



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
Manila



November 16, 2004

Administrative Order
No. 183 s. 2004

Subject: Rules and Regulations Governing the Licensure and Regulation of Ambulatory Surgical Clinics

I. RATIONALE:

Executive Order 102 "Redirecting the Functions and Operations of the Department of Health (DOH)" issued in 1999 stated: Section 2: Roles. To fulfill its responsibilities under this mandate, the DOH shall serve as ..."e) lead agency in ensuring equity, access and quality of health care services through policy formulation, standards development and regulations". This statement provided for the exercise of the licensure and regulatory functions of the DOH over hospitals and other health clinics with the following objectives: 1) to ensure safety, and 2) to protect the health of the public, through the development and enforcement of the basic licensure and regulatory standards for such clinics and services.

The Health Sector Reform Agenda (HSRA) was introduced to address the gaps in the delivery of health care services. One of the five major areas is the Health Regulation Reform. HSRA emphasized a less stringent licensure requirements and stronger health regulatory functions.

The advancement of various fields in medicine and its accompanying technology, specifically in the fields of surgery and anesthesiology vis a vis the prohibitive cost of in-hospital care for good risk patients who are candidates for elective surgery, prompted the health care sector to search for a novel, more affordable, easily accessible, stand-alone out-patient surgical centers. This need has been more emphasized in the advent of Health Maintenance Organizations (HMO), which particularly sought for ways and means through which quality health care can possibly be delivered down to its beneficiaries without necessarily incurring the high cost of care in the hospital.

II. SCOPE

These rules and regulations shall apply to all government and private ambulatory surgical clinics whether a) free standing or b) within the hospital premises but whose ownership is different as that of the hospital. For hospital-

based ASC, compliance to the prescribed standards and technical requirements shall be determined during inspection for the issuance of hospital license.

III. DEFINITION OF TERMS

- 3.1 Ambulatory Surgical Clinic (ASC) - a government or privately owned institution which is primarily organized, constructed, renovated or otherwise established for the purpose of providing elective surgical treatment of out-patients whose recovery, under normal and routine circumstances, will not require inpatient care.
- 3.2 Ambulatory Surgical Services – services that include elective (non-emergency) surgical procedures ranging from minor to major operations, whether requiring local, regional, or general anesthesia, where patients are safely sent home within the same day for continuing post-operative care.
- 3.3 BHFS – acronym for the Bureau of Health Facilities and Services, the licensing and regulatory arm of the Department of Health for health facilities.
- 3.4 License to Operate - a formal authority issued by the DOH to an individual, agency, partnership, or corporation to operate an ASC upon compliance with the requirements set forth in this regulation.
- 3.5 Licensee - any clinic, firm, partnership, corporation, company, association or joint stock association to which the license is issued.

IV POLICIES AND GUIDELINES

A. Classification of Ambulatory Surgical Clinics:

A.1 According to Ownership:

A.1.1 Government – operated and maintained partially or wholly by the national, provincial, city or municipal government or other political unit; or by any department, division, board or agency thereof.

A.1.2 Private – owned, established and operated with funds through donation, principal, investment or other means, by any individual, corporation, association or organization.

A.2 According to Service/Procedures Performed by the different surgical specialties

B. Standards and Technical Requirements

1. Efficient and effective governance ensures a planned and coordinated service delivery system appropriate to the needs of patients, families and service providers.
2. Medical records contain patient information that is uniquely identifiable, accurately recorded, current, confidential and accessible when required.
3. Human resource management processes are conducted in accordance with good employment practices.
4. Efficient and effective methods are used to identify areas for improvement of the quality management system performance.

5. The health facility appoints and allocates personnel who are suitably qualified, skilled and/or experienced to provide the service and meets patient needs
6. All equipment and instruments necessary for the safe and effective provision of services are available and properly maintained.
7. Services in an ASC are provided in an environment that ensures physical privacy and promotes safety, has adequate space and meets the needs of patients, service providers and other stakeholders.
8. The clinic observes safe and appropriate handling, storage and disposal of wastes that complies with current legislation, local government requirements and the Health Care Waste Management Manual of the Department of Health, 2004.
9. Each ASC shall have a Memorandum of Agreement with one or more hospitals with service capability of at least a secondary care hospital for the provision of inpatient care especially during emergencies and other hospital services. However, the patients or their relatives should be allowed to choose which hospital to patronize.

The criteria for the above mentioned standards and technical requirements shall be incorporated in the inspection checklist formulated by the Bureau in consultation with various stakeholders.

