

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

FILE COPY

SF-00006-05 (4/86)

DEPARTMENT : ATTORNEY GI RAL

TE OF MINNESOTA

Office Memorandum

DATE : August 22, 1989

TO : DAVID E. HOLMSTROM, Executive Director
Minnesota Board of Pharmacy
2700 University Avenue W., #107 (55114-1079)

FROM : MARTHA J. CASSERLY
Special Assistant Attorney General
515 Transportation Bldg. (55155)

PHONE : 296-6839

SUBJECT : In the Matter of the Adopted Rule Relating To Dispensing and Distribution of Legend Medical Cases and Distribution of Veterinary Drugs and Devices

The above-referenced rule has been approved as to its legality by the Attorney General on August 18, 1989.

Enclosed is the agency's copy of the approved rule. This office has already filed two copies with the Secretary of State who will forward one copy to the Revisor of Statutes. The fourth is being retained by this division of the Attorney General's Office for its records.

Also enclosed are any petitions, requests, submissions or comments received by the agency and any extra copies of documents which the agency submitted to the Attorney General.

Your next step is to arrange for publication of the Notice of Adoption in the State Register. In a day or two, you should receive from the Revisor's Office three copies of the notice of adoption of your rule. You should submit two copies of the Notice of Adoption to the State Register for publication. A permanent rule without a hearing does not become effective until five days after a notice of adoption is published in the State Register in accordance with Minn. Stat. § 14.27. An emergency rule becomes effective five working days after approval by the Attorney General; however, the agency must publish a notice in the State Register in accordance with Minn. Stat. § 14.34.

If you have any questions in this regard, please contact me.

MJC:bbl

cc: William Brown, Chief Judge
Office of Administrative Hearings

Maryanne Hruby, Exec. Dir.
Legislative Commission to Review
Administrative Rules

Robert Holley
Special Assistant Attorney General

JEA

RULE REVIEW CHECKLIST

File No. 1620 — Docket No. 05-0009-0484

DATE RECEIVED 8-8-89 — ADOPTED W/O HEARING ✓

→ REVIEW DATE 8-17-89 — EMERGENCY RULE _____

DUE DATE 8-22-89 — Revisor got 2 copies on 8-8-89

REVISOR APPROVED yes

APPROVED 8-18-89-mjc — REVISOR DISAPPROVED _____

DISAPPROVED _____ — FILED W/SEC. OF STATE 8/21/89

WITHDRAWN _____ — RETURNED TO AGENCY _____

✓ Stat Rule as adopted (4 copies)

~~Notice to Solicit Outside Information/Opinion (if applicable)~~

~~Date published in State Register~~

~~Comments~~

~~Petition for Adoption of a Rule (if applicable)~~

✓ Board's Authorizing Resolution
1-11-89 Date adopted

✓ Proposed Rule
yes Revisor's Certificate

✓ Notice of Intent to Adopt Rule
Statutory Authority 151.06, sub-1 (e) and 151.19, sub-3.
no Small Business Statement
yes Expenditure of public money statement
yes Signature

✓ Statement of Need and Reasonableness (if applicable)
no Small Business Statement
yes Fees - § 16A.128

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
3-8-89 Date (30)/25 days before adoption
no Notice attached
no Copy of rule or summary attached

✓ Publication in State Register missing - Holmstrom will send
2-27-89 Date (30)/25 days before adoption

✓ 180-day deadline from:
~~Effective date of law requiring rule~~
OK (14.12) (both rules) - Aug 1, 1988 → Feb 1, 1989
4-8-89 end of comment period (§ 14.26) (rules without hearing)
~~effective date of statutory authority (§ 14.29) (emergency rules)~~

✓ Resolution Adopting
4-19-89 Date adopted

✓ Findings of Fact, Conclusions & Order Adopting
4-27-89 Date

yes Written requests, submissions or comments

✓ Declaration of attorney
Robert T. Holley Name of SAAG representing agency

~~Notice of Submission to Atty. Gen. (if applicable)~~

~~Aff. of Mailing Notice to Atty. Gen. (if applicable)~~

Board of Pharmacy

Adopted Permanent Rules Relating to Dispensing and Distribution of Legend Medical Gases; Distribution of Veterinary Drugs and Devices

Rules as Adopted

DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES

6800.9920 DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES.

Parts 6800.9920 to 6800.9924 apply to the retail sale and distribution of legend medical gases.

6800.9921 REGISTRATION.

Subpart 1. **Annual registration required.** Every person or establishment selling or distributing legend medical gases in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in Minnesota Statutes, section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration, and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

Subp. 3. **Renewals.** The certificate expires on December 1 of each year, and must be renewed annually. Renewal applications received after December 1 are subject to a late filing fee of $25 in addition to the renewal fee.

Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The registration certificate must be displayed at the location for which it was issued. A change in the location of a registered facility will require reregistration.

6800.9922 RESTRICTED SALES.

No person or establishment shall sell or distribute legend

Approved by Revisor

medical gases at retail to anyone other than:

A. a patient on the basis of a prescription from a practitioner; or

B. a hospital, a practitioner as defined in Minnesota Statutes, section 151.01, subdivision 23, a licensed pharmacy, or other institution or person licensed to possess these drugs for use in the usual course of practice. The distributor of these items shall determine if the purchaser is licensed to possess them.

6800.9923 LABELING.

No person or distributor may sell or distribute any legend medical gas product at retail without the manufacturer's intact federally required label of "Caution: Federal Law Prohibits Dispensing Without Prescription."

