

LCB File No. R197-03

**PROPOSED REGULATION OF THE HEALTH DIVISION OF
THE DEPARTMENT OF HUMAN RESOURCES**

Certificate of free sale definition and Issuance of certificate of free sale, fee

Italicized type is new and will be added to the regulation, except for existing underlined type between parentheses. Type with a ~~parentheses~~ will be deleted from the regulation. Other type is existing in the regulation.

Cosmetics and Drugs

585.XXX “Certificate of Free Sale” means a certificate issued by the health division to document compliance with NAC 585.010 to 585.640, inclusive.

585.XXX Fee for certificate of free sale.....\$20

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SMALL BUSINESS IMPACT STATEMENT

Amendments to Fees by the Bureau of Health Protection Services Contained in Nevada Administrative Code (NAC) 585.

PROPOSED AMENDMENTS TO EXISTING REGULATIONS provide for fee increases to allow the Bureau of Health Protection Services (BHPS), a bureau within the State Health Division to recover the costs associated with issuing a certificate of free sale for drug and cosmetics plants.

This is the Small Business Impact Statement required under Nevada Revised Statutes (NRS) 233B.0608 and 233B.0609. A small business is defined in Nevada Revised Statutes (NRS) 233B.0382 as a "business conducted for profit which employs fewer than 150 full-time or part-time employees." **This statement only applies to businesses meeting the aforementioned definition.**

The State Board of Health's (SBOH) policy in addressing fees for business operators regulated under its authority is to minimize the impact by having fees decreased where possible and increased where necessary in a graduated schedule based upon actual cost of performing work.

The proposed amendments to Chapter 585 of the NAC to add a fee to issue a certificate of free sale for cosmetics and drugs.

Background

The Health Division receives no funding from the federal government for the purposes of administering the drugs and cosmetics program. Funding for this purpose is appropriated by the Nevada State Legislature. However, the State funding does not cover the actual costs by BHPS performing these statutory responsibilities. To meet this funding shortfall, the Nevada State Legislature has historically required that regulated entities pay an annual permit fee to the BHPS. In State Fiscal Year 04 (July 1, 2003 - June 30, 2004) and State Fiscal Year 05 (July 1, 2004 - June 30, 2005), the Legislature has budgeted a fee increase of approximately \$104,000 to merely cover the existing functions performed by the environmental health section of BHPS.

1. A description of the manner in which comment was solicited from affected small businesses, a summary of their response and an explanation of the manner in which other interested persons may obtain a copy of the summary.

Letters were sent to all entities that BHPS could identify as possibly being affected by these fee increases, and/or who normally do business with the BHPS and local health authorities advising them of the potential fee changes and providing notice of public workshops. A questionnaire soliciting comments was included. Copies of the proposed amendments will be posted at the

Health Division's web site. Public workshops were held in September 2003 and are scheduled again for October 28, 2003. Copies of proposed amendments have been provided to those individuals and businesses, which have requested direct service.

Several faxed responses and numerous phone calls provided initial general responses to the generic questionnaire included in the mass mailing, which included fee amendments to nine Chapters of the NAC. Generally, many responders, whether or not they met the definition of a small business, complained that any increase in state fees was an increase in consumer fees, which was an adverse impact, and therefore not warranted. No responses received thus far have been identified as specifically addressing this fee increase.

Interested persons may obtain a list of the recipients and a summary of written responses to the solicited comments by contacting Kinley Goodman, Supervisor EHS, BHPS, 1179 Fairview Dr., Ste 101, Carson City, NV 89701 or by calling (775) 687-6353, extension 261, after October 24, 2003.

2. The estimated economic effect of the proposed regulation on the small business which it is to regulate including, without limitation, both adverse and beneficial effects and both direct and indirect effects.

Direct Adverse and Beneficial Effects

A possible direct adverse effect may be that some small businesses will experience a nominal increase in costs for obtaining the certificate of free sale. A beneficial direct effect is that such a manufacturer will be able to sell its products out-of-state. The funding will help BHPS to offset the costs of providing this service.

The estimated direct and indirect beneficial economic effects of the proposed fee changes on affected small businesses cannot be quantified. The direct beneficial effect cannot be determined. The overall indirect effect of the proposed fees will provide adequate funding for better protection of the health and safety of the public by providing better equipped and better trained inspectors, thereby decreasing the risk to public health and subsequently decreasing associated medical costs, pain and suffering, and a negative impact on local economies that could result.

Direct and Indirect Costs

The estimated direct adverse economic effect of the proposed fee increases on establishments is not expected to be large and will primarily occur in the plan review process and the annual permits for establishments. Indirect costs may be incurred by the customers of those establishments in that the costs might be passed through rates/fees for service or products and those buying/selling a home may incur an increase cost associated with obtaining a home purchase loan. Costs would be determined on a case-by-case basis.

3. A description of the methods that BHPS considered to reduce the impact of the proposed regulation on small businesses and statement regarding whether the agency actually used those methods.

In considering methods to reduce the impact of the proposed regulation on small businesses as required by NRS 233B.0608 2 (b) (1), the agency shall consider simplifying the proposed regulation.

This fee proposal does not propose new regulations for compliance other than creation of some new fees as described above. The impact of these fee increases on small businesses has been minimized or eliminated to the extent possible. New fees are implemented, or existing ones increased in those areas where BHPS has experienced or expects increased activity and, therefore, increased costs.

In considering methods to reduce the impact of the proposed regulation on small businesses as required by NRS 233B.0608 2 (b) (2), the agency shall consider establishing different standards of compliance for a small business.

This fee proposal does not propose new regulations for compliance.

In considering methods to reduce the impact of the proposed regulation on small businesses as required by NRS 233B.0608 (2)(b)(3), the agency shall consider modifying a fee or fine set forth in the regulation so that a small business is authorized to pay a lower fee or fine.

Fees are structured to recover the cost of BHPS performing these functions.

4. The estimated cost to the agency for enforcement of the proposed regulation.

The estimated cost to the agency for enforcement of the proposed regulation is minimal and will be handled through the existing administrative process.

5. Total amount BHPS expects to collect from any fees and the manner in which the money will be used.

The total amount of revenue expected to be collected from this new fee proposal is estimated at about \$40. This revenue is intended to recover the currently unrecovered cost of performing the work.

6. An explanation of why any duplicative or more stringent provisions than federal, state or local standards regulating the same activity are necessary.

The proposed fee changes do not overlap or duplicate any federal, state or local regulations.