C. License to Operate:

1. A license shall be issued to an ASC that meets the requirements as set forth in these regulations. A license shall be issued only for the premises and person or persons named in the application and shall not be transferable or assignable. The license shall set forth the name, location/complete address, and name of the licensee, the license number and the service/procedures performed by the ASC.
2. Filing of application for renewal of license may be made ninety (90) days prior to its expiration. However, if the clinic has not applied for a renewal within thirty (30) calendar days after the expiration, it shall stop its operation and apply for a new license.
3. Every ASC is designated by a permanent and distinctive name which shall be used in applying for a license and shall not be changed without first notifying the BHFS in writing and receiving written approval of the change from the same. Such notice shall specify the name to be discontinued as well as the new name proposed. Two or more ASCs shall not be licensed under similar names in the same vicinity. No freestanding ASC shall include the word "hospital" in its name.
4. The BHFS shall be notified of any change in management/ownership with out disruption in ASC's operation (service capability, personnel, equipment/instrument and physical plant). In case of any change in management/ownership with disruption in ASC's operation, or in case of transfer of location, a new application for permit to construct and license to operate shall be required.
5. A separate license shall be required for all ASCs maintained in separate premises but operating under the same management.

6. The license to operate of the ASC shall be posted in a conspicuous space readily seen by the public. A copy of these rules and regulations shall be readily available for reference and guidance of the ASC staff and personnel.

V. IMPLEMENTING MECHANISM

A. Bureau of Health Facilities and Services

The BHFS shall regulate and license ASCs. The BHFS shall be responsible for the issuance, suspension or revocation of the license to operate.

B. Center for Health Development (CHD)

The CHD shall report to the BHFS any information regarding illegal operation of ASCs in their respective areas.

C. Philippine Health Insurance Corporation (PhilHealth)

In support of regulation, Philhealth shall be responsible for:

1. Accrediting health facilities and providers that meet the accreditation requirements subject to the conditions stipulated in the National Health Insurance Act of 1995 and other related Philhealth reimbursement guidelines and directives.
2. Conducting utilization reviews and performance monitoring in relation not only to cost efficiency measures and programs but also in support of accreditation standards with the end-view of institutionalizing best quality clinical and medical practices in ambulatory surgical service.

To effectively undertake their functions, the BHFS and PhilHealth shall regularly coordinate and synchronize their efforts to regulate ASCs.

VI PROCEDURAL GUIDELINES

A. Application for a Permit to Construct (PTC) - The PTC is a pre-requisite of a License to Operate.

- A.1 Applicant requests relevant information and prescribe form from the BHFS in person, or through mail, email or internet.
- A.2 Applicant accomplishes required documents listed below and submits them to the BHFS. Upon filing of application, the applicant pays the corresponding fees to the Cashier of the DOH in cash or through postal money order.
 1. BHFS Form – Application for Permit to Construct duly notarized
 2. Letter of application to the BHFS Director
 3. Letter of Endorsement to the BHFS Director if application is submitted to the CHD
 4. Department of Trade and Industry (DTI) Certificate or Security and Exchange Commission (SEC) Registration (for private clinic)
 5. Four sets of floor plans/layout (excluding plumbing, electrical, etc. layouts)

- a.) Showing required areas with the appropriate dimensions properly identified and labeled
 - b.) Signed and sealed by an Architect or Engineer
- A.3 The BHFS reviews the documents and approves or disapproves the issuance of permit to construct.
- If approved –the BHFS issues the permit to construct.
 - If disapproved – the BHFS sends the findings and recommendations to the applicant for compliance.
- A.4 Applications for PTC, which are not processed by Health Facility Evaluation Review Committee within the thirty (30) day period after its official receipt are considered approved.

B. Application Procedure for a License to Operate

- B.1 Applicant requests relevant information and prescribed form from the BHFS, in person or through mail, e-mail, fax transmittal (781-4189) or internet (www.doh.gov.ph).
- B.2 Applicant accomplishes required documents listed below and submits them to the BHFS. Upon filing of application, the applicant pays the corresponding fees to the Cashier of the DOH in cash, or through postal money order.

