

STATE OF MINNESOTA  
OFFICE OF ADMINISTRATIVE HEARINGS  
FOR THE MINNESOTA BOARD OF PHARMACY

In the Matter of the Proposed  
Amendments to Pharmacy Rules  
Relating to Continuing Education,  
JUDGE  
Patient Medication Profiles, Poisons,  
Transfer of Prescriptions, Unprofessional  
Conduct and Waivers of Board Requirements

REPORT OF THE  
ADMINISTRATIVE LAW

The above-entitled matter came on for hearing before Administrative Law Judge Allan W. Klein on September 12, 1985 in Minneapolis.

This report is part of a rule hearing proceeding held pursuant to Minn. Stat. 14.131 to 14.20 to determine whether the Board has fulfilled all relevant, substantive and procedural requirements of law, whether the proposed rules are needed and reasonable, and whether or not the rules, if modified, are substantially different from those originally proposed.

Members of the Agency panel appearing at the hearing included: David E. Holmstrom, Executive Secretary, Minnesota Board of Pharmacy (hereinafter the "Board" or "Agency") and Robert T. Holley, Special Assistant Attorney General. Also appearing were Board members J. Roger Vadheim, Joseph Zastera, Jr., George Medich, Ove Wangensteen, Patricia Lind, and Michael Hart.

Approximately 30 persons attended the hearing. Twenty-one people signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed rules

The Board must wait at least five working days before taking any final action on the rules; during that period, this Report must be made available to all interested persons upon request.

Pursuant to the provisions of Minn. Stat. 14.15, subd. 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval. If the Chief Administrative Law Judge approves the adverse findings of this Report, he will advise the Board of actions which will correct the defects and the Board may not adopt the rule until the Chief Administrative Law Judge determines that the defects have been corrected. However, in those instances where the Chief Administrative Law Judge identifies defects which

relate to the issues of need or reasonableness, the Board may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the Board does not elect to adopt the suggested actions, it may submit the proposed rule to the Legislative Commission to Review Administrative Rules for the Commission's advice and comment.

If the Board elects to adopt the suggested actions of the Chief Administrative Law Judge and makes no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, then the Board may proceed to adopt the rule and submit it to the Revisor of Statutes for a review of the form. If the Board makes changes in the rule other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, then it shall submit the rule, with the complete record, to the Chief Administrative Law Judge for a review of the changes before adopting it and submitting it to the Revisor of Statutes.

When the Board files the rule with the Secretary of State, it shall give notice on the day of filing to all persons who requested that they be informed of the filing.

Based upon all the testimony, exhibits and written comments, the Administrative Law Judge makes the following:

#### FINDINGS OF FACT

##### Procedural Requirements

1. On July 25, 1985, the Board filed the following documents with the Chief Administrative Law Judge:
  - (a) A copy of the proposed rules certified by the Revisor of Statutes.
  - (b) The Order for Hearing.
  - (c) The Notice of Hearing proposed to be issued.
  - (d) A Statement of the number of persons expected to attend the hearing and estimated length of the Agency's presentation.
  - (e) The Statement of Need and Reasonableness.
  - (f) A Statement of Supplemental Notice.
2. On August 2, 1985, the Board filed a signed copy of the certificate of the Board's Authorizing Resolution. An unsigned version had been filed on July 25, and the only difference between it and the document filed on August 2 was that the latter was executed.
3. On August 8, 1985, the Board mailed the Notice of Hearing to all persons and associations who had registered their names with the Board for the purpose of receiving such notice.
4. On August 9, 1985, the Board filed the Notice of Hearing as mailed.
5. On August 12, 1985, a Notice of Hearing and a copy of the proposed rules were published at 10 State Register page 383.
6. On September 12, 1985, at the hearing, the Board introduced the

following additional documents into the record:

- (a) The Board's certification that its mailing list was accurate and complete.
- (b) The Affidavit of Mailing the Notice to all persons on the Board's list.
- (c) All materials received following a Notice of Intent to Solicit

1983 Outside Opinion published at 7 State Register 1781 on June 13,  
and a Notice of Intent to Extend the Comment Period published  
at 8 State Register 481 on September 12, 1983.

- (d) The names of Board personnel who will represent the Board at the hearing together with the names of any other witnesses solicited by the Board to appear on its behalf.
- (e) A copy of the State Register containing the proposed rules.

7. A number of the documents described in the preceding Finding were not filed in a timely manner. See, Minn. Rule part 1400.0600. This was disclosed at the hearing, and it was ascertained that one person had inquired at the Office of Administrative Hearings as to whether a Notice of Intent to Solicit Outside Opinion had, or had not, been published. As there was no Notice in the file at the Office of Administrative Hearings, he was told that none had been published. This individual appeared at the hearing, and a discussion ensued as to whether or not he felt he had been prejudiced by the failure to file. He stated that he had not been prejudiced, and thus, the Administrative Law Judge ruled that the hearing could go forward despite the lack of filing of the required documents.

8. The period for submission of written comment and statements remained open until October 2, 1985; the period for responses remained open until October 7, 1985.

#### Nature of the Proposed Rules

9. The proposed rules include both amendments to existing rules (some major and some minor) and entirely new rules. The primary proposed rules are five in number. The first amends existing rules on continuing pharmaceutical education. The second amends an existing rule prohibiting unprofessional conduct by expanding the "anti-kickback" provision. The third is a new rule mandating patient medication profiles. The fourth major proposal is entirely new language relating to transfers of prescriptions between pharmacies. Finally, the last major proposed sets forth criteria for the granting of variances from Board rules.

#### Statutory Authority

10. Minn. Stat. 151.06, subd. 1, provides, in part, as follows:

The Board of Pharmacy shall have the power and it shall be

its duty: (7) to . . . make rules for the conduct of its business . . . (9) for the purposes of the aforesaid it shall be the duty of the board to make and publish uniform rules and regulations not inconsistent herewith for carrying out and enforcing the provisions of this chapter.

Minn. Stat. 214.12 provides authority for the rule relating to continuing education.

11. It is found that the Board has statutory authority to adopt all of the proposed rules, except as specifically noted below.

## Compliance With Small Business Considerations In Rulemaking

12. Minn. Stat. 14.115, subd. 2 (1984) sets forth certain requirements relating to the impact of proposed rules on small businesses. The Board did, in its Statement of Need and Reasonableness, address this statute and the Board's efforts to comply with it. It is found that the Board has complied with Minn. Stat. 14.115, subd. 2.