6800.9924 RECORDS.

A sale or distribution of legend medical gases by registered distributors of these items at retail must be limited to the prescription or order of a licensed practitioner. These orders or prescriptions must be maintained for at least two years, must be filed by patient name or date, and must be readily retrievable and available for inspection by the Board of Pharmacy. The prescription must bear at least the patient's name and address, date, name and quantity of legend medical gas distributed, and name and address of the prescriber. Refills of legend medical gases must be recorded on the patient's prescription record. The distributor of these articles is responsible for obtaining authority for refills from the prescriber.

~~DISTRIBUTION OF VETERINARY DRUGS AND DEVICES~~

~~6800.9930 DISTRIBUTION OF VETERINARY DRUGS AND DEVICES.~~

~~Parts 6800.9930 to 6800.9932 apply to the retail sale and distribution of veterinary drugs and devices.~~

~~6800.9931 REGISTRATION.~~

~~Subpart 1. Annual registration required. Every person or~~

Approved by Revisor _____

establishment selling or distributing veterinary drugs and devices in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in Minnesota Statutes, section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

Subp. 3. **Renewals.** The certificate expires on December 1 of each year, and shall be renewed annually. Renewal applications received after December 1 are subject to a late filing fee of $25 in addition to the renewal fee.

Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The certificate shall be displayed at the location for which it was issued. A change in the location of the registered facility will require reregistration.

6800.9932 PACKAGING.

A veterinary drug retailer shall deliver veterinary drugs to a client or a client's agent only in the original manufacturer's package.

Approved
by Revisor _____

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

AUG 21 1989

Joan Anderson Growe

Secretary of State

3:15PM

APPROVED AS TO FORM AND LEGALITY

August 18 1989

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY MJ Carsely

SPECIAL ASSISTANT ATTORNEY GENERAL

SF-00006-05 (4/86)

DEPARTMENT : ATTORNEY GENERAL

STATE OF MINNESOTA

Office Memorandum

DATE : August 18, 1989

TO : ROBERT HOLLEY
Special Assistant
Attorney General

FROM : MARTHA J. CASSERLY mjc
Special Assistant
Attorney General

PHONE : 296-6839

SUBJECT : Board of Pharmacy Rules Governing Veterinary Drugs

I have approved the above-entitled rules; however, I would like to point out a concern that I have which you or your client should consider resolving.

Minn. Stat. § 14.12 requires:

> The agency shall, within 180 days after the effective date of a law requiring rules to be promulgated, unless otherwise specified by law, publish an appropriate notice of intent to adopt a rule in accordance with sections 14.05 to 14.36. If an agency has not given this notice, it shall report to the legislative commission to review administrative rules, other appropriate committees of the legislature, and the governor its failure to do so, and the reasons for that failure.

The Board of Pharmacy was directed by the Legislature in Minn. Stat. § 151.19, subd. 3 (Laws of 1988, Ch. 550, sec. 11) as follows:

> The Board shall require and provide for the annual registration of every person or establishment not licensed as a pharmacy or a practitioner engaged in the retail sale or distribution of federally restricted medical gases or of veterinary drugs or devices. Upon the payment of a fee to be set by the board . . . .

The law was approved April 18, 1988, and since I don't see an effective date in the Legislation, presumably the law

became effective August 1, 1988 (Minn. Stat. § 645.02). 180 days after August 1, 1988 is January 27, 1989. However, your Board published the Notice of Intent on February 27, 1989, and mailed out the Notice of Intent on April 8, 1989.

Thus, I raise a concern whether your client has complied with Minn. Stat. § 14.12. That section does not provide a deadline for giving the notices about the delay and the Attorney General Rule does not require such proof to be submitted to us for review. Thus, I am not rejecting the rule for this reason. I do recognize that you may take the view that a section 14.12 notice is not required, for example argue that Minn. Stat. § 151.19, subd. 3, does not "require the rules to be promulgated," or that your client may have already given the notices. I only wanted to raise the issue with you so that you or your client may consider complying with section 14.12. You especially may wish to consider giving the notices if you are having a hearing on the fee portion of the rules.

MJC:cms

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the Registration of Distributors of Legend Medical Gases and Distributors of Veterinary Drugs and Devices

FINDINGS OF FACT, CONCLUSIONS, AND ORDER ADOPTING RULE WITHOUT PUBLIC HEARING

Notice of the Board's intent to adopt the above-entitled rule was published in the State Register on February 27, 1989 and was sent by United States mail to all persons on the list maintained by the agency pursuant to Minnesota Statutes, sections 14.14, subdivision 1a and 14.22 on March 8, 1989. The statement of need and reasonableness was prepared before the notice of intent to adopt a rule without a public hearing was mailed to all persons on the rulemaking mailing list and published in the State Register and was available to the public.

All persons were given the opportunity to submit comment on the rule for 30 days after notice of proposed rulemaking. No requests for a public hearing on the portion of the rule relating to the distribution of medical gases were received by the agency. The statutorily required number of requests for a public hearing were received on those portions of the rule relating to the fee associated with the registration of distributors of veterinary drugs. Thus this section is being withdrawn at this time and a public hearing on that portion will be scheduled in the near future.

Only one submission or comment on the rule was received by the agency. That submission addressed only the Veterinary drug portion as discussed above. A copy of that submission is attached hereto. No requests for notice of submission to the attorney general were received by the agency.