Documentary Requirements:

For initial license:

1. Notarized duly accomplished BHFS Application Form
2. Letter of Endorsement to the BHFS Director (if filed at the CHD)
3. Memorandum of Agreement of the ASC to the nearest secondary or tertiary care hospital
4. Fire Safety Inspection Certificate
5. List of Surgical Operations to be performed within the health clinic
6. ICD 10 Training Certificate
7. List of personnel
8. List of Equipment
9. Contract of Lease (if clinic is rented)
10. Copies of License or License to Operate of other services being provided: Pharmacy; X-Ray; Laboratory etc.
11. Quality Assurance Program
12. Letter of Intent to comply with the evidence-based Clinical Practice Guidelines

For renewal of license:

1. Notarized duly accomplished BHFS Application Form
2. Letter of Endorsement to the BHFS Director (if filed at the CHD)
3. Previous DOH License
4. List of Surgical Operations
5. ICD 10 Training Certificate
6. Quality Assurance Program

- B.3 The BHFS conducts survey on site to determine compliance with standards and technical requirements for licensing. The BHFS pursuant to an appropriate Memorandum of Agreement with the Philippine College of

Surgeons will allow the latter's duly representative to provide technical assistance to the licensing team in the inspection of ASC.

B.4 The BHFS approves or disapproves the issuance of the license.

- If approved, the BHFS registers the ASC and issues the license to the applicant.
- If disapproved, the BHFS sends the findings and recommendations to the applicant for compliance.

B.5 Applications for LTO, which are not processed within the sixty (60) day period after its official receipt are considered approved.

VII. MONITORING

The BHFS and the CHD are authorized to monitor and conduct on-site visits to the ASC at any given time. The ASC shall make available to the monitoring team all pertinent records to determine the level of compliance with the licensure and regulatory standards.

VIII. VALIDITY

The license to operate shall be valid for a period of three (3) years.

IX. PENALTIES

The BHFS may suspend or revoke the license to operate an ASC if, upon investigation and hearing the latter shall be found guilty of violation of the provision under these rules or any rule related to the operation of such clinics in the Philippines.

Any ASC operating without a valid license duly issued by the BHFS shall be immediately closed and shall be fined not less than ten thousand (10,000) pesos but not more than fifty thousand (50,000) pesos.

X. INVESTIGATION OF CHARGES AND COMPLAINTS

The BHFS on its own, or upon receipt of complaints or charges against a licensed ASC by any person or interested party, shall investigate the complaints or charges. If upon fact finding or monitoring visits the ASC is found to be violating the rules and regulations or any law or rules related to the operation of such, the BHFS may preventively suspend its operation. Preventive suspension shall not be more than sixty (60) days.

XI. APPEAL

The DOH will provide an opportunity for a fair hearing to every licensee who is dissatisfied with administrative decisions made in the suspension or revocation of license.

- a. The BHFS shall notify the licensee by registered mail or personal service the particular reasons for the suspension or revocation of license. A written request of the licensee within ten (10) days after the date of such notice, the agency shall fix a date not less than thirty (30) days

- from the date of such notice at which time the licensee shall be given an opportunity for a prompt and fair hearing.
- b. On the basis of such hearing or upon default of the licensee, the BHFS shall make a determination specifying its findings of fact and conclusions of law. A copy of such determination shall be sent by registered mail to the last known address of licensee or served personally to the licensee.
 - c. The decision of revoking or suspending the license shall become final thirty (30) days from receipt unless the licensee, within such thirty (30) day period, appeals the decision to the Office of the Secretary of Health or his representative in the area where the ASC is located. An additional period of time may be granted at the discretion of the BHFS.

XII. SEPARABILITY / REPEALING CLAUSE

In the event that any rule, section, paragraph, sentence, clause or words of these rules and regulations is declared not valid for any reason, the other provisions thereof shall not be affected thereby.

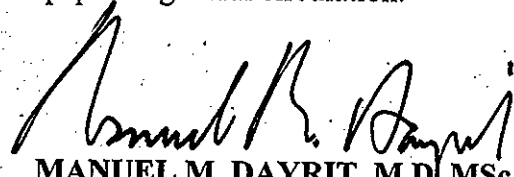
These Rules and Regulations shall repeal and supercede all administrative orders and previous issuances inconsistent thereof.

XIII. MORATORIUM

Any ASC which is in operation at the time of promulgation of these rules and regulations shall be given a period of one (1) year from the date of such promulgation to comply with such rules and regulations. But during this period all existing clinics must apply for a license with the BHFS. ASCs without proper application shall be immediately closed.

XIV. EFFECTIVITY

These rules and regulations shall take effect fifteen (15) days after publication in the official gazette or in a newspaper of general circulation.


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Secretary of Health