## General

13. Some of the proposed rules drew a fair number of comments, while others drew very few or none at all. Some comments were critical, some supportive, and others merely suggested minor wording changes. In order to avoid an unnecessarily lengthy report, discussion will be focused on those proposed rules which drew adverse comments or have problems which require discussion. Although the Board's justification for each rule has been considered, all will not be mentioned. Any rule or subpart which is not mentioned below has been determined to be (a) statutorily authorized and (b) justified as both needed and reasonable.

## Part 6800.1500 - Continuing Pharmaceutical Education

14. Under the existing regulatory scheme, the Board requires every pharmacist to complete at least 30 hours of approved continuing education during the previous two-year period. Education is "accredited" on a program-by-program basis. In other words, in order to be accepted as part of a pharmacist's continuing education, each individual program must have been accredited by the Board. Under the present scheme, there is no such thing as a "blanket approval" for all programs offered by an individual sponsor, nor is there any provision for accrediting sponsors. The major change proposed by the Board in this area is to add to the existing system the concept of "approved providers". Programs offered by approved providers would be automatically accepted as satisfactory for meeting the continuing education requirement. Programs offered by persons other than approved providers could still be submitted for approval, as they are under the existing system. In other words, the concept of approving providers is an addition to, rather than a replacement for, the existing system of approving individual programs.

15. The concept of approved providers comes from the American Council on Pharmaceutical Education, which is the national accrediting body for colleges of pharmacy in the United States. In the early 1970's, the Council (which will hereinafter be referred to as the "ACPE") established a national continuing educational provider approval system, and more recently, ACPE has developed a series of "criteria for quality" which are the standards it uses

in determining whether or not to approve a provider. After studying the ACPE, for several years, the Board believes that ACPE's criteria have now evolved to the point where it feels comfortable in moving toward the concept of provider approval based on those criteria.

16. The Board's proposal for provider approval provides for two types of approved providers. The first is a provider who has been recognized by the Board as having met certain stated criteria. These would be known as state-approved providers. The second group are providers who have already been approved by the ACPE itself. These would be known as nationally-approved providers.

17. A question was raised as to whether or not Board acceptance of ACPE approval constituted an impermissible delegation of authority. It is concluded that, under current Minnesota law, Board acceptance of ACPE provider approval does not constitute an impermissible delegation of authority. See, *Draganosky v. Minnesota Board of Psychology*, 367 N.W.2d 521 (Minn. 1985) and *Application of Hansen*, 275 N.W.2d 790 (Minn. 1978), appeal dismissed 441 U.S. 938, 99 S.Ct. 2154, 60 L.Ed. 2d 1040 (1979). If anything, the facts in the record concerning the status of the ACPE are stronger than the facts concerning the outside agency at issue in *Draganosky*. Moreover, the Board has proposed that even ACPE approved program sponsors must apply to the Board for recognition and provide certain information to the Board every two years. This procedure provides a safeguard in the event that the Board desires to withhold or withdraw its approval of an ACPE approved provider.

18. In addition to ACPE approved providers, the Board also proposes to grant blanket approval to programs offered by state-only approved providers. At the hearing, a representative of the Minnesota State Pharmaceutical Association spoke in opposition to this dual system, alleging that it is far more difficult to approve or disapprove an application for a provider than to approve or disapprove an application for a program. He stated that the Board of Pharmacy is ill-equipped for this responsibility and should defer only to the ACPE or, in the alternative, it should drop the whole idea of provider approval and continue with the existing scheme of program-by-program approval. The Board responded by pointing out that the Association is one of the few ACPE approved providers in Minnesota and that its opposition to the establishment of a state-only provider approval system is motivated by not wanting any other providers to be given blanket approval for the marketing of their programs in competition with the Association.

19. In 1981, roughly 52% of all of the programs submitted to the Board for approval were submitted by ACPE approved providers; 48% were submitted by non-ACPE approved providers. One of the primary arguments in favor of the change from program approval to provider approval was that the Board, and its continuing education advisory task force, were faced with a tremendous amount of paperwork in having to approve each and every program, particularly as the concept of continuing education has expanded throughout the country. By switching from program approval to provider approval, this paperwork will be dramatically reduced. It will, therefore, give more time for analysis of state-only providers who elect not to seek ACPE approval. Moreover, the same rationale that supports the concept of provider approval on a national basis applies with equal force to provider approval on a state basis: the approving entity is in a better position to "guide" a provider towards compliance with the criteria for approval when both are facing a long-term relationship, rather than an intermittent and sporadic one. If the goal is to ensure the

quality of the education which pharmacists receive, and if the criteria in the rule are properly drafted and applied, then the criteria are more likely to be met when a program sponsor knows that trying to cut corners will result in not only the disapproval of one program, but rather the disapproval of all similar programs which it would like to market to Minnesota pharmacists. While there are certainly pros and cons to both approaches, it is found that the concept of state-only provider approval has been demonstrated to be needed, reasonable and feasible.

20. The potential impact of disapproval of a provider prompted the State Pharmaceutical Association to also oppose subpart 4 of the proposed rule, which provides the standards for revocation or suspension of approved providers. The Association stated that it is one thing for the Board to revoke or deny an individual program application; it is quite another for the Board to revoke or suspended a provider's accreditation. Revocation of accreditation would constitute an unwarranted economic hardship on the provider, whereas denial of an individual program application has a much more limited effect. This is essentially the "flip side" of the argument that providers would be more responsive to the Board because of the long-term nature of their relationship. The Association argued that the entire concept of provider accreditation is tantamount to issuing a "provider license", and that since the Legislature has not authorized the Board to license providers, the Board's proposal for provider approval is beyond its statutory authority. Although this point was raised specifically in connection with the subpart relating to revocation or suspension, it goes to the heart of the entire switch from program approval to provider approval, for if the Board is beyond its statutory authority in revoking or suspending approval, then it is also beyond its statutory authority in granting it as well.

