No. 7 s., 1993 dtd. Jan. 18, 1993-Amendment to Sec. 8-4 Subsection 1 of A.O. No. 85- A s., 1990- Revised Rules and Regulations Governing Accreditation of Medical Clinics -Stop Shop System for the Regulation of Medical Facilities for Overseas Workers and Seafarers, Non-Hospital-Based Dialysis Clinics and Non-Hospital-Based Ambulatory Surgical Clinics with Ancillary Services

Department Order No. 190-C s., 1993 dtd. June 1, 1993-Lifting of the Ban in Metro Manila on Regular Accreditation of Medical Clinics and Hospital to Conduct Medical Exam. of Overseas Workers and Seafarers

A.O. No. 9 s., 1993 dtd. Feb. 18, 1993-Authority of the Maritime Industry Authority (MARINA) from the DOH to Authenticate Medical Certificates of Seafarers

A.O. No. 7 s., 1993 dtd. Jan. 18, 1993-Amendment to Sec. 8-4 Subsection 1 of A.O. No. 85-A s., 1990- Revised Rules and Regulations Governing Accreditation of Medical Clinics

Newborn Screening Center

RA 9288 dtd. April 7, 2004 "Newborn Screening Act of 2004" An Act Promulgating a Comprehensive Policy and a National System for Ensuring Newborn Screening.

A.O. No. 2008-0026-A dtd. Nov. 20, 2008 – Amendment to the A.O. No. 2008-0026 on Addendum to the Rules and Regulations Implementing Republic Act No. 9288, Otherwise Known as the "Newborn Screening Act of 2004."





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A.O. No. 2008-0026 dtd. Aug. 8, 2008 – Addendum to the Rules and Regulations Implementing Republic Act No. 9288, Otherwise Known as the "Newborn Screening Act of 2004"

Occupational Establishment Dental Clinics

Private School Dental Clinics R A 951 An Act to Amend R A 124, Approved June 20, 1953 Amended Section 1 of RA 951-

It shall be the duty of the schools with a total enrolment of **at least 300 and 1,000** to provide a part or full time physician and dentist, to give medical and dental service to the students enrolled therein, who shall render reports at the end of every quarter to the Director of Health. Said physician and dentist shall be placed under the direct supervision of the Bureau of Health.

Sec. 2 – it shall be the duty of the Bureau of Health to issue rules and regulations relative to the medical and dental service which private schools, colleges and universities in the Philippines shall provide.

R.A. 3814 – An Act creating the Bureau of Dental Health Services (as amended by RA 5211)

A.O. No. 4 s., 1998 dtd. Feb. 4, 1998 Revised Rules and Regulations and Standards Requirements for Private School Dental Services in the Phils.- BHFS mandate

A.O. No. 3 s., 1998 dtd. Feb. 4, 1998-Revised Rules and Regulations and Standard Requirements for Occupational Dental Services in the Philippines

A.O. 44 s., 1996 dtd. Dec. 27, 1996 – Revised Standards Individual Patient Dental Health Record (DHS Form 1) – BDHS-DOH

A.O. No. 32 s., 1979 dtd. July 12, 1979 – **Amended Rules and Regulations** and Standard Requirements for Private School Dental Services – BDHS-DOH

A.O. 116 s., 1969 dtd. March 5, 1970 – Regulations Concerning the Dental Services for Private Schools in Accordance with the Provisions of RA 124 as amended by RA 951 (Dental Health Service-DOH)

Psychiatric Care Facility

A.O. No. 2012-0012 * Rules and Regulations Governing the New Classification of Hospitals and Other Health Facilities in the Philippines

Bureau Circular No. 002 s., 2005 dtd. June 3, 2005- Licensure Standards for Psychiatric Care Facilities

Stem Cell Facility


A.O. No. 2013-0012 * dtd January 18, 2013 Rules and Regulations Governing the Accreditation of Health Facilities Engaging in Human Stem Cell and Cell Based or Cellular Therapies in the Philippines*

Schedule of Fees

A.O. 2007-0001 dtd. Jan. 5, 2007 – **Revised Schedule of Fees** for Certain Services Rendered by BHFS and CHDs in Relation to the Regulation of Health Facilities and Services and Validity Period of License to Operate, Accreditation, Authority to Operate and Clearance to Operate for Certain Health Facilities and Services



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4.0 Definition of Terms

Authority to Operate (ATO)-a formal authorization issued by the Department of Health to blood station/ blood collecting unit upon meeting the licensing requirements.

