ADOPTED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R033-07

Effective August 26, 2008

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: §§1-19, NRS 639.070.

A REGULATION relating to medical products; adopting certain standards of professional conduct; requiring a medical products provider that wishes to sell, lease or otherwise provide to a consumer a customized orthotic or prosthetic device to be approved by the State Board of Pharmacy; establishing the requirements for such approval; establishing the requirements to sell, lease or otherwise provide such a device; requiring an order or prescription from a practitioner to obtain a customized orthotic or prosthetic device; requiring a medical products provider that provides an insulin pump to a consumer to provide training to the consumer concerning the pump; requiring a medical products provider that provides certain pressurized stockings to a consumer to provide training to the consumer concerning the stockings; providing that redundant life-sustaining equipment provided to a consumer must operate in substantially the same manner as the primary life-sustaining equipment provided to the consumer; making various changes concerning medical products providers and medical products wholesalers; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 9, inclusive, of this regulation.

Sec. 2. ***"Accreditation and certification organization" means:***

1. The American Board for Certification in Orthotics, Prosthetics & Pedorthics; or

2. The Board for Orthotist/Prosthetist Certification.

Sec. 3. ***"Customized orthotic or prosthetic device" means a medical product that is built, assembled or altered specifically to accommodate the anatomy of a particular consumer,***

including, without limitation, a customized breast prosthesis and a customized mastectomy form.

Sec. 4. *1. The State Board of Pharmacy hereby adopts by reference:*

(a) The most recent version of the "Code of Ethics" of the Board for Orthotist/Prosthetist Certification, unless the State Board of Pharmacy gives notice pursuant to subsection 2 that the most recent version is not suitable for this State. The Code may be obtained, free of charge, from the Board for Orthotist/Prosthetist Certification, 7150 Columbia Gateway Drive, Suite G, Columbia, Maryland 21045, or at the Internet address http://www.bocusa.org.

(b) The most recent version of the "Code of Professional Responsibility" of the American Board for Certification in Orthotics, Prosthetics & Pedorthics, unless the State Board of Pharmacy gives notice pursuant to subsection 2 that the most recent version is not suitable for this State. The Code may be obtained, free of charge, from the American Board for Certification in Orthotics, Prosthetics & Pedorthics, 330 John Carlyle Street, Suite 210, Alexandria, Virginia 22314, or at the Internet address http://www.abcop.org.

2. The State Board of Pharmacy will review each successive edition of the codes adopted by the Board pursuant to subsection 1 to ensure their suitability for this State. If the Board determines that an edition is not suitable for this State, the Board will hold a public hearing within 6 months after the date the code was revised to review its determination. If the Board does not revise its determination, the Board will give notice within 30 days after the hearing that the revised edition of the code is not suitable for this State.

Sec. 5. *1. A medical products provider, or an applicant for a license to engage in business as a medical products provider, that wishes to sell, lease or otherwise provide a customized orthotic or prosthetic device to a consumer must be approved by the Board. The*

medical products provider or applicant must apply for approval in the manner prescribed by the Board.

2. The Board will not give its approval unless the medical products provider or applicant submits evidence to the Board that the medical products provider or applicant:

(a) Has employed, contracted with or otherwise retained the services of a person who is certified by an accreditation and certification organization; and

(b) Except as otherwise provided in this subsection, possesses a facility at which to provide a customized orthotic or prosthetic device to a consumer:

(1) That is accredited by an accreditation and certification organization; or

(2) For which the medical products provider or applicant has applied to an accreditation and certification organization for accreditation.

➥ The provisions of paragraph (b) do not apply to a medical products provider or applicant if the only customized orthotic or prosthetic device to be provided by the medical products provider or applicant is a customized breast prosthesis or customized mastectomy form.

