REVISED RULES AND REGULATIONS GOVERNING THE REGISTRATION, LICENSURE OF DENTAL LABORATORIES IN THE PHILIPPINES

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I. Rationale

The Department of Health (DOH) is constitutionally mandated to protect and preserve the health of the people including oral health. In support to its mandate, Presidential Decree No. 1542, "Providing for the Registration and Licensing of Dental Prosthetic Laboratories," was issued on June 11, 1978. To implement this decree, the DOH formulated the rules and regulations governing the registration, licensing and operation of Dental Prosthetic Laboratories. The latest revision is embodied in Administrative Order No. 117-B s. 1992. With the current advances in the field of dentistry, services of Dental Laboratories expanded. Hence, the need to revise A.O. 117-B, s. 1992.

II. Scope

The rules and regulations embodied herein shall apply to any person, firm, corporation, or entity, whether government or private, operating and maintaining dental laboratories, to include dental prosthetic laboratories.

III. Definition of Terms

Dental Laboratory — an establishment engaged in making, repairing, providing or altering oral prosthodontic and orthodontic appliances which are given back to the dentist and inserted to human mouth. This shall include the services rendered in the so-called Dental Prosthetic Laboratory.

License — a formal authorization issued by the DOH to an individual, partnership, corporation or association to operate a dental laboratory.

Prosthodontic Appliance — takes the place of a natural part or correct a congenital abnormality (e.g. full dentures, crown or bridge or any appliance to correct cleft palate).

Orthodontic Appliance — used in the treatment and prevention of malocclusion or irregular positioning of teeth (e.g. retainers, braces, space maintainers)

IV. Classification of Dental Laboratories

A. Ownership

- Private — privately owned, established and operated with funds through donation, capital or other means, by any individual, corporation, association or organization.

- Government — operated and maintained partially or wholly by a national, provincial, city or municipal, government or other political unit, or by any department, division, board or agency thereof.

B. Service Capability

- Primary Category — performs basic acrylic work, complete dentures, fixed and/or removable dentures and plastic jacket crowns.

- Secondary Category — performs all services in the primary category plus porcelain jacket crowns and bridges, and metal casting.

- Tertiary Category — performs all services in the secondary category plus manufacture of integral parts or accessories in denture making.

C. Operation

- General — renders all types of dental laboratory services appropriate for a given category.

- Special — renders specialized prosthodontic work such as but not limited to metal casting, porcelain crowns.

V. Technical Requirements

All dental laboratories shall comply with the technical licensing standard requirements. Please see Annex A (Text available at ONAR, U.P. Law Center, Diliman, Quezon City)..

- The Dental Laboratory shall have adequate numbers of appropriately qualified professional and support personnel to meet the needs of the clients.

- The physical plant shall be well ventilated, lighted, clean, safe and adequate to accommodate its activities.

- The equipment shall be available for the efficient, hygienic and safe operation of the laboratory.

VI. Procedural Guidelines

1. Documentary Requirements

All dental laboratories, both government and private, desiring to establish or operate and maintain a dental laboratory shall submit to the Bureau of Health Facilities and Services (BHFS)/Center for Health Development (CHD) the following documents:

1.1 Initial License

1.1.1 Notarized application form – BHFS-DL Form No. 1. Please see Annex B1[*].
1.1.2 Notarized information sheet – BHFS-DL Form No. 2 with a picture of the applicant and a vicinity map of the Dental Laboratory. Please see Annex B2[*].
1.1.3 Photocopy of Professional Regulation Commission Certificate of the Dentist Consultant.
1.1.4 DTI/SEC Registration
1.1.5 Barangay Clearance

1.2 Renewal of License:

1.2.1 Notarized application form for renewal – BHFS-DL Form No. 3/CHD-DL Form. Please see Annex B3[*] – for tertiary.
1.2.2 Original license to operate dental laboratory.
1.2.3 Photocopy of valid Professional Regulation Commission Certificate of the Dentist Consultant.

2. License Fees:

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2.1 Every government or private dental laboratory desiring to operate for the first time or to resume operation after ceasing to operate for some period of time, shall pay a non-refundable fee based on currently prescribed schedule of fees.

