8-0906-7340-1

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

FOR THE MINNESOTA BOARD OF PHARMACY

In the Matter of Proposed Adoption of Rule Amendments and New Rules of the Board of Pharmacy Relating to the Licensing of Pharmacies, Patient Counseling, Drug Use Review, Standards of Practice, Inactive Status Licensure, Registration of Preceptors, and Dispensing by NonPharmacist Practitioners; Minn. Rules, Pts. 6800.0100 to 6800.9952.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

The above-entitled matter came on for hearing before Administrative Law Judge Jon L. Lunde on March 12, 1993, at 9:30 a.m. in Conference Room A, Lower Level, 2700 University Avenue West, St. Paul, Minnesota.

This Report is part of a rulemaking proceeding held pursuant to Minn. Stat. §§ 14.131 to 14.20, to hear public comment, to determine whether the Minnesota Board of Pharmacy (the Board) has fulfilled all relevant substantive and procedural requirements of law applicable to the adoption of the rules, whether the proposed rules are needed and reasonable and whether or not modifications to the rules proposed by the Board after initial publication are impermissible, substantial changes.

Robert Holley, Special Assistant Attorney General, Suite 200, 525 Park Street, St. Paul, Minnesota 55103, appeared on behalf of the Board at the hearing. The Board's hearing panel consisted of David E. Holmstrom, Executive Director of the Board. Also present at the hearing were Board President Henry Capiz, R.Ph.; and Board members Carol Peterson; Wendy Simenson, R.Ph.; Denise Groehler, R.Ph.; and Howard Juni, R.Ph. Nearly one hundred persons attended the hearing. Seventy-five persons signed the hearing register. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the adoption of these rules.

The record remained open for the submission of written comments for twenty calendar days following the date of the St. Paul hearing, to April 1, 1993. Pursuant to Minn. Stat. § 14.15, subd. 1 (1988), an additional five working days were allowed for filing responsive comments. At the close of business on April 8, 1993, the rulemaking record closed for all purposes. The Administrative Law Judge received written comments from interested persons during the comment period. The Board submitted written comments responding to matters discussed at the hearings and proposing further amendments to the rules. The due date for this Report was extended by the Chief Administrative Law Judge from May 10, 1993 to May 25, 1993 at the Administrative Law Judge's request.

The Board must wait at least five working days before the agency takes any final action on the rule(s); 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, DHS may either adopt the Chief Administrative Law Judge's suggested actions to cure the defects or, in the alternative, if the Department does not elect to adopt the suggested actions, it must 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 Chief Administrative Law Judge, then it shall submit the rule, with the complete hearing 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 January 6, 1993, 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) the Statement of Need and Reasonableness (SONAR);
(e) a list of additional persons to receive the Notice of Hearing;
(f) a statement of the number of persons expected to attend the hearing and the estimated length of hearing; and
(g) a statement of mailing a copy of the rules to finance and appropriation committee chairs.

2. On January 29, 1993, 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.

3. On February 1, 1993, the Notice of Hearing was published at 17 State Register 1861. That Notice referenced the State Register, Volume 17, Number 22 as the location of the proposed rules. The rules were published on November 30, 1992, at 17 State Register 1317.

4. On February 11, 1993, the Board filed the following documents with the Administrative Law Judge:

(a) the Notice of Hearing as mailed;
(b) a copy of the State Register pages containing the Notice of Hearing and its proposed rules;
(c) a copy of the Notice of Solicitation of Outside Opinion and all materials received pursuant to that Notice;
(d) the names of agency personnel and witnesses called by the Board to testify at the hearing;
(e) the Board's certification that its mailing list was accurate and complete; and,
(f) the Affidavit of Mailing the Notice to all persons on the Board's mailing list.

Nature of the Proposed Rules and Statutory Authority.

5. The proposed rules affect a wide range of subjects including the licensing of pharmacies, requiring offers to counsel and patient counseling when prescriptions are filled, requiring drug use reviews, modifying pharmacists' standards of practice, creating an inactive license status, modifying the lists of controlled substances, registering preceptors, and dispensing by nonpharmacist practitioners. The Board is responsible for setting standards of pharmaceutical care and the provision of pharmaceutical services under Minn. Stat. § 151.06, subd. 1. Under the statute, the Board has the power to regulate the practice of pharmacy, the manufacture and sale of drugs, and the labeling, purity and quality of drugs dispensed. It is also authorized to examine and license pharmacists and drug distributors, and take disciplinary action against pharmacists or other registrants for violations of state statutes or Board rules relating to the practice of pharmacy and the manufacture, labeling and sale of drugs.