3. If the Board gives its approval to a medical products provider or applicant whose facility is not accredited by an accreditation and certification organization, the medical products provider or applicant shall:

(a) Pursue its application for accreditation of the facility in good faith; and

(b) Unless excused by the Board, obtain accreditation of the facility within 12 months after the submission of its application to the accreditation and certification organization.

4. The Board may withdraw its approval if the medical products provider:

(a) Ceases to satisfy any condition set forth in this section for which the Board could have initially withheld its approval; or

(b) Violates any provision of NAC 639.693 to 639.6958, inclusive, and sections 2 to 9, inclusive, of this regulation.

Sec. 6. *A medical products provider that sells, leases or otherwise provides a customized orthotic or prosthetic device to a consumer shall:*

1. Make available to its consumers the services of a person who is certified by an accreditation and certification organization.

2. Except as otherwise provided in section 5 of this regulation, provide a customized orthotic or prosthetic device to a consumer only at a facility that is accredited by an accreditation and certification organization.

3. Provide emergency services to a consumer within 12 hours after the consumer or his caregiver or agent requests the services.

4. Keep confidential any records concerning the treatment of a consumer to whom the medical products provider sells, leases or otherwise provides a customized orthotic or prosthetic device.

5. Develop and use policies and procedures to ensure that a person employed, contracted with or otherwise retained by the medical products provider complies with the provisions of NAC 639.693 to 639.6958, inclusive, and sections 2 to 9, inclusive, of this regulation.

Sec. 7. *An order from a practitioner is required in order to obtain a customized orthotic or prosthetic device from a medical products provider.*

Sec. 8. *A medical products provider that sells, leases or otherwise provides an insulin pump to a consumer shall provide training to the consumer or his family, caregiver or agent in the proper use and maintenance of the pump and the procedures for dealing with a malfunction or other problem that may arise in the use of the pump. The training must be*

provided by a person who is certified by the manufacturer of the insulin pump in the operation of the pump.

Sec. 9. ***1. A pressurized stocking that has a pressure rating of 20 millimeters of mercury or more may not be sold, leased or otherwise provided to a consumer without an order from a practitioner.***

2. A medical products provider that sells, leases or otherwise provides to a consumer a pressurized stocking that has a pressure rating of 20 millimeters of mercury or more shall provide training to the consumer or his family, caregiver or agent in the use, maintenance and potential problems in the use of the stocking. The training must be provided by a person who is certified by the manufacturer of the pressurized stocking in the fitting and use of the stocking.

Sec. 10. NAC 639.693 is hereby amended to read as follows:

639.693 As used in NAC 639.693 to 639.6958, inclusive, ***and sections 2 to 9, inclusive, of this regulation,*** unless the context otherwise requires, the words and terms defined in NAC 639.6931 to 639.6938, inclusive, ***and sections 2 and 3 of this regulation*** have the meanings ascribed to them in those sections.

Sec. 11. NAC 639.6931 is hereby amended to read as follows:

639.6931 "Assistive equipment" means a medical product intended to aid a consumer in the performance of one or more bodily activities. The term includes, without limitation, a ***customized orthotic or prosthetic device, and a*** wheelchair, walker or other similar device. The term does not include respiratory equipment.

Sec. 12. NAC 639.6935 is hereby amended to read as follows:

639.6935 1. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

2. The term does not include:

(a) Controlled substances;

(b) Dangerous drugs, except medical gases and supplies that facilitate the use of a dangerous drug, including, without limitation, normal saline and other similar inert liquids; ~~[and]~~

(c) Medical devices, equipment, supplies or gases the regulation of which is governed by any other board or agency other than the Board ~~[.]~~ ***; and***

(d) Pressurized stockings that have a pressure rating of less than 20 millimeters of mercury.