21. The Board is one of a number of health-related licensing boards governed by the general provisions of Minn. Stat. Ch. 214. Section 214.12, enacted in 1976, provides that health related licensing boards may promulgate by rule requirements for continuing professional education or training. The enactment of this provision, along with the other provisions of Ch. 214, replaced a plethora of individual requirements imposed by the various boards governed by that Chapter. For example, prior to 1976, the Board's authority to require continuing professional education was found in Minn. Stat. 151.13, subd. 2, which provided, in pertinent parts, as follows:

No annual license renewal shall be issued to a pharmacist until such pharmacist shall have submitted to the board satisfactory evidence that he has completed an accredited program of continuing pharmaceutical education . . . . The board shall adopt rules and regulations for accrediting programs, establishing the number of hours of credit for each program, the number of hours, not less than 25 nor more than 40, to be completed in each two year period by each pharmacist, and such other rules as are necessary to implement, enforce, and administer this subdivision. . . .

This relatively specific statute was replaced by the more general provisions of section 214.12 in 1976.

The repeal of this statute and substitution of the 1976 statute removes much of the weight from the Association's argument. The 1976 statute covers

not only the Board of Pharmacy, but also a number of other health-related boards, including the Board of Dentistry, the Board of Optometry, the Board of Chiropractic Examiners and the Board of Medical Examiners. Pursuant to the 1976 version of the statute, each of those Boards has now adopted some variant of provider approval. No mention was made, nor is the Administrative Law Judge aware, of any decision holding that provider approval in those situations is beyond the statutory authority contained in Minn. Stat.

214.12, It is found that there is no merit to the Association's position that provider approval is beyond the authority granted in the statute.

22. Subpart 3a of the proposed rule is the subpart which carries forward the existing scheme concerning program-by-program approval. It sets forth detailed criteria for evaluating programs submitted for approval. In subpart D(3), the program provider is required to submit evidence that:

The program includes a statement of educational goals, behavioral objectives, or both, that are measurable.

A comment was made at the hearing that this language was not clear. Essentially the same language appears in subpart 3, paragraph C(1) relating to provider approval. The Board explained that the goal of this language was to allow the provider to determine if the program had "hit the mark", and if it had informed the potential attendee of the goal of the program. Generally, evaluation sheets are used to measure these factors. The Board submitted a book entitled Preparing Instructional Objectives by Robert F. Mager which discusses these matters in detail. The Board suggested that persons knowledgeable in educational matters understand the language in the proposed rule. While the Board may consider clarifying the language to make it more understandable to the lay person, it is found that the language is not so vague as to render the rule invalid.

23. In a letter, Ray Varbel, Director of the Pharmacy Central Supply at Rochester Methodist Hospital, urged that on page 2, line 22, the word "group" should be inserted between "organization" and "person", but with no explanation. From the context of the cited sentence, it appears that he is concerned that the list of types of organizations which can become approved providers is incomplete without the word "group." It is found that the proposed addition of the word "group" is unnecessary. In common parlance, the word "organization" includes a "group." It is found that the rule has been justified as both needed and reasonable without the proposed change, but that the proposed change could be made without it being a substantial change. The Board is free to make the change if it desires to.

24. All of the other changes to the continuing education provisions flow from the switch from program approval to provider approval, or are merely minor housekeeping matters. It is found that they have been justified as both needed and reasonable, and may be adopted.

#### Part 6800.1600 - Continuing Education Advisory Committee

25. In 1973, when the continuing education requirements were added to Chapter 151, the Legislature also added a provision for an advisory council on continuing education. Chapter 655, Laws of Minnesota 1973, section 1, provided, in part, that:

The board shall appoint an advisory council on continuing

education, consisting of not more than ten members to study continuing education programs and requirements and to submit its report and recommendations to the board.

The statute went on to specify the composition of the council, including the requirement that five members be pharmacists designated by the Minnesota State Pharmaceutical Association.

26. In 1976, as part of a much larger bill streamlining procedures for a number of health-related boards, the title of the council was changed to "Advisory Task Force on Continuing Education". The requirements as to various constituency organizations designating members of the Task Force were repealed, and a new provision was added to the statute which provided that the Task Force shall expire "as provided in section 15.059." That section provided, in subdivision 6, that advisory task forces created after July 1, 1975 should expire two years after the effective date of the Act creating the advisory task force, or the date of appointment of the members, whichever is later.

27. The statutory requirement for an Advisory Task Force on Continuing Education continued through 1982. In 1983, as part of an overhaul of numerous executive branch advisory groups and task forces, the requirement for a task force was removed, and the Board was given discretion to appoint an Advisory Task Force on Continuing Education. It was a simple one word change, from "shall" to "may". The reference to the task force's expiration pursuant to section 15.059 remained.

28. In 1983, the Legislature also amended section 15.059 relating to expiration of advisory task forces. It provided, in relevant part, as follows:

If the existence of a task force is authorized but not mandated by statute, the task force shall expire at the pleasure of person or group which creates the task force, or two years after the first members of the task force are appointed, whichever is sooner. A person or group with discretionary authority to create a task force may create another task force to continue the work of a task force which expires, unless prohibited by other law.

The status of the Task Force at the close of the 1983 Session was, therefore, that of a discretionary task force. Its existence expired two years after the first members were appointed, but upon its expiration, another task force could be appointed by the Board. That is the status that continues to this date.

29. Prior to this rule hearing, the Board had a rule (6800.1600) which referred to the "Advisory Task Force on Continuing Education". The Board is now proposing to amend this rule to rename the body the "Continuing Education Advisory Committee". That is the only change which the Board proposed in its publication of the rule in the State Register. Although the proposal seems innocuous, it cannot be adopted because the authorizing statute, Section 151.13, subd. 2, only allows the Board to appoint an advisory task force on continuing education. There is a legal difference between an advisory task

force and an advisory committee. For example, in section 15.095, subd. 3, members of an advisory committee may be compensated at the rate of \$35 per day spent on committee activities. Subdivision 5 of that statute requires each advisory committee to terminate on June 30, 1988. Advisory task forces are treated differently from advisory committees. Subdivision 6 of that statute prohibits the payment of a \$35 per diem to members of an advisory task force, and as described above, it has different expiration provisions. Changing the title from Task Force to Committee would, at the least, create confusion. At

worst, it could result in illegal payments. The proposed title change is found to be contrary to law and may not be adopted. In order to cure this defect, the Board should delete the proposed changes in the title.