Based on the comments and evidence in the record before the agency, I find the following:

8 The above-captioned rule as it relates to distributors of medical gases is needed and reasonable.

9 NOW, THEREFORE, IT IS ORDERED that the rule identified as Relating to Fees for Licensure of Distributors of Medical Gases is adopted this 27th day of April, 1989, pursuant to authority vested in the Board by Minnesota Statutes, section 151.06.

David C. Holmstrom

Executive Director
Minnesota Board of Pharmacy

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the Registration of Distributors of Legend Medical Gases and Distributors of Veterinary Drugs and Devices

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Board of Pharmacy (Board), pursuant to Minn. Stat. sections 14.22, and 14.23 and Minn. Rules part 1400.0500 hereby affirmatively presents the needs for and facts establishing the reasonableness of the above-captioned proposed rules. The statutory authority for these proposed rules is contained in Minn. Stat. section 151.19, subdivision 3 (1988), which requires the Board to provide for the annual registration of every person or establishment not licensed as a pharmacy or practitioner engaged in the retail sale or distribution of federally restricted medical gases or of veterinary drugs or devices, Minn. Stat. 214.06, which requires the Board to adjust fees so that the total fees collected "....will as closely as possible equal anticipated expenditures during the fiscal biennium" and Minn. Stat. section 151.06, subdivision 1 (9), which authorizes the Board to make and publish uniform rules and regulations to enforce the provisions of the statute.

The rules captioned above are being adopted according to the procedures set forth in Minn. Stat. section 16A.128. A copy of the approval of the Commissioner of Finance relative to the proposed fees is incorporated herein.

The legislature, in the 1988 session, recognized the fact that certain gaseous substances have a recognized use in medical practice and are restricted in their application by the Federal Food and Drug Administration to use only upon the receipt of a prescription from a licensed practitioner. Similarly, the legislature recognized that certain veterinary drugs and devices are also being distributed in this state and are likewise restricted, in the case of veterinary devices, to the order of a licensed veterinarian. In the case of veterinary drugs, the legislature recognized that the unregulated distribution of veterinary drugs poses a potential health risk to the population of the state and recognized that at the federal level veterinary drug distribution is divided into two categories just as the distribution of human use drugs are. Namely, drugs requiring the prescription of a licensed veterinarian and drugs available over the counter without such a prescription. In the case of veterinary drugs, however, evidence has shown that the extra-label use of OTC veterinary drugs poses a potential health risk when used in food producing animals. Studies done by the Food and Drug Administration and other state and federal agencies have shown that inappropriate or extra-label use of OTC veterinary drugs may result in drug residues occurring in the food chain. These drug residues, when consumed by humans, pose significant health risks.

In view of the restrictions on distribution of legend medical gases and veterinary devices and in view of the potential health risks associated with unregulated distribution of veterinary drugs the legislature determined that the state should have a record of who is involved in the

distribution of all of these items and should establish standards for the recordkeeping involved in the distribution of legend gases and veterinary devices.

To that end, the legislature has directed the Board of Pharmacy to license distributors of these products and to establish rules relating to the recordkeeping associated with the distributions.

Because of the similarities involved in the distribution of these products compared to the distribution of drugs for human use the Board has established similar recordkeeping requirements. The registration and recordkeeping requirements associated with the distribution of legend medical gases are virtually identical to those required for the distribution of legend drugs. In both cases, the Food and Drug Administration has determined that these drugs are not safe for use without the supervision of a licensed practitioner and in both cases have required that the products contain a warning from the manufacturer to the effect that "Federal law prohibits dispensing without prescription". Since the restrictions on distribution are identical at the federal level the Board has established a registration and recordkeeping system at the state level that is also similar.

In the case of OTC veterinary drugs the Board did not propose any recordkeeping requirements. Since OTC veterinary drugs are not restricted to the order of a licensed veterinarian at the federal level the Board has not required recordkeeping at the state level. It appears sufficient, at this time, to simply establish a registration of who the individuals are that are distributing veterinary drugs so that inspections of their

facilities can be undertaken, any unauthorized sales of veterinary prescription drugs by OTC distributors can be detected, and issues surrounding extra label use of OTC drugs can be discussed.

Based on the Board's experience with licensing and inspecting pharmacies, drug wholesalers, and drug manufacturers a fee of $50 for the registration of distributors of legend medical gases and veterinary drugs and devices seems appropriate. Once the licensure and inspections begin, additional information can be obtained as to costs of this licensure program and the fee can be adjusted accordingly.

General Board expenses associated with the operation of the Board are paid through appropriations from the legislature. During each biennium, the Board is required to establish its fees in such a manner that the revenues received from licensing fees will, as closely as possible, approximate the appropriations granted the Board by the legislature. Based on an anticipated six hundred new licensees the new fee will ultimately generate additional fees to the Board of $30,000.

It has been determined that Minn. Stat. section 14.11 does not apply to this proposed rule, therefore, the Statement of Need and Reasonableness does not address the topic referenced in that statute.

Whenever an agency proposes a new rule or seeks to amend an exiting rule, Minn. Stat. section 14.115 requires the agency to consider whether the rules will have an impact on small businesses. If the agency determines that they will, the agency must consider whether certain methods, set forth in subdivision 2 of the statute, could be adopted to reduce the impact of the rule on small businesses. The statute requires

the agency to document in its Statement of Need and Reasonableness how it considers these methods and the feasibility of adopting any of the specific methods.

In addition to the licensure of distributors of medical gases and distributors of veterinary drugs and devices the Board licenses pharmacists, pharmacies, drug manufacturers and drug wholesalers. The Board has reviewed the impact, if any, its rule will have on these existing as well as the potential new licensees. It is anticipated that the new licensees, the distributors of medical gases and veterinary drugs and devices, like virtually all of the other Board licensees, qualify under the statutes as "small business" therefore, virtually everything that the Board does impacts on "small business".