Sec. 13. NAC 639.6945 is hereby amended to read as follows:

639.6945 ***1.*** The Board may waive the license fee, or any part thereof, for a medical products provider that:

~~[1.]~~ ***(a)*** Is a tax-exempt charitable organization pursuant to 26 U.S.C. § 501(c);

~~[2.]~~ ***(b)*** Provides medical products to a majority of the consumers served by the medical products provider at no charge; and

~~[3.]~~ ***(c)*** Verifies to the satisfaction of the Board that ***at least*** 75 percent of the ~~[funds]~~ ***money*** of the medical products provider ~~[are]~~ ***is*** used for bona fide charitable purposes.

2. A medical products provider that the Board has determined satisfies the requirements for a waiver of the license fee pursuant to subsection 1:

(a) May:

(1) Accept donations of medical products and food products;

(2) Except as otherwise provided in paragraph (b), dispense donated medical equipment in an "as is" condition if:

(I) The medical equipment does not require an order from a practitioner to be dispensed; and

(II) The consumer or his caregiver or agent signs a waiver acknowledging that he understands that the equipment is in an "as is" condition; and

(3) Dispense a donated food product, other than a product for which an enteral or parenteral pump is required, if the food product is not adulterated and the medical products provider dispenses the food product before the expiration date set forth on the packaging of the food product.

(b) May not dispense a donated medical product that bears an indication that the product was provided by or originated with another medical products provider unless it obtains the consent of the original medical products provider.

Sec. 14. NAC 639.6946 is hereby amended to read as follows:

639.6946 1. ~~[A]~~ ***Except as otherwise provided in NAC 639.6945, a*** medical products provider shall:

(a) Provide services for all medical products sold, leased or otherwise provided by the medical products provider, including, without limitation, setup, repair and maintenance.

(b) Employ an administrator and other employees sufficient to provide the services described in paragraph (a).

(c) Ensure that each employee is trained to:

(1) Use, setup, repair and maintain the medical products sold, leased or otherwise provided by the medical products provider that an employee is authorized to sell, lease or otherwise provide to a consumer; and

(2) Instruct consumers concerning the use, setup and maintenance of the medical products sold, leased or otherwise provided by the medical products provider that an employee is authorized to sell, lease or provide to a consumer.

(d) Maintain an inventory of medical products that is adequate to serve the needs of the consumers served by the medical products provider.

(e) Maintain a ***suitable*** physical location ***, other than a residence,*** at which the medical products provider can:

(1) Store inventory;

(2) Repair or service any equipment which the medical products provider sells, leases or otherwise provides; and

(3) Keep all current records related to the business of the medical products provider.

(f) Have a functioning restroom containing a toilet and a sink with hot and cold water at the place of business of the medical products provider.

(g) Maintain the place of business of the medical products provider in a clean, orderly and sanitary condition.

(h) Ensure that the place of business complies at all times with applicable federal, state and local laws, regulations and rules, including, without limitation, applicable occupational safety rules, fire codes, building codes and health codes.

(i) Maintain liability insurance of at least $1,000,000, which must include product liability insurance if the medical products provider:

(1) Designs, fabricates or manufactures medical products; or

(2) Substantially modifies commercially available medical products.

(j) Maintain a log or other record regarding all repairs made to a medical product provided by the medical products provider. For a medical product repaired by the medical products provider, the log or record must identify:

(1) The type of medical product;

(2) The manufacturer;

(3) The model or model number;

(4) The serial number;

(5) The date of the repair;

(6) The specific repair made;

(7) The name of the person or company who performed the repair; and

(8) A certification that the medical product has been returned to the specifications of the manufacturer as a result of the repair.

2. If the medical products provider cannot certify that the repaired medical product has been returned to the specifications of the manufacturer as a result of the repair, the medical products provider must:

(a) Determine whether the medical product can be safely and effectively used for a limited purpose, in which case the medical products provider must note that the medical product must only be used for a limited purpose and must ensure that the medical product is only used for such a limited purpose; or

(b) Ensure that the medical product is removed from service and is not sold, leased or otherwise provided to any person without a written statement acknowledging that the medical product:

(1) Was repaired;

(2) Could not be repaired to the specifications of the manufacturer; and

(3) Cannot be used by the consumer for the purposes for which the medical product was intended.