30. At the hearing, a representative of the Minnesota Society of Hospital Pharmacists proposed the addition of two members to the Task Force which would increase its size from ten to twelve. He proposed that one of these additional members be appointed by the Society, and the other by the Board. The Board's executive secretary stated that the Board would not oppose the proposed change. This drew a strong comment in opposition to the change from the Minnesota State Pharmaceutical Association. It is not necessary to go into the pros and cons of the proposed expansion of the Task Force because it cannot be adopted. Minn. Stat. 151.13, subd. 2, provides that the Task Force shall consist of "not more than ten members". Adopting the proposed change would, therefore, violate the statute. Although the Association raised the issue of whether this proposed change would constitute a prohibited "substantial" change, that issue need not be reached because the Board lacks authority to expand the Task Force beyond the statutory maximum. In order to cure this defect, the Board should not adopt the Hospital Pharmacist's proposal.

#### Part 6800.2250 - Unprofessional Conduct

31. The Board's existing rule, in subpart 1 D., defines "unprofessional conduct" to include:

Participation in agreements or arrangements, with any person, corporation, partnership, association, firm, or others involving rebates, "kickbacks," fee-splitting or special charges in exchange for professional pharmaceutical services.

The Board proposed that this be expanded by adding the following language:

including but not limited to the giving, selling, donating, or otherwise furnishing or transferring, or the offer to give, sell, donate, or otherwise furnish or transfer money, goods, or services free or below cost to any licensed health care facility or the owner, operator, or administrator of a licensed health care facility as compensation or inducement for placement of business with that pharmacy or or pharmacists. Goods or services which may not be provided free or below cost include consultations required by state and federal regulatory bodies, drug reference texts, computer print-outs of physicians' orders or the provision of other forms used in charting, drug carts, or anything else not directly related to the drug dispensing process. Monetary rebates or discounts which are returned to the actual purchaser of

drugs as a cost justified discount or to meet competition are permitted if the rebates or discounts conform with other existing state and federal rules and regulations.

32. In its Statement of Need and Reasonableness, the Board justified this addition as needed because a pharmacist had indicated that there may be some uncertainty as to just what the Board would include as "Kickbacks,

fee-splitting or special charges". The Board desires to give greater insight into its interpretation of the existing rule. The Board indicated that situations have "occasionally" come to its attention where nursing home administrators have approached pharmacists indicating that a majority of the home's business could be steered to the pharmacy if certain equipment and records were provided to the nursing home. The Board stated that oftentimes pharmacists felt compelled to provide whatever was asked in order to maintain or expand business from the home. The Board pointed out that an existing rule (which is not being proposed for any change in this proceeding) prohibits any pharmacist from participating in agreement or plan which infringes upon any patient's right to freedom of choice as to the provider of prescription services. Minn. Rule part 6800.6600.

In its oral presentation at the hearing, the Board stated that the term "kickback" is a rather broad term, and the Board has learned of cases where charts, drug storage hardware, reports and records useful to a home's nursing staff have been provided in addition to outright cash payments from a pharmacist to a nursing home administrator. The Board was uncertain as to whether these, in fact, constituted "kickbacks" because of the uncertainty in determining what motivation lay behind a pharmacist's supplying them to a home. If the motivation was to provide the materials in exchange for steering business to the pharmacy, then the Board is opposed to it because the Board believes it is the patient who ought to be able to select the pharmacy of his or her choice.

33. Robert Gale, President of Pharmacy Corporation of America, Inc., was the only person to adversely comment on this rule. His comment can be best understood with a brief explanation of his business. Pharmacy Corporation of America, Inc., specializes in providing pharmaceutical services (both drugs and consultations) to 35,000 patients of long-term care facilities in three states. Five thousand of these patients are located in Minnesota. It attempts to garner business by offering more services for the same cost, or offering services at lower costs, than could be obtained from competing suppliers. Although he addressed concerns of statutory authority, lack of need, lack of reasonableness, and vagueness, these concerns were addressed in the overall context of his feeling that this proposed addition of the rule was essentially anti-competitive and subject to capricious enforcement because it required determining the intent of the pharmacist. The primary thrust of his arguments can be gleaned from the following excerpts from his statement:

I do not believe that this board has the statutory authority to "tell" a nursing home or a patient that they may not do business with a pharmacy who, through

efficiency, economies of scale, and a willingness to accept reduced profit, is able to provide a greater quantity or quality of service in conjunction with their major product (in this case, drugs and pharmaceutical consulting services).

The board should not be regulating against new and innovative services which entrepreneurs choose to provide their clients in order to obtain a competitive edge in the

marketplace. How the pharmacist charges for unit dose carts, reference texts and computerized medical records should be left up to the individual business person.

As an example of the nonspecificity and unreasonableness of the proposed regulation, as written, consider the following: Pharmacy A charges \$2.75/patient/month for consulting services. Pharmacy B charges \$2.75/patient/month for consulting services. Pharmacy A and Pharmacy B have exactly the same components to their consulting services except that Pharmacy B pharmacists routinely provide Therapeutic Drug Monitoring . . . as part of their Drug Regimen Reviews. Pharmacy B does this because it is good medicine and because it gives Pharmacy B a competitive edge to retain existing business and to get additional business. Would Pharmacy B be guilty of an illegal rebate by providing TDM "free"? According to the way this proposed regulation is written, it could be.

34. The Board does not have authority to regulate the prices that a pharmacist charges for drugs or consulting services. It is clear from a reading of the statute and existing rules that retail price competition between pharmacists is allowed and, in fact, it is encouraged. Minn. Stat.

151.061, subd. 1, an unfair price discrimination provision, does not apply to sales at retail. Minn. Stat. 151.06, subd. 2a only makes sense if price competition is permitted. The repeal of prior rule Part 6800.0900, subd. 3 ended the Board's prohibition of words such as "discount" or "bargain" in advertising. The last sentence of Minn. Stat. 151.26 explicitly allows discounts for senior citizens.

35. Minn. Stat. 151.06, subd. 1, empowers the Board to regulate the practice of pharmacy, and to regulate the retail sale of drugs or medicines within the state. Is that adequate authority for the Board to prohibit kickbacks? It is found that the Board does have statutory authority to limit kickbacks as a result of its authority to regulate the practice of pharmacy and the retail sale of drugs or medicines. Since the Board has authority to prohibit kickbacks, the Board also has authority to define what is a "kickback". That is essentially what the Board is proposing to do by its addition to the existing rule.