2.2 Fees for all initial license and renewal of tertiary dental laboratory shall be payable to the cashier of the DOH in person or through postal money order.

2.3 Fees for renewal of license, shall be payable to the respective CHD concerned.

2.4 Three hundred pesos (P300.00) in addition to the renewal fee shall be paid if the application for renewal is filed on anniversary date.

2.5 One hundred pesos (P100.00) shall be charged for replacement of lost, worn-out, laminated license.

3. Inspection

A dental licensing inspection team shall schedule the date of inspection of the establishment to verify compliance with the requirements prescribed in the DOH licensing rules and regulations.

3.1 Each license shall allow the BHFS/CHD Director or his duly representative(s) at reasonable hours to inspect the dental laboratory.

3.1.1 The BHFS/CHD Director or his representative(s) may be assisted by experts from a professional organization/association in the conduct of inspection.

3.2 The BHFS/CHD Director or its duly authorized representatives shall issue a notice of deficiency to any owners/proprietors for noted technical deficiency(ies) during the evaluation. A period of ninety (90) days shall be given to concerned parties to comply. Failure to comply within the specified period will merit cancellation of application and corresponding fees or license to operate.

4. Issuance of License:

4.1 Initial License

The initial license shall be issued upon full compliance to all requirements.

4.2 Renewal of License

4.2.1 Application for renewal of license shall be filed ninety (90) days before the anniversary date of license.

4.2.2 If the application is found to be meritorious, license shall be renewed.

5. Validity

License issued shall be valid for the period covered and expire on the anniversary date.

VII. Terms and Conditions

- The license is granted on the basis of specific conditions and limitations in compliance with requirements as established during the inspection and defined in the issuance of the license.

- Any right under the license shall not be assigned or otherwise transferred directly or indirectly to an unauthorized party.

- The owner or representative of any dental laboratory desiring to transfer the physical plant of a registered dental laboratory to another place shall inform the BHFS in writing within fifteen (15) days after transfer has been

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completed. The laboratory at its new location shall apply for a new license and comply with the licensing requirements.

- Every dental laboratory and every branch thereafter shall maintain a license to operate.

- Any change in ownership or head of the dental laboratory shall be reported within fifteen (15) days to the BHFS for notation and approval. When change in ownership of license is found to be meritorious, an application for a new license by the new owner shall be required.

- Failure to report the change of ownership will automatically revoke the license of the dental laboratory.

- The license of the dental laboratory must be placed in a conspicuous place within the laboratory.

- The dental laboratory may continue operation during the pendency of the final action on its application for renewal, unless, otherwise, advised or ordered by the proper authorities to cease operation.

- A license issued that has not been renewed for sixty (60) days after the anniversary date shall be considered lapsed and the registration shall be cancelled.

- After the license of a dental laboratory has lapsed, an application for registration and a new license to operate the same laboratory shall be required. For a dental laboratory to be allowed to operate again, the owner/proprietor/manager shall send a notification in writing cessation of its operation, surrender its latest license to operate to the BHFS and pay fees for new license.

- In case, however, where the dental laboratory concerned did not actually close its operation after its license had been considered lapsed, or in cases, where the said laboratory had actually ceased operation but its owner/proprietor/manager failed to give the corresponding notification of such cessation to operate, or failed to surrender its last license to operate to the BHFS, the said laboratory applying for registration and new license shall also pay all arrears corresponding to the years that its license not been renewed.

VIII. Violations

Violation of P.D. 1542 or its rules and regulations issued in pursuance thereof, including the commission of the following acts by the proprietor or persons operating a dental laboratory or by persons under their authority:

8.1 Operating, managing or maintaining a dental laboratory without valid license to operate for the current year.

8.2 Change of ownership, management, name or location without informing the BHFS in writing within fifteen (15) days.

8.3 Any material false statement in the application.

8.4 Refusal to allow inspection of the dental laboratory by persons authorized by the BHFS/CHD Director during reasonable hours.