3. Any device used by a medical products provider to calibrate or test equipment must be accurate and must be maintained according to the directions and specifications of the manufacturer. The scales used to weigh reservoirs of liquid oxygen must be accurate and must be certified annually by the State Sealer of Weights and Measures.

4. The business premises of any medical products provider must be open and accessible to the public and the Board at all times during regular hours of operation.

5. A medical products provider shall develop and use a written procedure for addressing consumer complaints, including, without limitation, procedures for maintaining a complaint file that documents all complaints from consumers and the resolution of each complaint.

Sec. 15. NAC 639.6948 is hereby amended to read as follows:

639.6948 Any person or business that is not a medical products provider who sells, leases or otherwise provides medical products to a consumer must comply with NAC 639.693 to 639.6958, inclusive, ***and sections 2 to 9, inclusive, of this regulation*** for any sale, lease or other disposition of medical products as though that person were a medical products provider.

Sec. 16. NAC 639.6954 is hereby amended to read as follows:

639.6954 1. A medical products provider that sells, leases or otherwise provides medical gases and associated equipment, or respiratory equipment shall:

(a) Comply with all applicable federal, state and local laws regarding the providing and transportation of such gases and equipment, including, without limitation, all requirements regarding the tracking and recalling of gases and equipment;

(b) Comply with all applicable federal, state, and local laws regarding transfilling and repackaging of such gases;

(c) Comply with all applicable federal, state and local laws, including, without limitation, fire codes, occupational safety rules, building codes and health codes;

(d) Service equipment sold, leased or otherwise provided by the medical products provider according to the directions and specification of the manufacturer, regardless of where the equipment may be located at the time that the equipment is due for servicing;

(e) Make and keep records regarding the servicing of equipment by the medical products provider; and

(f) Provide only gases that are:

(1) Medical grade; and

(2) Intended for use by humans.

2. Before providing any equipment pursuant to this section, a medical products provider shall verify that the equipment:

(a) Has been checked and is free of defects;

(b) Is operating within the specifications of the manufacturer;

(c) Has not been modified in any way that will jeopardize the effectiveness or safety of the equipment;

(d) Does not present a hazard of fire or shock; and

(e) Has all warning labels and tags that were provided by the manufacturer, wholesaler or seller of the equipment.

3. A medical products provider that sells, leases or otherwise provides medical gases and equipment or respiratory equipment shall develop and use policies and procedures that require:

(a) Making and keeping records to track and recall all gases dispensed by the medical products provider, including, without limitation:

(1) Recording the lot numbers ~~[and expiration dates for]~~ ***of*** each cylinder or unit of gas provided;

(2) Maintaining a written or computerized system to track and locate all gases and equipment provided by the medical products provider; and

(3) Recording the serial numbers and model numbers of all equipment provided by the medical products provider;

(b) Maintaining and cleaning equipment provided by the medical products provider, including, without limitation:

(1) Documenting that the function and safety of the equipment was verified before the equipment was provided to the consumer;

(2) Cleaning and disinfecting equipment pursuant to an established protocol to remove aerobic and anaerobic pathogens from the equipment to the specifications of the manufacturer for that equipment;

(3) Making and keeping a material safety data sheet for the solutions and products used in cleaning and disinfecting the equipment;

(4) Designating areas at the business of the medical products provider that must be used to store separately clean and unclean equipment; and

(5) Designating a separate area at the business of the medical products provider that must be used to store quarantined equipment.

4. When a medical products provider provides oxygen, the medical products provider must also provide an emergency supply of oxygen, supplies and equipment to maintain therapy while the primary supply of oxygen and related equipment is inoperable or unusable.