36. Is the rule needed? It is clear from the Board's presentation and the comments of Mr. Gale that there is a need to define what is a kickback. Mr. Gale's license to practice pharmacy in this state, along with the licenses of all other pharmacists, are at risk of revocation for violation of these rules. A pharmacist is entitled to know what conduct is prohibited, and what

is allowed. To the extent that there is confusion as to what constitutes a kickback and to what does not, there is a need to clarify the existing rule. The Board's proposal is found to be needed.

37. Is the Board's proposal reasonable? What the Board is attempting to do, by its proposed addition to the rule, is to specify some items which it would define as kickbacks under certain situations. There are, however, a

wide range of practices which, technically, would fall within the proposed language but which would not normally be considered kickbacks. For example, what if a pharmacist gives a nursing home administrator (or any other good customer) a bottle of whiskey at the holiday season? What if a pharmacist provides free deliveries to a nursing home even though he charges its other customers \$1.00 for each delivery? What if a pharmacist gives a nursing home administrator a drug reference text? Would it matter if the text were given at the holiday season? Mr. Gale gave some other examples, such as pharmacists paying excessive billing and collection fees to nursing homes, pharmacists "renting" non-existent rooms in nursing homes, or storage closets for exorbitant fees, a pharmacist buying untraceable airline tickets for owners and/or key staff members, pharmacists allowing a home's personnel the freedom to run up big charge accounts with the pharmacy and then making no legitimate attempt to collect the debt. Certainly the list could go on and on. Each of the items noted above, from the bottle of whiskey to large amounts of cash "under the table" are technically within the ambit of the proposed language.

38. There are a number of ways in which the Board could deal with this problem. It could adopt an absolute prohibition against the providing of any goods or services free or below cost to any specified groups. Another approach would be to attempt to draw a clear line between what will be deemed acceptable conduct, and what will be deemed unacceptable conduct. The Board has attempted the latter method, which is certainly within its discretion. However, the Board's proposal lists certain items followed by a "catchall" which prohibits the furnishing of "anything else not directly related to the drug dispensing process." This catchall embraces everything from the bottle of whiskey to exorbitant amounts of cash. Such sweeping language constitutes excessive discretion and leaves the legitimate pharmacist in a quandary. As Mr. Gale stated:

In an area as sensitive and serious as that of "kickbacks" I believe that as a pharmacist bound by such regulations,

have a right to know, up front, what constitutes an illegal practice. This regulation does not do this.

In order to cure the defect, there are a number of options open to the Board.

It could simply remove the sentence which begins "Goods or services which may not be provided . . .", or it could insert a more ascertainable standard, such as "This rule does not apply to gifts with a retail value of not more than \$XX per recipient per year." In the alternative, the Board could withdraw the entire proposal and attempt to refine it. But the Board may not adopt the proposal in its present form.

#### Part 6800.3110 - Patient Medication Profiles

39. Patient medication profiles are records concerning a patient's past prescriptions and other known medications, any known allergies, and other information designed to assist a pharmacist in determining the possibility of harmful drug interaction or reaction prior to providing the patient with a prescribed medication. The Board is proposing, for the first time in these rules, that pharmacists be required to maintain patient medication profiles and use those profiles to avoid potentially harmful interactions or reactions.

The Board has determined that roughly 80% of Minnesota pharmacies currently maintain some form of patient medication profiles, but is concerned for the well-being of the patients who are served by the remaining 20%. While there were some suggestions for changes in the proposed rule, the thrust of the objection to the proposal was more philosophical than anything else: commentators universally agreed that patient medication profiles were a good idea and operated in the best interest of the patient; nonetheless, a number of people and organizations testified in opposition to requiring their maintenance and use as an unnecessary intrusion of government into the practice of pharmacy.

40. After several years of work, the American Pharmaceutical Association and the American Association of Colleges of Pharmacy promulgated revised Standards of Practice for the Profession of Pharmacy. Although these standards of practice do have any specific legal force in Minnesota (i.e., there is no statute or rule which requires that they be followed or cites them as a basis for denial or revocation of a license), they have received recognition by practitioners within the state. Failure of a pharmacist to adequately maintain a professional standard of practice endorsed by the American Pharmaceutical Association or the Minnesota State Pharmaceutical Association can result in a "Dutch Uncle talk" or a reprimand or termination of membership in the pharmacist's professional association. The standards clearly and unequivocally require the maintenance and use of patient medication profiles. In 1973, the State Pharmaceutical Association endorsed the use of profiles by all pharmacists, and that position was essentially reaffirmed by the Association's House of Delegates in 1979. Nevertheless, the Association (and numerous other commentators) opposed the Board's proposed rule mandating their maintenance and use. Perhaps the matter can best be summed-up by reference to an editorial written by Donald A. Dee, Executive Director of the State Association, in the Minnesota Pharmacist:

This issue is a classic confrontation between differing political philosophies: if an idea appears to be good, should government impose such a requirement on all individuals? Or, should the marketplace determine which services the public is willing to support?

The underlying basis for the state regulation of pharmacists, which is the same as state regulation of other professionals, is that of public protection, because the public is operating in an area where it is not equipped, either by training or experience, to protect itself. A distinction should be drawn

between regulations which are designed to protect the public, and regulations which are designed to protect the profession itself. For example, the same Standards of Practice for the Profession of Pharmacy that mandate the maintenance and use of patient medication profiles also mandate that pharmacists establish a pricing structure based upon sound management principles which would provide a fair and reasonable return on investment.

They also mandate the establishment of procedures for periodically reviewing and evaluating a pharmacy's performance with respect to its budget. They mandate the preparation of fiscal budget reports. These latter functions are aimed at the sound operation of a business, not the protection of the public. While the question is not free from doubt, it is concluded that where a proposed rule has a direct impact upon the protection of the public, the Board does have authority to promulgate it under the aegis of its general regulatory

authority set forth in Minn. Stat. 151.06, subd. 1(1) and (2). Therefore, the Board does have statutory authority to adopt the proposed rule relating to patient medication profiles.