In Statute 14.115, subdivision 2, enumerates the following five methods an agency must consider the reduce the impact of the rules on small business:

(a) the establishment of less stringent compliance or reporting requirements for small businesses;

(b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

(c) the consolidation or simplification of compliance or reporting requirements for small business;

(d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule, and;

(e) exemption of small businesses from any or all of the requirements.

The provisions in the proposed rules relating to licensure fees and recordkeeping requirements do impact on small business but the recordkeeping requirements and proposed fees are in line with that established over many years for pharmacies, drug wholesalers and drug manufacturers and have not shown themselves to be problematical in relation to those licensees. Therefore, these requirements will not adversely affect small business.

Since virtually all of the new licensees will qualify as small business it is impossible for the Board to establish less stringent compliance or reporting requirements, less stringent schedules or deadlines or less stringent performance standards for small business. Similarly, it is not possible to exempt small business from these requirements.

In summary, the Board believes it's proposed fee is needed and reasonable in order to meet the statutory requirement of balancing income and expenditures and believes that it's recordkeeping requirements associated with the distribution of legend medical gases and veterinary devices is both needed and reasonable in view of the similarities with recordkeeping requirements already in place for distributors of human use drugs and in view of the restrictions and requirements associated with these distributions at the federal level.

Attached is a copy of the approval of the fee increase from the Department of Finance.

David Hotmstrom

EXECUTIVE DIRECTOR

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rules Relating to Dispensing and Distribution of Legend Medical Gases and the Distribution of Veterinary Drugs and Devices

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy (hereinafter "Board") proposes to adopt Minn. Rules pts. 6800.9920, through 6800.9932 relating to medical gases and to veterinary drugs and devices. A copy of the proposed amendments is attached to this Notice. One additional free copy is available from the Board upon request. Procedures for the adoption of noncontroversial rules found in Minn. Stat. 14.22 to 14.28 (1986) will be used.

THE PUBLIC IS HEREBY ADVISED that:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged.

2. Each comment should identify the portion of the proposed rules addressed, the reason for the comments, and any change proposed.

3. In addition to submitting comments, interested persons may request in writing during the 30 day comment period that a hearing be held on the proposed rule amendment.

4. All comments, including requests for a public hearing, shall be submitted to David E. Holmstrom, Executive Director, Minnesota Board of Pharmacy, Room 107, Colonial Office Building, 2700 University Avenue West, St. Paul, Minnesota 55114-1079.

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any change proposed.

6. The proposed amendments may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language.

7. A public hearing will be held only if 25 or more persons submit in writing requests for a hearing on the proposed rules or a portion thereof within 30 days of this notice. If a hearing is required, it will be held in accordance with the provisions of Minn. Stat. 14.131 to 14.20 (1986).

8. Under the procedure for adopting noncontroversial rules, the Board must submit any action on its rules to the Attorney General for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the Attorney General for review will be mailed to any person requesting to receive the notice. Requests to receive notice must be submitted to Mr. Holmstrom at the above address.

9. Authority to adopt Minn. Rules pts. 6800.9920 through 6800.9932 is contained in Minn. Stat. sections 151.06 sub. 1 (c) and 151.19, Sub. 3. Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

10. The approval of the Commissioner of Finance for adoption of rules relating to fees is required by Minn. Stat. section 214.06, subd. 1. A document entitled "Commissioner of Finance Approval" in which the Commissioner has approved the proposed Rules pt. 6800.9921 and 6800.9931 is available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

B3 11. Promulgation of the proposed fee changes will not result in the expenditure of public monies by local public bodies and will not affect agricultural land in the state. Likewise, it is not believed that the changes will have a quantitative or qualitative impact on any small business. Persons representing small businesses are nevertheless invited to participate in the rulemaking process.

12. Any rules adopted pursuant to this proceeding shall be effective five working days after publication in the State Register of a notice of the adoption of the rules.

January 30, 1989

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Director

CERTIFICATE OF BOARD OF PHARMACY

AUTHORIZING RESOLUTION

I, David E. Holmstrom, do hereby certify that I am the Executive Director of the Minnesota Board of Pharmacy, a Board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete, and correct copy of a resolution adopted at a meeting of the Board duly and properly called and held on the 11th day of January, 1989, that a quorum was present at the meeting, that a majority of those present voted for the resolution and that the resolution is set forth in the minutes of the meeting and has not been rescinded or modified:

"RESOLVED, that David E. Holmstrom, Executive Director of the Minnesota Board of Pharmacy, be and hereby is granted the authority and is directed to sign and publish a notice of intent to adopt rules without a public hearing for the purpose of amending existing Board rules by adding new sections relating to the registration of distributors of legend medical gases and to the registration of distributors of veterinary drugs and devices. If the statutorily required number of persons request a hearing in response to the notice, Mr. Holmstrom is also granted the authority and is directed to call such a hearing and to perform any and all acts incidental thereto, including the requesting of the appointment of an Administrative Law Judge, and complying with all the applicable provisions of the Minnesota Administrative Procedures Act and the rules of the Office of Administrative Hearings."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 10th day of July, 1989.