8.5 Failure to make necessary correction of deficiencies required by the BHFS/CHD in order to comply with standards and requirements after due notice.

8.6 Any dental technician/persons illegally practicing dentistry for the purpose of constructing dental prosthesis and/or orthodontic appliances.

8.7 Displaying/selling ready-made prosthetic or orthodontic appliances like retainers/dentures of varying

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designs for public use/consumption.

8.8 Putting-up misleading sign boards of a dental laboratory.

IX. Investigation of Charges of Complaints

The BHFS/CHD Director or his duly authorized representative(s) shall investigate the complaint or charges filed by any person, interested party or corporation against a dental laboratory or any of its personnel. This includes violations of the provisions in P.D. 1542. The BHFS/CHD Director or his representative(s) shall verify the merit of the complaint. If upon investigation, a person(s) is found violating the provisions of P.D. 1542 or any of these Rules and Regulations, the BHFS/CHD Director shall either suspend for a definite or indefinite period of time, cancel, revoke the license of the laboratory and authority of the offending person(s) without prejudice to taking the case to judicial authorities for criminal action.

X. Modification and Revocation of License

- The terms and conditions of each license shall be subject to these Rules and Regulations, and to all such amendments thereto as the Secretary of Health may deem necessary.

- Any license may be revoked, suspended or modified, in full/in part, for any material false statement in the application as revealed by subsequent statement of the applicant or as shown by the record of inspection, or for a violation thereof, or for failure to observe any of the provisions of these rules and regulations.

- Except in cases of willful, or repeated violation hereof, or where public health interest or safety requires otherwise, no license shall be modified, suspended, or revoked, unless prior notice to the owner has been made and the corresponding investigation conducted.

XI. Appeal

Any dental laboratory or any of its personnel aggrieved by the decision of the BHFS may within thirty (30) days after receipt of notice of the decision, file a notice of appeal in the Office of the Secretary, and serve a copy of the notice of appeal to the BHFS. Thereupon the BHFS shall promptly certify and file a copy of the decision, including the transcript of the hearings on which the decision is based with the Office of the Secretary for review. The decision of the Office of the Secretary shall be final and executory.

XII. Closure

The BHFS in coordination with the CHD shall immediately order the closure of the facility that violates the rules and regulations embodied herein, and shall seek assistance of appropriate agency to effectively enforce the actual or constructive closure.

XIII. Penal Provision

Any person who violates any provision of P.D. 1542 or its rules and regulations and standard requirements implementing the decree shall be punished by imprisonment of not less than one month but not more than one year or by a fine of not less than two hundred pesos (P200.00) but not more than one thousand pesos (P1,000.00) or both such fine and imprisonment in the discretion of the court.

XIV. Implementing Mechanisms

Responsibilities of the DOH-BHFS:

- Issue initial license to operate a dental laboratory except for tertiary category dental laboratories.

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- Provide technical assistance when necessary/as requested.

- Monitor dental laboratories at any given time within reasonable hours.

- Publish the list of licensed dental laboratories according to their categories.

Responsibilities of the DOH-CHD:

- Issue renewal of license to operate a dental laboratory, except for tertiary category dental laboratories.

- Provide technical assistance when necessary/as requested.

- Monitor dental laboratories.

Responsibilities of the Dental Laboratory:

In addition to complying with all the above requirements, it shall be the responsibility of a licensed dental laboratory to:

- Maintain a standard record book reflecting ordered and finished jobs.

- File and maintain original prescription or work authorization signed by the dentist.

- Ensure that the dental laboratory records are available for inspection at all times.

XV. Repealing and Separability Clause

Any Administrative Orders, Rules and Regulations and other Department issuances inconsistent herewith are hereby repealed, modified, or amended accordingly.

In the event that any section, paragraph, sentence, clause or word of this Order is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

XVI. Effectivity

These rules and regulations shall take effect upon approval and publication in a newspaper of general circulation.

Adopted: 14 March 2003

(SGD.) MANUEL M. DAYRIT, M.D., MSC.
Secretary of Health

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[*] Text Available at Office of the National Administrative Register, U.P. Law Complex, Diliman, Quezon City

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