41. Has the Board demonstrated the need for the proposed rule? Much of the comment which was summarized above with regard to statutory authority also goes to the question of need. But there are some additional factors to be noted. In its oral presentation, the Board expanded upon the purpose of such profiles, noting that they should alert a pharmacist to potential drug-drug interactions, drug-allergy interactions, drug-diet interactions, drug-disease interactions, and drug-laboratory test interference. The Board pointed out that 3% of all hospitalizations in the United States are caused by drug induced problems. A Board member, testifying as a consumer and member of the public, read from a magazine article entitled "How to Choose a Pharmacist" which was written by R. Keith Campbell, a clinical professor at Washington State University, for the magazine Diabetes: Self Management. The first criterion discussed in the article was whether the pharmacist kept records about his patients, including what medications they were taking. Finally, the editorial by Donald A. Dee noted earlier, pointed out that the use of patient medication profiles is the contemporary standard of practice for pharmacy in Minnesota (emphasis in original).

Based upon all of the foregoing, it is concluded that the record does demonstrate that there is a need for requiring pharmacies which do not presently maintain and use patient medication profiles to begin doing so.

42. With regard to reasonableness, however, there were some problems noted in the comments.

A representative from Walgreen Co., which operates 25 pharmacies in Minnesota, urged that the requirement that a pharmacist examine the patient medication profile before dispensing a medication be limited to cases where the prescription to be dispensed is both (a) a new prescription and (b) checking is appropriate in the pharmacist's professional judgement. It was argued that these changes would remove the need for pharmacists to look at the profile on refill prescriptions and on other types of prescriptions where checking is not appropriate. With regard to the first proposal (limiting checking to new prescriptions), it would make sense so long as there was no change in the data in the profile from the last time the prescription was refilled. However, if there had been some change in the intervening period, then what was appropriate at the start of that period may no longer be appropriate when it comes time to refill. The Judge is sympathetic to Walgreen's desire to avoid wasteful checking. The Board may adopt the comment or it may reject it. It would not be a substantial change if it adopted it. The rule has been justified without the change.

43. The second change proposed by Walgreens, however, is a more difficult question. It would allow a pharmacist to elect whether or not to check the profile based upon "professional judgement". It is reasonable to predict that adoption of this proposal would lead to secondguessing whether or not the failure to check a profile was based on professional judgement and would engender debate about the quality of that judgement. Pharmacists are entitled to know, with some precision, what the rules require them to do. Adoption of the second proposal would create more problems than it would solve. It is

found that the Board's original proposal is reasonable without Walgreens' "professional judgement" amendment, and that the amendment ought not to be adopted.

44. Group Health, Inc., argued that the rule ought not to be adopted because its clinics are "self-contained" facilities, with accessible patient medical records, and greater communication between physician, pharmacist and patient than in a traditional pharmacy. A representative stated that Group Health supports the idea of patient medication profiles, and that it will have such profiles in use "in due time". But because of its organization, with self-contained facilities, it argued that it ought not be required to comply with the proposed rule. It is found that while the organization of the various entities within Group Health (and similarly organized organizations) certainly does provide the Potential for greater communication between the doctor, the pharmacist, and the patient, there has been an inadequate showing that such communication does, in fact, occur. It is reasonable to impose the rule upon Group Health (and others similarly situated) and allow them to come forward on a case-by-case basis under the variance provisions so that the Board can determine whether, in fact, there exists sufficient safeguards for the public to exempt them from the operation of the rule.

45. Group Health did, however, suggest that if the rule is to be adpted, there ought to be a sufficient lead time before the rule became effective to allow it to come into compliance. The Board agreed, stating that it has been the Board's practice to allow a substantial amount of time for education and acquisition of necessary hardware, etc., before placing any of its rules into force. Based upon the testimony of Group Health others, and based upon the terms of the rule itself, the Judge agrees with Group Health that immediate enforcement would work a hardship on those pharmacies which are not presently using patient medication profiles. Quick adoption of this rule would place pharmacies in jeopardy of violation. While there is insufficient evidence in the record for the Judge to require any specific time period prior to making the rule effective, he does recommend that the Board place an effective date on this rule which is adequate to allow pharmacies to explore existing alternatives and implement a well thoughtout system.

46. Rochester Methodist Hospital submitted a comment pointing out that hospital pharmacies serve a varying clientele. Some have policies prohibiting continuing outpatient services, and thus, while they may fill prescriptions while a patient is in the hospital, or they may fill dismissal prescriptions, they do not provide continuing outpatient services. Some hospital pharmacies may, however, provide prescription services to employees on an on-going basis. The comment suggested that profiles should be required for employees' prescriptions, but not for dismissal prescriptions where the hospital pharmacy does not provide continuing outpatient services. To require the maintenance of profiles when it is unlikely that the patient would ever use the pharmacy again will only increase the cost of patient care without achieving the patient protection which is the underlying basis for the rule.

47. A similar situation exists where a patient is only temporarily in an area (such as a tourist) or where a patient knows that he will not be returning to a pharmacy. The Board's response to those situations is a provision in the proposed rule which would allow a patient to state, in writing, that he does not want a patient profile established. A pharmacist

possessing such a writing would not be required to prepare or maintain a profile. This provision, however, places a burden upon both the pharmacist and the patient to obtain the written statement. While such a "waiver" is appropriate in the case of a tourist, it seems inappropriate to require one for every patient in a hospital where there are no outpatient pharmaceutical privileges. It is found that it is neither needed nor reasonable to require the preparation and maintenance of patient medication profiles on hospital patients in the case of hospital pharmacies which do not provide continuing outpatient pharmaceutical services. In order to cure this defect, an exemption should be written into the rule so that a hospital pharmacy which does not provide continuing outpatient pharmaceutical services need not prepare or maintain patient medication profiles for hospital patients.

48. Subpart 3 of the proposed rule relates to the recording of allergies, idiosyncrasies, and chronic conditions of patients. It provides that the pharmacist "shall attempt to ascertain and shall record any allergies, idiosyncrasies, and chronic conditions . . .". At the hearing, the Board admitted that the proposed language does not require that the pharmacist collect and record the information, but rather only encourages it. The Board stated that it was seeking a good faith attempt, but that it knew that it would be impossible to acquire the information in all cases. In its post-hearing response to comments, the Board agreed to support a clarification of this portion of the rule, so that the rule would read as follows:

The pharmacist shall request from the patient or the patient's agent and shall record information on any allergies, idiosyncrasies or chronic conditions of the patient . . .

While the rule is not unreasonable without this change, the change does clarify the intent of the Board and improves the workability of the rule. It would not be a substantial change. It is recommended (but not required) that the change be adopted.