Lois Kauppila

LOIS KAUPPILA
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
MY COMMISSION EXPIRES APRIL 28, 1992

STATE OF MINNESOTA

BOARD OF PHARMACY

David E. Holmstrom

DAVID E. HOLMSTROM
Executive Director

Board of Pharmacy

Proposed Permanent Rules Relating to Dispensing and Distribution of Legend Medical Gases; Distribution of Veterinary Drugs and Devices

Rules as Proposed (all new material)

DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES

6800.9920 DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES.

Parts 6800.9920 to 6800.9924 apply to the retail sale and distribution of legend medical gases.

6800.9921 REGISTRATION.

Subpart 1. **Annual registration required.** Every person or establishment selling or distributing legend medical gases in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in Minnesota Statutes, section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration, and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

Subp. 3. **Renewals.** The certificate expires on December 1 of each year, and must be renewed annually. Renewal applications received after December 1 are subject to a late filing fee of $25 in addition to the renewal fee.

Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The registration certificate must be displayed at the location for which it was issued. A change in the location of a registered facility will require reregistration.

6800.9922 RESTRICTED SALES.

No person or establishment shall sell or distribute legend

Approved by Revisor

medical gases at retail to anyone other than:

A. a patient on the basis of a prescription from a practitioner; or

B. a hospital, a practitioner as defined in Minnesota Statutes, section 151.01, subdivision 23, a licensed pharmacy, or other institution or person licensed to possess these drugs for use in the usual course of practice. The distributor of these items shall determine if the purchaser is licensed to possess them.

6800.9923 LABELING.

No person or distributor may sell or distribute any legend medical gas product at retail without the manufacturer's intact federally required label of "Caution: Federal Law Prohibits Dispensing Without Prescription."

6800.9924 RECORDS.

A sale or distribution of legend medical gases by registered distributors of these items at retail must be limited to the prescription or order of a licensed practitioner. These orders or prescriptions must be maintained for at least two years, must be filed by patient name or date, and must be readily retrievable and available for inspection by the Board of Pharmacy. The prescription must bear at least the patient's name and address, date, name and quantity of legend medical gas distributed, and name and address of the prescriber. Refills of legend medical gases must be recorded on the patient's prescription record. The distributor of these articles is responsible for obtaining authority for refills from the prescriber.

DISTRIBUTION OF VETERINARY DRUGS AND DEVICES

6800.9930 DISTRIBUTION OF VETERINARY DRUGS AND DEVICES.

Parts 6800.9930 to 6800.9932 apply to the retail sale and distribution of veterinary drugs and devices.

6800.9931 REGISTRATION.

Subpart 1. **Annual registration required.** Every person or

Approved
by Revisor _____

establishment selling or distributing veterinary drugs and devices in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in Minnesota Statutes, section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

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Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The certificate shall be displayed at the location for which it was issued. A change in the location of the registered facility will require reregistration.

6800.9932 PACKAGING.

A veterinary drug retailer shall deliver veterinary drugs to a client or a client's agent only in the original manufacturer's package.

Approved
by Revisor _____

Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Dispensing and Distribution of Legend Medical Gases; Distribution of Veterinary Drugs and Devices

AGENCY: Board of Pharmacy

MINNESOTA RULES: Chapter 6800

The attached rules are approved for publication in the State Register

Carla M. Riehle
Assistant Revisor

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : MINNESOTA BOARD OF PHARMACY

DATE : January 27, 1989

TO : Bruce T. Reddemann, Director
Budget Operations & Support
Department of Finance

FROM : David E. Holmstrom
Executive Director



PHONE : 642-0541

SUBJECT : Approval of Fee Implementation

A request is hereby made for approval of a fee implementation as follows:

	PRESENT	PROPOSED
Medical Gas Distributors	$00.00	$50.00
Veterinary Drug/Device Distributors	$00.00	$50.00

The 1988 legislature passed an amendment to M.S. 151.19 requiring the Board to provide for the licensure of retail distributors of legend medical gases and of veterinary drug and devices. At this time it is more or less unknown as to how much additional expense will be incurred by the Board in this additional responsibility. It is also unknown as to how many of these distributors there are. Best estimates place the number between 600 and 1,000.

Based on the Board's experience with licensing and inspecting pharmacies, drug wholesalers and drug manufacturers a fee of $50 seems appropriate until additional information can be obtained as to costs and income associated with these new licensees.

Based on an anticipated 600 new licensees the new fee will ultimately generate additional receipts to the Board of $30,000. Because not all of the new licensees will be identified immediately it is being anticipated that only 300 will be licensed in FY 90. (An insignificant number may yet be identified and licensed in FY 89 but these are being considered as zero.)

Upon approval of these fees the Board's total fee structure for FY 90 will be as follows:

Source Code	Fee Title	Present Fee	#	$ Generated	New Fee	#	New $ Generated
000001	Pharmacist Renewal	65.00	4364	$283660.			
000002	Pharmacy License (New)	100.00	110	$ 11000.			
000002	Pharmacy Renewal	100.00	1026	$102600.			

000003	Wholesaler Renewal	100.00	240	$ 24000.			
000004	Manufacturer Renewal	100.00	152	$ 15200.			
000015	Medical Gas Distributors	-0-	-0-	-0-	$50.00	50	$ 2500
000016	Veterinary Drug Distributors	-0-	-0-	-0-	$50.00	250	$12500.
000007	Exam Fee	200.00	134	$ 26800.			
000007	Partial Exam Fee	100.00	18	$ 1800.			
000008	Original Licensure Fee	65.00	117	$ 7605.			
000009	Reciprocity Fee	165.00	78	$ 12870.			
000010	Internship Registration	20.00	137	$ 2740.			

Total increase of $50 x 300: $ 15,000.