Health Facilities and Services Regulatory Bureau (HFSRB) – The regulatory body of the Department of Health in charge of licensing and accreditation of hospital and other health facilities (formerly Bureau of Health Facilities and Services)

Certificate of Need (CON)- the document issued to proponents of general hospital after satisfying a set of criteria. It is a prerequisite to issuance of Permit to Construct

Certificate of Accreditation (COA)- a formal authorization issued by the Department of Health to an individual, partnership corporation or association to operate a hospital and other health facilities. Unlike licensing, Accreditation focuses on continuous improvements strategies, achievement of optimal quality standards, and on-going education and consultation; set at a minimum achievable level to stimulate improvement overtime.

Client- constitutes the regulated facilities, stakeholders or the members of the general public.

Health Facility- a building or physical structure providing healthcare.

Hospital- a health facility for the diagnosis, treatment and care of individuals suffering from deformity, disease, illness or injury or in need of surgical, obstetrical, medical or nursing care. It is an institution where there are installed bassinets or beds for 24 hour use or longer by patients in the management of deformities, diseases, injuries, abnormal physical and mental conditions and maternity cases.

Inspection- actual visit to hospital and other health related facilities to verify compliance to standard minimum requirements as to service capability, physical plant, personnel, equipment/ instrument.

License to Operate (LTO)-A formal authorization issued by the Department of Health to an individual, partnership corporation, or association to operate a hospital and other health facilities. Licensing focuses on adherence to minimum standards intended to assure public safety; set at a minimum level to ensure an environment with minimum risk to health and safety.


One-Stop-Shop Licensure System (OSS)- a strategy of the DOH to harmonize the licensure of hospitals, their ancillary and other facilities including but not limited to, clinical laboratory, HIV testing, drinking water analysis and drug testing; blood bank, blood collection unit and blood station; dialysis clinic; ambulatory surgical clinic; pharmacy and medical X-ray facility.

Permit to Construct (PTC)- the document required for the construction of a new hospital or other health facility; with substantial alteration, expansion or renovation, change in classification, or increase in bed capacity; it is a prerequisite for a License to Operate.

Regulations, Licensing, and Enforcement Division (RLED) -A division at the Regional Office responsible for the issuance of Certificate of Need, license to operate/authority to operate of health facilities such as but not limited to the following: Infirmary, Birthing Homes, Laboratory for Drinking Water Analysis, Clinical Laboratory, Blood Station/ Blood Center Unit, Dental Laboratory and conducts monitoring of regulated health facilities.



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5.0 Responsibilities

CON Committee	responsible for evaluating application for CON based on criteria and recommends issuance/non-issuance of CON.
Director IV	responsible for final approval of License to Operate (LTO)/Certificate of Accreditation (COA)/Authority to Operate (ATO), Permit to Construct (PTC), Certificate of Need (CON), resolution on complaints and other regulatory actions such as issuances of Notice of Violations and Cease and Desist Order.
Division Chief	responsible for recommending the approval of License to Operate (LTO)/Certificate of Accreditation (COA)/Authority to Operate (ATO), Permit to Construct (PTC), Certificate of Need (CON), resolution on complaints and other regulatory actions such as issuances of Notice of Violations and Cease and Desist Order.
Health Facility Establishment Review Committee (HFERC).	responsible for reviewing all applications of PTC with respect to compliance with planning and design guidelines.
Licensing Officers/OSS Team	responsible for inspection and evaluation of hospitals and other health related facilities as to four (4) major areas: service capability, physical plant, personnel, and equipment/ instruments
Records Section	responsible for recording, safekeeping, and releasing the copies of CON/PTC/LTO/COA/ATO and other related records




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6.0 Procedure

Ref No.	Key Activities		Responsibilities	Reference Document/record
6.1	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">Receipt of Application for CON/ PTC/ LTO COA/ ATO</div> <div style="text-align: center; margin-top: 10px;">↓</div>	<ol style="list-style-type: none"> 1. Receipt and checking of completeness of required documents 2. Issuance of order of payment 	-Receiving Clerk or Licensing Officer	<ul style="list-style-type: none"> • Accomplished Application Form for CON/ PTC /LTO COA/ ATO • Logbook/Log Sheet • Order of payment • Official Receipt • Proof of Compliance (for renewal) • COC from FDA • Refer to applicable references
6.2	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">Processing of application for CON/PTC/ LTO/COA/ ATO</div> <div style="text-align: center; margin-top: 10px;">↓</div>	<ol style="list-style-type: none"> 1. Evaluation of application as to compliance to requirements 2. Inspection for LTO, COA, and ATO 3. Review and recommendation 	- CON Committee - HFERC - LO	<ul style="list-style-type: none"> • Accomplished Application Form for CON/PTC/LTO/ COA/ATO • Accomplished HF Assessment Tool • Compliance Report • Refer to applicable references
6.3	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">Issuance or non-issuance of CON/PTC/ LTO/COA/ATO</div>	<ol style="list-style-type: none"> 1. Approval/ disapproval 2. Release CON/PTC/ LTO/COA/ATO 	HFSRB/RLED	<ul style="list-style-type: none"> • CON /PTC /LTO/ COA/ATO or • Letter of Disapproval

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Procedure Details:

7.1 The Clerk/LO receives Client application for CON for the establishment of new hospital/ conversion from special to general hospital/conversion or upgrading of a birthing home into a general hospital.