5. In addition to any communication and advisement required pursuant to NAC 639.693 to 639.6958, inclusive, ***and sections 2 to 9, inclusive, of this regulation,*** a medical products provider who provides medical gas and related equipment, or respiratory equipment, must advise the consumer receiving the medical gas and related equipment, or respiratory equipment, regarding:

(a) Cleaning of the equipment;

(b) Potential hazards and warning signs of malfunctioning or inadequately functioning equipment;

(c) Maintenance procedures for the equipment;

(d) The telephone number, contact name, and contact address for emergency servicing or repair of the equipment, and for routine servicing or repair of the equipment; and

(e) The written materials about the equipment that are available from the medical products provider or the manufacturer of the equipment.

6. For the purposes of this section, “material safety data sheet” has the meaning ascribed to it in 29 C.F.R. § 1910.1200.

Sec. 17. NAC 639.6955 is hereby amended to read as follows:

639.6955 A medical products provider who sells, leases or otherwise provides life-sustaining equipment shall:

1. Maintain a sufficient number of employees who are:

(a) Trained to service and repair the life-sustaining equipment provided by the medical products provider; and

(b) Available to service and repair the life-sustaining equipment within 1 hour of any call for service or repair;

2. Inform all consumers to whom the medical products provider has sold, leased or otherwise provided life-sustaining equipment of a toll-free telephone number that the consumer may call at any time the life-sustaining equipment has malfunctioned;

3. Ensure that information and procedures in the event of an emergency are in writing and attached to the life-sustaining equipment; and

4. Provide the consumer with sufficient emergency supplies and equipment ***, including, without limitation, redundant life-sustaining equipment,*** necessary to sustain the consumer until the medical products provider can service or repair the ***primary*** life-sustaining equipment. ***Redundant life-sustaining equipment provided pursuant to this subsection must operate in substantially the same manner as the primary life-sustaining equipment.***

Sec. 18. NAC 639.6957 is hereby amended to read as follows:

639.6957 1. A medical products wholesaler shall:

(a) Employ a facility administrator and other employees sufficient to operate, set up, repair, maintain and service all medical products sold, leased or otherwise provided by the medical products wholesaler.

(b) Ensure that employees of the medical products wholesaler are trained to operate, set up, repair, maintain and service the medical products sold, leased or otherwise provided by the medical products wholesaler.

(c) Ensure that employees of the medical products wholesaler are trained to instruct medical products providers regarding the operation, set up, repair, maintenance and service of all medical products sold, leased or otherwise provided by the medical products wholesaler.

(d) Maintain an inventory of medical products necessary to serve the needs of the medical products providers served by the medical products wholesaler.

(e) Maintain a ***suitable*** physical location ***, other than a residence,*** at which the medical products wholesaler can:

(1) Store inventory;

(2) Repair or service any equipment which the medical products wholesaler sells, leases or otherwise provides; and

(3) Keep all current records related to the operation of the medical products wholesaler.

(f) Have a functioning lavatory with a toilet and a sink with hot and cold water at the facility of the medical products wholesaler.

(g) Maintain the facility of the medical products wholesaler in a clean, orderly and sanitary condition.

(h) Ensure that the facility of the medical products wholesaler complies with all applicable federal, state and local laws, regulations and rules, including, without limitation, occupational safety rules, fire codes, building codes and health codes.

(i) Maintain liability insurance of at least $1,000,000, which must include product liability insurance if the medical products wholesaler:

(1) Designs, fabricates or manufactures a medical product; or

(2) Substantially modifies a commercially available medical product.

(j) Maintain a log or other record regarding all repairs made to medical products provided by the medical products wholesaler. For each medical product repaired by the medical products wholesaler, the log or record must identify:

(1) The type of medical product;

(2) The manufacturer;

(3) The model or model number;

(4) The serial number;

(5) The date of the repair;

(6) The specific repair made;

(7) The name of the person or company who performed the repair; and

(8) A certification that the medical product has been returned to the specifications of the manufacturer as a result of the repair.