49. Rochester Methodist Hospital also pointed out that there is a reference to a profile "card" in one part of the rule, although other parts of the rule are written to allow computerized or other forms of recording the data. It suggested that the word "card" be changed to "record". The editorial by Donald A. Dee, noted earlier, pointed out that many profile maintenance systems are computerized. Walgreens, in its comment, noted that it has an on-line system so that a profile can be accessed at any of its pharmacies. An existing rule (Part 6800.4000, subp. 2D) on computerized records specifically refers to patient profiles. While there is no reason to believe that the Board intended that these computerized systems could not be used, the reference to "card" does raise a legitimate question. Based on the record as a whole, the Judge believes that there would be a substantial outcry

if the rule were interpreted to require the use of cards to the exclusion of other systems. While the reference to "card" was most likely inadvertent, it must be changed in order for the rule to be found reasonable. In order to cure this defect, the reference to "card" in subpart 1 of the rule should be changed to "record".

50. Subpart 5 of the rule requires that the profile record must be maintained for a period of not less than two years from the date of the last entry. Walgreens requested that for purposes of subpart 4, which requires

drug interaction examinations, that the time period be reduced to one year from the date of the last entry so as to avoid wasted time looking at old or irrelevant prescription information. Rochester Methodist Hospital made a slightly different comment, stating that the rule appeared to suggest that if a patient had any activity within a two year period of time, all old prescription records would have to be kept.

The Board, in its Statement of Need and Reasonableness, supported the two year requirement as conforming to the statutory requirement that all prescription records be maintained for two years (Minn. Stat. 151.211). It is clear from the context, however, that what the Board was considering was the question of how long a profile had to be maintained before it could be destroyed. The problems raised by the commentators are different.

51. With respect to the comment from Walgreens, the proposed rule is silent on the question. It does not state how far back a pharmacist has to look in checking a patient medication profile. At the hearing, the Board responded to Walgreens' comment by stating that it intentionally left the question unanswered to allow for the exercise of professional judgement on a case-by-case basis. Walgreens responded to the Board's position by stating that they believed the rule ought to specify how far back a pharmacist had to look because pharmacists were entitled to know what was required of them to avoid disciplinary action. It is found that the rule is impermissibly vague by failing to address this question at all. As the Minnesota Supreme Court stated in *In re Charges of Unprofessional Conduct Against N.P.*, 361 N.W.2d 386, 394 (Minn. 1985): "A rule, like a statute, is void for vagueness if it fails to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited or fails to provide sufficient standards for enforcement." The Court went on to note, however, that ". . . difficulty in construction is not in itself sufficient to set aside a rule, and a rule should be upheld unless the terms are so uncertain and indefinite that after exhausting all rules of construction it is impossible to ascertain legislative intent." The rule which was challenged in that case was a rule which required a person to cooperate with an investigatory body by complying with "reasonable requests" from the investigator. The Court held that a rule need not contain an explicit definition of every term, and that all that is necessary is that the rule prescribe general principle so that those subject to the rule are reasonably able to determine what conduct is appropriate. Applying those

standards to the rule in question here results in a finding that the rule must contain some standard, but that it need not be one of absolute precision. In other words, the Board would be free to adopt a standard which would require inspection of historical data in patient medication profiles "to the extent that, in the professional judgement of the pharmacist, the patient will be reasonably protected from harm." That is the kind of language that the Board intended to have applied, and that is all that is necessary. The Board could insert a specific length of time, or it could use a "professional judgement" standard. While the Board is free to choose whatever words it deems appropriate to express a standard, it is found that without any standard, the rule is impermissibly vague, and cannot be adopted. In order to cure the defect, some standard must be stated.

52. With respect to the Rochester Methodist Hospital comment, there is another omission in the rule which must be filled in. What the rule requires is that the patient profile record must be maintained for a period of not less than two years from the date of the last entry on the profile record. The

comment suggests that there must be some limit to how long a time data given on a given prescription must be maintained on the profile record to avoid all old prescription records having to be kept if the patient had some activity on new prescriptions within a two year period of time.

Minn. Stat. 151.211 (1984), requires that all prescriptions dispensed must be kept on file for a period of at least two years. That statute relates to the prescription itself, not the patient medication profile. The proposed rule does not explicitly answer the question posed by Rochester Methodist. However, the answer can be inferred from a reading of the rules as a whole for at least some patients. If there has been no activity in a patient's profile for a period of two years, it may be destroyed. But if a patient has had activity in his or her profile within a two year period, how far back must the data in the profile go? A clear example of this is a patient who comes into a pharmacy once a year for five years in a row. Each time a different prescription is filled. If the Board were to make an inspection of the patient's profile the day after the fifth visit, would it expect to find data in the patient's profile that extended all the way back to the very first prescription or, would the inspector be satisfied if the profile contained data only for the last two years? The rule does not answer that question. However, since the Board stated in its Statement of Need and Reasonableness that its intent was to be consistent with Minn. Stat. 151.211, it would seem logical that the inspector ought to be satisfied upon finding the data for the last two years, but not the earlier data. Again, this question must be clarified. It is found that the rule is impermissibly vague without it. In order to cure this defect, the Board must specify a time period for retention of data in the profile. It would not be a substantial change if the Board were to require that data more than two years need not be maintained, but if the Board picked some different time period, then there is a risk that its selection might constitute a substantial change.

#### Part 6800.3120 - Transfer of Prescriptions

53. This entirely new rule sets forth detailed procedures to be followed when a patient seeks to refill a prescription at a different pharmacy than the one which has the original prescription on file. The Board has long held that a copy of a prescription transferred from one pharmacy to another is not a valid prescription order. It has required pharmacists receiving such copies to contact the prescribing practitioner for verification. However, no system

of uniformity has ever been established regarding the transferring of prescriptions. This has resulted incomplete transfer records in pharmacies, and patients have often been obtaining the same prescription from more than one pharmacy at the same time, in some cases intentionally abusing the system. The proposed rule would allow a pharmacist two choices when confronted with an empty container, a copy of a prescription, or anything other than an original prescription. The pharmacist can either contact the prescribing practitioner for authorization to dispense the prescription (the same as the old system) or the pharmacist can comply with all of the requirements of the new rule. If he or she complies with all the requirements of the new rule, then there is no need to attempt to contact the prescribing practitioner.