- 7.1.2 The Clerk/LO reviews submitted application for completeness of application/documents.
- 7.1.3 If complete, issues order of payment to client. If incomplete, notify client of lacking requirements in writing.
- 7.1.4 The Clerk/LO forwards complete application is to CON Committee for evaluation.
- 7.1.5 CON Committee recommends approval/disapproval to Director IV.
- 7.1.6 Regional Director approves/disapproves CON; If disapproved, the committee has to notify the client of the disapproval through letter.
- 7.1.7 RO endorses approved CON and evaluation report to HFSRB.

Prescribed period from receipt of application to approval/disapproval is twenty (20) working days.

7.2 Receiving Clerk/LO receives client application for PTC for new facility, expansion and renovation of existing facility

- 7.2.1 LO reviews the completeness of documents
- 7.2.2 If complete, the LO issues order payment
- 7.2.3 RO endorses all applications to HFSRB for approval/ disapproval except for HFEP Projects
- 7.2.4 HFERC evaluates application based on guidelines and recommends approval or disapproval.
- 7.2.5 Director IV approves/disapproves PTC. If disapproved, inform applicant in writing.

Prescribed period from receipt of application to approval/disapproval of PTC is fifteen (15) working days.

7.3 Processing of application for LTO/COA/ATO

- 7.3.1 Receiving Clerk/LO receives client's application for Initial/renewal of LTO/COA/ATO
 - 7.3.1.1 Receiving Clerk/LO reviews and check completeness of application form and documents. If complete, Receiving Clerk/LO issues Order of Payment
If incomplete, notify the client of lacking documents in writing.

7.3.2 Team Leader sets Schedule for Inspection

- 7.3.3 Pre-inspection activities
 - 7.3.3.1 Team Leader identifies facility to be inspected
 - 7.3.3.2 LO prepares Office Order.
 - 7.3.3.3 LO notifies client.
 - 7.3.3.4 LO prepares assessment tools
 - 7.3.3.5 LO arranges for transport



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7.3.4 Inspection Activities

- 7.3.4.1. Team leader conducts pre-conference with concerned staff
- 7.3.4.2. Inspection team performs ocular inspection through observation, interview, and facility tour and evaluate facility in terms of service capability, personnel, physical plant, equipment/instruments.
- 7.3.4.3. Inspection team deliberates and consolidates findings.
- 7.3.4.4. The inspection team conducts exit conference with the concerned staff and provide copy of Assessment Tool to the facility.

If with deficiencies noted, the team recommends submission of proof of compliance of the facility before issuance of LTO/COA/ATO.

If no compliance report or incomplete compliance within thirty (30) calendar days, deny the application and inform the client in writing.

If complied/No deficiencies, division chief recommends issuance LTO/COA/ATO. Validity date of initial LTO starts on the day of full compliance of deficiency/ies.


- 7.3.4.5 Director approves LTO/COA/ATO
- 7.3.4.6 LO forwards approved LTO to Record Section for release to the owner.

ANNEX A. Specific Requirements for Health Facility

	Hospital/ PCF (OSS)	Clinical Lab	BSF	LDWA	DL
Acknowledgement (Notarized)	/	/	/	/	/
List of personnel (with proof of qualification)	/	/	/	/	/
List of equipment	/	/	/	/	/
List of ancillary services (if applicable)	/				
Application form (Med X-ray)	/				
Application form (Hospital Pharmacy)	/				
Location map of the facility	/	/	/	/	/
Photographs of exterior and interior of health facility	/			/	
Copy of OR for application fee	/	/	/	/	/
SEC/DTI Registration/ Board Resolution		/	/	/	
Quality manual	/	/	/	/	/
Floor layout		/	/	/	/
Certificate of inclusion in the Regional Blood Service Network (RBSN)		/			



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7.0 Attachments


Assessment Tool
 Templates of CON/PTC/LTO/COA/ATO
 Authority to Travel
 Itinerary of Travel

8.0 Approval

Prepared by:


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 OIC, Regulatory Compliance and
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 Health Facilities and Services
 Regulatory Bureau (HFSRB)

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