2. If the medical products wholesaler cannot certify that the repaired medical product has been returned to the specifications of the manufacturer as a result of the repair, the medical products wholesaler must:

(a) Determine whether the medical product can be safely and effectively used for a limited purpose, in which case the medical products wholesaler must note that the medical product can only be used for a limited purpose and must ensure that the medical product is only used for such limited purpose; or

(b) Ensure that the medical product is removed from service and is not sold, leased or otherwise provided to any person without a written statement acknowledging that the medical product:

(1) Was repaired;

(2) Could not be brought up to the specifications of the manufacturer; and

(3) Cannot be used for the purposes for which the medical product was intended.

3. Any device used by a medical products wholesaler to calibrate or test equipment must be accurate and must be maintained according to the directions and specifications of the manufacturer. The scales used to weigh reservoirs of liquid oxygen must be accurate and must be certified annually by the State Sealer of Weights and Measures.

4. The physical premises of any medical products wholesaler must be open and accessible to the Board at all times during regular hours of operation.

5. The owner of a medical products wholesaler is responsible for the acts of his facility administrator and employees.

Sec. 19. 1. Notwithstanding the provisions of sections 5 and 6 of this regulation, a medical products provider that has been approved by the State Board of Pharmacy on or before August 26, 2008, to sell, lease or otherwise provide to a consumer a customized orthotic or prosthetic device is not required to possess a facility that is accredited by an accreditation and certification organization or to provide to a consumer a customized orthotic or prosthetic device only at an accredited facility until August 27, 2009.

2. As used in this section:

(a) "Accreditation and certification organization" has the meaning ascribed to it in section 2 of this regulation.

(b) “Customized orthotic or prosthetic device” has the meaning ascribed to it in section 3 of this regulation.

(c) “Medical products provider” has the meaning ascribed to it in NAC 639.6936.

NOTICE OF ADOPTION OF PROPOSED REGULATION
LCB File No. R033-07

The State Board of Pharmacy adopted regulations assigned LCB File No. R033-07 which pertain to chapter 639 of the Nevada Administrative Code.

INFORMATIONAL STATEMENT

1. A DESCRIPTION OF HOW PUBLIC COMMENT WAS SOLICITED, A SUMMARY OF PUBLIC RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Public comment was solicited through public notices posted in county courthouses and through mailings to interested parties.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

2. THE NUMBER OF PERSONS WHO: (A) ATTENDED EACH HEARING; (B) TESTIFIED AT EACH HEARING; AND (C) SUBMITTED TO THE AGENCY WRITTEN STATEMENTS.

The number of persons who attended the hearing was __1___.
The number of persons who testified at the hearing was __1___.
The number of agency submitted statements was __1___.

3. A DESCRIPTION OF HOW COMMENT WAS SOLICITED FROM AFFECTED BUSINESSES, A SUMMARY OF THEIR RESPONSE, AND AN EXPLANATION HOW OTHER INTERESTED PERSONS MAY OBTAIN A COPY OF THE SUMMARY.

Comments were solicited from affected businesses through posting of public notices in the county courthouses, by direct mailings to all interested persons who have requested notices of board of pharmacy meeting agendas and by direct mailings to professional and trade associations.

All response from affected businesses relative to this proposed regulation expressed support for the amendment.

All interested parties may obtain a summary of public response by written or verbal request to: Nevada State Board of Pharmacy, 431 West Plumb Lane, Reno, Nevada, 89509.

4. IF THE REGULATION WAS ADOPTED WITHOUT CHANGING ANY PART OF THE PROPOSED REGULATION, A SUMMARY OF THE REASONS FOR ADOPTING THE REGULATION WITHOUT CHANGE.

The proposed regulation was adopted without change.

5. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

This regulation should have no economic impact on affected businesses or on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

This regulation will have no immediate or long-term economic effects on business or the public.

6. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

Enforcement of the regulation will be performed during annual inspections of all pharmacies. There will be no additional cost incurred by the board.

7. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

8. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

9. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.