FY89 Receipts (anticipated): $488,385.

Total Anticipated Receipts (FY 90): 496,000 + 15,000 = $511,000.

Since approval of this request must be included as part of the Statement of Need and Reasonableness required for adoption of a new rule your prompt attention to this request for approval would be greatly appreciated.

Thank you for your assistance.

DEH:pe

APPROVED _____ DATED 2/7/89

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the Registration of Distributors of Legend Medical Gases and Distributors of Veterinary Drugs and Devices

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT A RULE WITHOUT A PUBLIC HEARING AND CERTIFICATION OF MAILING LIST

Patricia Eggers, being sworn says:

I hereby certify that the list of persons and associations who have requested, pursuant to Minnesota Statutes, sections 14.14, subdivision 1a and 14.22 or 14.30, that their names be placed on the Board of Pharmacy rulemaking mailing list is accurate, complete, and current as of this 8th day of March, 1989.

That on the 8th day of March, 1989, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Intent to Adopt A Rule Without a Public Hearing by depositing in the United States mail, a copy thereof, with postage prepaid, to all persons and associations on the aforementioned mailing list.

Patricia Eggers

Subscribed and sworn to before me this 27th day of April, 1989.

Lois Kauppila

LOIS KAUPPILA
NOTARY PUBLIC-MINNESOTA
RAMSEY COUNTY
MY COMMISSION EXPIRES APRIL 28, 1992

Proposed Rules

Pursuant to Minn. Stat. §§ 14.22, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing, as long as the agency determines that the rules will be noncontroversial in nature. The agency must first publish a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register.* The notice must advise the public:

1. **that they have 30 days in which to submit comment on the proposed rules;**
2. **that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;**
3. **of the manner in which persons shall request a hearing on the proposed rules; and**
4. **that the rule may be modified if the modifications are supported by the data and views submitted.**

If, during the 30-day comment period, 25 or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of §§ 14.14-14.20, which state that if an agency decides to hold a public hearing, it must publish a notice of intent in the *State Register*.

Pursuant to Minn. Stat. §§ 14.29 and 14.30, agencies may propose emergency rules under certain circumstances. Proposed emergency rules are published in the *State Register* and, for at least 25 days thereafter, interested persons may submit data and views in writing to the proposing agency.

Board of Pharmacy

Proposed Permanent Rules Relating to Dispensing and Distribution of Legend Medical Gases; Distribution of Veterinary Drugs and Devices

Notice of Intent to Adopt Rules Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Board of Pharmacy (hereinafter "Board") proposes to adopt *Minnesota Rules* pts. 6800.9920, through 6800.9932 relating to medical gases and to veterinary drugs and devices. A copy of the proposed amendments is attached to this Notice. One additional free copy is available from the Board upon request. Procedures for the adoption of noncontroversial rules found in *Minnesota Statutes* 14.22 to 14.28 (1986) will be used.

THE PUBLIC IS HEREBY ADVISED that:

1. They have 30 days in which to submit comment in support of or in opposition to the proposed amendments, and comment is encouraged.

2. Each comment should identify the portion of the proposed rules addressed, the reason for the comments, and any change proposed.

3. In addition to submitting comments, interested persons may request in writing during the 30 day comment period that a hearing be held on the proposed rule amendment.

4. All comments, including requests for a public hearing, shall be submitted to David E. Holmstrom, Executive Director, Minnesota Board of Pharmacy, Room 107, Colonial Office Building, 2700 University Avenue West, St. Paul, Minnesota 55114-1079.

5. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule addressed, the reason for the request, and any change proposed.

6. The proposed amendments may be modified if the modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language.

7. A public hearing will be held only if 25 or more persons submit in writing requests for a hearing on the proposed rules or a portion thereof within 30 days of this notice. If a hearing is required, it will be held in accordance with the provisions of *Minnesota Statutes* 14.131 to 14.20 (1986).

8. Under the procedure for adopting noncontroversial rules, the Board must submit any action on its rules to the Attorney General for review of the form and legality of the rule change. Notice of the date of submission of the proposed amendments to the Attorney General for review will be mailed to any person requesting to receive the notice. Requests to receive notice must be submitted to Mr. Holmstrom at the above address.

9. Authority to adopt *Minnesota Rules* pts. 6800.9920 through 6800.9932 is contained in *Minnesota Statutes* sections 151.06 sub. 1 (c) and 151.19, Sub. 3. Additionally, a Statement of Need and Reasonableness that describes the need for and reasonableness of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

10. The approval of the Commissioner of Finance for adoption of rules relating to fees is required by *Minnesota Statutes* section 214.06, subd. 1. A document entitled "Commissioner of Finance Approval" in which the Commissioner has approved the

proposed *Minnesota Rules* pt. 6800.9921 and 6800.9931 is available. Anyone wishing to receive a copy of this document may contact Mr. Holmstrom at the above address.

11. Promulgation of the proposed fee changes will not result in the expenditure of public monies by local public bodies and will not affect agricultural land in the state. Likewise, it is not believed that the changes will have a quantitative or qualitative impact on any small business. Persons representing small businesses are nevertheless invited to participate in the rulemaking process.

12. Any rules adopted pursuant to this proceeding shall be effective five working days after publication in the *State Register* of a notice of the adoption of the rules.

Dated: 30 January 1989

David E. Holmstrom
Executive Director

Rules as Proposed (all new material)

DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES

6800.9920 DISPENSING AND DISTRIBUTION OF LEGEND MEDICAL GASES.

Parts 6800.9920 to 6800.9924 apply to the retail sale and distribution of legend medical gases.