54. There were a number of changes proposed to the rule, both by the Board and by affected persons. First of all, subpart 3 of the proposed rule deals with "controlled substances in Schedules III-V". The same reference

also appears in subpart 4. It was suggested that there be further clarification of where these "schedules" appear. The Board proposed that the first time this reference occurs, it would be appropriate to add the following language:

(Minn. Rule part 6800.4230 - 4250)

The reference is to an existing set of Board rules which define, with specificity, what are controlled substances. It is found that the concept of "controlled substances" is well-known to pharmacists, and is the subject of extensive rules as well as detailed statutory provisions. Minn. Stat. Ch. 152. Under these circumstances, the Board may elect whether or not to include the reference in the rule. The rule, as proposed without the addition, has been demonstrated to be both needed and reasonable, and it is up to the Board to decide whether it would be desirable to add the reference or not. If it were added, it would not be a substantial change.

55. Subpart 7 of the proposed rule is an attempt to deal with the widespread introduction of computerized prescription recordkeeping systems. It provides that the computerized system must satisfy all of the requirements of the proposed rule even when a prescription is transferred between pharmacies of the same ownership or pharmacies accessing the same prescription records. Walgreens argued that the Board's proposed rule did not go far enough in dealing with common data bases shared by more than one pharmacist. Walgreens, for example, would like to keep one of its pharmacies open 24 hours a day, and allow persons to refill prescriptions there even if the pharmacy where the prescription was originally filed were closed for business. It urged that the subpart be amended so that it would read:

A computerized prescription record keeping system must satisfy all the requirements of subparts 2 to 6 including invalidation of the original prescription. Pharmacies accessing a common electronic file or data base used to maintain required dispensing information are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file; provided, however, that any such common file must contain complete records of each prescription and refill dispensed and further, that a hard copy record of each prescription transferred or accessed for purposes of refilling must be generated and maintained at the pharmacy to which the prescription has been transferred.

Walgreens also urged that subpart 8 be amended to reflect that change by adding prefatory language to the last sentence of the Board's proposed subpart

8 which would read "Except as provided for in subpart 7,".

In its post-hearing comments, the Board supported the proposed language, stating that it should accommodate those pharmacies which do access common data bases but still provide the records needed to provide an audit trail of drug dispensing.

It is found that the amended proposal has been demonstrated to be both needed and reasonable, and that it would not be a substantial change from the rule as originally proposed.

56. Subpart 9 of the proposed rule deals with unprofessional conduct in the context of transferring prescriptions. It consists of two paragraphs, each of which begins with identical language, which is: "The board may consider it unprofessional conduct . . .". It was pointed out by the Administrative Law Judge that the use of the word "may" created a problem because it created unguided discretion in the Board and would allow it to treat different persons who are in similar situations differently. The Board responded, at the hearing, by stating that it would like to keep prosecutorial discretion so as to evaluate violations on a case-by-case basis, but it could live with a change in language which would provide: "The Board shall consider it evidence of unprofessional conduct

It is found that the rule, as originally proposed, does grant unbridled discretion to the Board, and cannot be adopted. In order to cure the defect, the wording must be changed to remove the discretion. The alternate wording suggested by the Board at the hearing would cure the defect, and would not be a substantial change.

#### Part 6800.3650 - Labeling of Poisons

57. Minn. Stat. 151.23 (1984) makes it unlawful to sell at retail any poison without affixing a label conspicuously bearing the word "poison" and certain other information. The existing rule of the Board expands upon that requirement by adding a requirement that the "Mr. Yuk" symbol also be applied. The only change proposed by the Board in this proceeding is to remove the requirement that the "Mr. Yuk" symbol be required on prescription containers. The Board presented evidence that the use of this symbol has run its course and is no longer prevalent. The symbol has been copywritten, and the Board feels that requiring pharmacists to use it would be forcing them to underwrite what has become a commercial venture. No person opposed the deletion of the symbol. It is found that the Board has justified the need and reasonableness of it.

#### Part 6800.9900 - Variances

58. This is an entirely new rule which would allow the Board to grant a variance to an existing rule. It is proposed in response to Minn. Stat.

14.05, subd. 4 (1984), which requires an agency to adopt such a rule setting forth procedures and standards by which variances shall be granted or denied before it may grant a variance. The proposed rule is straightforward, and drew no adverse comment. The Board has justified its need and reasonableness.

Based upon the foregoing Findings of Fact, the Administrative Law Judge makes the following:

#### CONCLUSIONS

1. That the Board gave proper notice of the hearing in this matter.

2. That the Board has fulfilled the procedural requirements of Minn. Stat. 14.14, subds. 1, 1a and 14.14, subd. 2, and all other procedural requirements of law or rule, except as noted at Finding 7, but that the violations noted there do not prohibit the Board from proceeding with the rule adoption process.

3. That the Board has demonstrated its statutory authority to adopt the proposed rules and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. 14.05, subd. 1, 14.15, subd. 3 and 14.50 (i)(ii), except as noted at Findings 29, 30, 51, 52 and 56.

4. That the Board has documented the need for and reasonableness of its proposed rules with an affirmative presentation of facts in the record within the meaning of Minn. Stat. 14.14, subd. 2 and 14.50 (iii), except as noted at Findings 38, 47 and 49.

5. That the amendments and additions to the proposed rules which were suggested by the Board after publication of the proposed rules in the State Register do not result in rules which are substantially different from the proposed rules as published in the State Register within the meaning of Minn. Stat. 14.15, subd. 3, and Minn. Rule 1400.1000, Subp. 1 and 1400.1100.

6. That the Administrative Law Judge has suggested action to correct the defects cited in Conclusions 3 and 4 as noted at Findings 29, 30, 38, 47, 49, 51, 52, and 56.

7. That due to Conclusions 3 and 4, this Report has been submitted to the Chief Administrative Law Judge for his approval pursuant to Minn. Stat. 14.15, subd. 3.

8. That any Findings which might properly be termed Conclusions and any Conclusions which might properly be termed Findings are hereby adopted as such .

9. That a finding or conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Board from further modification of the proposed rules based upon an examination of the public comments, provided that no substantial change is made from the proposed rules as originally published, and provided that the rule finally adopted is based upon facts appearing in this rule hearing record.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

It is hereby recommended that the proposed rules be adopted except where specifically otherwise noted above.

Dated this 6th day of November, 1985.

ALLAN W. KLEIN  
Administrative Law Judge

Recorded: Tape Recorded