6800.9921 REGISTRATION.

Subpart 1. **Annual registration required.** Every person or establishment selling or distributing legend medical gases in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in *Minnesota Statutes,* section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration, and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

Subp. 3. **Renewals.** The certificate expires on December 1 of each year, and must be renewed annually. Renewal applications received after December 1 are subject to a late filing fee of $25 in addition to the renewal fee.

Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The registration certificate must be displayed at the location for which it was issued. A change in the location of a registered facility will require reregistration.

6800.9922 RESTRICTED SALES.

No person or establishment shall sell or distribute legend medical gases at retail to anyone other than:

A. a patient on the basis of a prescription from a practitioner; or

B. a hospital, a practitioner as defined in *Minnesota Statutes,* section 151.01, subdivision 23, a licensed pharmacy, or other institution or person licensed to possess these drugs for use in the usual course of practice. The distributor of these items shall determine if the purchaser is licensed to possess them.

6800.9923 LABELING.

No person or distributor may sell or distribute any legend medical gas product at retail without the manufacturer's intact federally required label of "Caution: Federal Law Prohibits Dispensing Without Prescription."

6800.9924 RECORDS.

A sale or distribution of legend medical gases by registered distributors of these items at retail must be limited to the prescription or order of a licensed practitioner. These orders or prescriptions must be maintained for at least two years, must be filed by patient name or date, and must be readily retrievable and available for inspection by the Board of Pharmacy. The prescription must bear at least the patient's name and address, date, name and quantity of legend medical gas distributed, and name and address of the prescriber. Refills of legend medical gases must be recorded on the patient's prescription record. The distributor of these articles is responsible for obtaining authority for refills from the prescriber.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

DISTRIBUTION OF VETERINARY DRUGS AND DEVICES

6800.9930 DISTRIBUTION OF VETERINARY DRUGS AND DEVICES.

Parts 6800.9930 to 6800.9932 apply to the retail sale and distribution of veterinary drugs and devices.

6800.9931 REGISTRATION.

Subpart 1. **Annual registration required.** Every person or establishment selling or distributing veterinary drugs and devices in Minnesota at retail that is not currently licensed as a pharmacy, pharmacist, or practitioner as defined in *Minnesota Statutes*, section 151.01, shall annually apply for registration by the board. Employees of an establishment need not register if the establishment is registered or has applied for registration.

Subp. 2. **Issuance.** Upon the filing of an application for registration and upon the payment of a fee of $50, the board shall issue a registration certificate in a form it prescribes.

Subp. 3. **Renewals.** The certificate expires on December 1 of each year, and shall be renewed annually. Renewal applications received after December 1 are subject to a late filing fee of $25 in addition to the renewal fee.

Subp. 4. **Separate registration required.** A separate registration is required for each location and is not transferable. The certificate shall be displayed at the location for which it was issued. A change in the location of the registered facility will require reregistration.

6800.9932 PACKAGING.

A veterinary drug retailer shall deliver veterinary drugs to a client or a client's agent only in the original manufacturer's package.

Pollution Control Agency

Proposed Permanent Rules Relating to Acceptance of Hazardous Waste at the Stabilization and Containment Facility

Notice of Intent to Adopt Rules Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Pollution Control Agency (MPCA) intends to adopt the above-entitled rules without a public hearing following the procedures set forth in the Administrative Procedure Act for adopting rules without a public hearing in *Minnesota Statutes* §§ 14.22 to 14.28 (1988). The MPCA's authority to adopt the rules is set forth in *Minnesota Statutes* §§ 115A.175, subd. 5 and 116.07 (1988).

All persons have until 4:30 p.m. on March 29, 1989, to submit comments in support of or in opposition to the proposed rules or any part or subpart of the rules. Comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the proposed rules within the comment period. If 25 or more persons submit a written request for a public hearing within the comment period, a public hearing will be held unless a sufficient number withdraw their requests in writing. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rules addressed, the reason for the request, and any change proposed. If a public hearing is required, the MPCA will proceed pursuant to *Minnesota Statutes* §§ 14.131 to 14.20 (1988).

Comments or written requests for a public hearing must be submitted to:

Carol Nankivel
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, Minnesota 55155
612/296-7260

The proposed rules may be modified if the modifications are supported by data and views submitted to the MPCA and do not result in a substantial change in the proposed rules as noticed.

The proposed rules if adopted, will govern the acceptance of waste at the stabilization and containment facility that is to be sited in Minnesota by the Environmental Quality Board under the authority of *Minnesota Statutes* § 115A. The facility will accept industrial waste, waste that has been rendered nonhazardous, and hazardous waste for stabilization and subsequent containment. The proposed amendments will establish standards for the acceptance of each of these types of wastes at the facility. The standards proposed for the acceptance of a hazardous waste are very specific. A person proposing a hazardous waste for containment must

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed Rule Relating to the Registration of Distributors of Legend Medical Gases and Distributors of Veterinary Drugs and Devices

CERTIFICATE OF THE MINNESOTA BOARD OF PHARMACY RESOLUTION ADOPTING THE RULE

I, Henry Capiz, do hereby certify that I am a member and the President of the Minnesota Board of Pharmacy, a board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete, and correct copy of the resolutions adopted at a meeting of the Board, duly and properly called and held on the 19th day of April, 1989, that a quorum was present, and that a majority of those present voted for the resolution which has not been rescinded or modified.

"RESOLVED, that the proposed rule relating to the fee for registration of distributors of medical gases be and hereby is approved and adopted pursuant to authority vested in the Board of Pharmacy by Minnesota Statutes 151.06, subdivision 1 (9) and that David E. Holmstrom, Executive Director of the Board of Pharmacy, be and hereby is authorized to sign the Findings of Fact, Conclusion, and Order adopting the rule and further is authorized to modify the rule, if necessary, to obtain the approval of the rule by the Attorney General and is authorized to perform the necessary acts to provide that this rule will have the force and effect of law."

"RESOLVED, that David E. Holmstrom, Executive Director of the Minnesota Board of Pharmacy, be and hereby is granted the authority and is directed to sign and publish a Notice of Intent to adopt rules for the purpose of establishing registration fees relating to the registration of distributors of OTC veterinary drugs and is also granted the authority and is directed to schedule the necessary hearing and to perform any and all acts incidental thereto, including the requesting of an appointment of an Administrative Law Judge, and complying with all the applicable provisions of the Minnesota Administrative Procedures Act and the rules of the Office of Administrative Hearings."

IN WITNESS WHEREOF, I have hereunto subscribed my name this 7th day of July, 1989.

Henry D. Coggins
President of the Board

Patricia Ford
Attest by one other Board member

March 21, 1989



Mr. David E. Holmstrom, Exec. Dir.
Minnesota Board of Pharmacy
Room 107, Colonial Office Building
2700 University Avenue West
St. Paul, Minnesota 55114-1079

Dear Mr. Holmstrom:

We respectfully request that you schedule a public hearing to address the issue of the proposed annual fee of $50 for retail establishments selling veterinary drugs and devices. In some cases, small feed stores and similar establishments offer a small selection of such products as a convenience to nearby residents. Such a fee may cause undue hardship on consumers in rural areas if the retail establishment is motivated to drop these products because of the fee.

We would also request that you communicate your scheduled hearings to such establishments, most of whose owners would have no knowledge of or reason to read a State Register.

Thank you.

1. Rep. Stephen E. Dille
2. Rep. Marvin K. Dauner
3. Rep. Glen H. Anderson
4. Rep. Michael Jaros
5. Rep. Henry J. Kalis
6. Rep. John Dorn
7. Rep. Gene Pelowski, Jr.
8. Rep. Edgar Olson
9. Rep. Stephen C. Wenzel
10. Rep. Steven A. Sviggum
11. Rep. Doug Swenson
12. Rep. Katy Olson
13. Rep. Bill Macklin
14. Rep. Terry Dempsey
15. Sen. Pat Pariseau
16. Sen. R. D. Decker
17. Sen. Dennis R. Frederickson
18. Sen. Mel Frederick
19. Rep. Sylvester Uphus
20. Sen. Duane Benson
21. Sen. Pat Piper
22. Sen. Steve Morse
23. Sen. Jim Vickerman
24. Sen. Chuck Davis
25. Sen. Charles Berg

STATE OF MINNESOTA

COUNTY OF RAMSEY

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of the Proposed
Rule Relating to the Registration
of Distributors of Legend Medical
Gases and Distributors of
Veterinary Drugs and Devices

DECLARATION OF
COUNSEL

I, Robert T. Holley, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules, and the supporting rulemaking record, and that, based on my examination, the Administrative Procedures Act and Minnesota Rules, chapter 2010 have been followed. Any exceptions are listed below. For Attorney General billing purposes, the four-digit docket client code is 0484.

Robert T. Holley

Robert T. Holley
Special Assistant
Attorney General

Dated: August 2, 1989

MINNESOTA BOARD OF PHARMACY

An Equal Opportunity Employer

2700 University Ave. W., #107 • St. Paul, MN 55114-1079 • Telephone: (612) 642-0541

July 12, 1989

RECEIVED
AUG - 8 1989
ATTORNEY GENERAL'S OFFICE
515 TRANSPORTATION BLDG.
ST. PAUL, MN 55155

Office of the Attorney General
Public Finance Division
515 Transportation Bldg.
John Ireland Boulevard
St. Paul, MN 55155

Attention: Martha J. Casserly

RE: In the Matter of the Proposed Adoption of Rules of the Minnesota Board of Pharmacy Relating to Dispensing and Distribution of Legend Medical Gases and the Distribution of Veterinary Drugs and Devices

Dear Ms. Casserly:

Herewith submitted for your review under Minn. Stat. Subd. 14.26 and Minn. Rules pt. 2010.0300 are the following noncontroversial rulemaking documents of the Minnesota Board of Pharmacy in the above subject matter:

1. certificate of Board's authorizing resolution;

2. proposed rules with a certificate of approval as to form by the revisor of statutes;

3. notice of proposed adoption of rules without a public hearing;

4. statement of need and reasonableness in support of the proposed rules;

5. affidavit of mailing the notice of proposed adoption of rules without a public hearing along with the certificate of mailing list;

6. photocopy of the notice of proposed adoption of the rules without a public hearing as published in the State Register;

7. four copies of the rules as adopted;

8. certificate of Board's resolution adopting the rules;

9. findings of fact, conclusions, and order adopting the rules;

10. copy of written comment; and

11. statement of compliance with rulemaking procedures (Declaration of Counsel).

In connection with the foregoing, please note that Minn. Rules pts. 2010.0300 A, B, N and O are not applicable to this proceeding. Also, enclosed herewith is the approval from the Commissioner of Finance regarding the fee involved.

If there are any questions about this submission please notify me as soon as possible.

Very truly yours,

David E. Holmstrom
Executive Director

DEH:pe

Enc. (11)