6. In order to carry out its responsibilities, the Board has statutory rulemaking authority. Minn. Stat. § 151.06, subd. 1(c) states:

> (c) Rules. For the purposes aforesaid, it shall be the duty of the board to make and publish uniform rules not inconsistent herewith for carrying out and enforcing the provisions of this chapter. The board shall adopt rules regarding prospective drug utilization review and patient counseling by pharmacists. A pharmacist in the exercise of the pharmacist's professional judgment, upon the presentation of a new prescription by a patient or the patient's caregiver or agent, shall perform the prospective drug utilization review required by rules issued under this subdivision.

Under the cited statute, the Board generally has authority to adopt the rules proposed in this proceeding.

Small Business Considerations in Rulemaking.

7. Minn. Stat. § 14.115, subd. 2, provides that state agencies proposing rules affecting small businesses must consider methods for reducing the rules' adverse impact on those businesses. The methods that must be considered for reducing the impact of rules on small businesses include the establishment of less stringent compliance or reporting requirements, less stringent schedules or deadlines for compliance or reporting requirements, the consolidation or simplification of compliance or reporting requirements, the establishment of performance standards to replace design or operational standards, and the exemption of small businesses from any or all requirements of the rule. Agencies must implement feasible methods of reducing their rules' impact on small business. In its statement of need and reasonableness, agencies must document how they considered these methods and the results reached. One reason documentation in the SONAR is required is to assure that agencies meaningfully consider small business factors before rules are proposed and the agency's position becomes fixed. The same rationale is reflected in Minn. Stat. § 14.131, which requires that the SONAR be prepared and reviewed before an agency orders publication of a rulemaking notice.

8. The Board acknowledged that 75 to 80 percent of the pharmacies it licenses are small businesses for purposes of the statute, but it did nothing in the rules to accommodate small businesses. It explained its decision as follows:

> . . .[T]he Board is unable to establish a less stringent requirement for a small business and is unable to exempt small business from any or all of the requirements of these rules, in that in many cases the federal government has mandated minimum requirements that all pharmacies must comply with, and further, patients obtaining pharmaceutical services from a "small business" pharmacy are just as deserving of the protections afforded them by these rules as are those patients who do business with large pharmacies. In that the proposed rules generally do not exceed the federal mandated minimums, the statutorily mandated minimums, or the requirements found in model rules, the Board is unable to further accommodate small business.

SONAR AT 67.

9. The Board's conclusory assertions do not meet statutory requirements because they do not show how the Board considered specific methods of reducing the impact of the proposed rules on small businesses and the conclusions reached. Compliance with the provisions of Minn. Stat. § 14.115 requires more than a few conclusory assertions. For example, many pharmacists complained about the Board's decision to expand the requirements of its rules beyond the new federal requirements applicable to Medicaid recipients. The Board concluded that patients receiving pharmaceutical services from small businesses are just as deserving of the protections afforded by the rules as

patients who are served by large pharmacies. However, it does not follow that federal requirements applicable to Medicaid prescriptions should be applied generally. In fact, Congress likely may have concluded that nonMedicaid patients were not in need of the same services as Medicaid patients. The Board did not consider the need factor or the financial consequences of applying the counseling and profiling requirements applicable to Medicaid recipients to all patients. In addition, for example, in its SONAR, the Board did not consider permitting a designee to make offers to counsel, the experience required of preceptors in small retail operations or different documentation requirements for small business. In short, the Board's SONAR fails to show how the Board considered methods of reducing the impact of its rule amendments on small businesses and the results of its deliberations. Greater specificity is required. The Board's failure to consider small business issues in drafting its SONAR constitutes a defect for purposes of Minn. Stat. § 14.15, subd. 3 (1992).

10. Under Minn. Stat. § 14.15, subd. 5, administrative law judges are required to disregard errors or defects in rulemaking proceedings resulting from an agency's failure to satisfy procedural requirements imposed by law or rule if the administrative law judge finds that the failure did not deprive any person or entity of an opportunity to participate meaningfully in the rulemaking process or that the agency has taken corrective action to cure the error or defect so that the failure did not deprive any persons of an opportunity for meaningful participation. In a rulemaking context, the distinction between "substantive" and "procedural" requirements is unclear. Because section 14.15, subd. 5 was just enacted, rules of the Office of Administrative Hearings do not define "procedural requirements" and the courts have not considered the issue. In a judicial context, procedural requirements are distinguished from the body of law courts are established to administer (i.e., substantive law). Substantive law is generally defined as that part of th law that "creates, defines and regulates rights." Procedural law, on the other hand, prescribes the method of enforcing rights. Black's Law Dictionary, 1598 (4th ed. 1957). The small business considerations in Minn. Stat. § 14.115 seem to be more substantive than procedural. Procedural requirements relate to the publication, filing and content of rulemaking notices and documents. Delays and irregularities regarding them do not necessarily invalidate the proceeding. For example, if an agency fails, in good faith, to meet a deadline, its tardiness will not invalidate the rules as long as the defect did not impair meaningful participation. The small business considerations are, however, akin to the burdens of proof on production which have traditionally been treated as procedural in nature.

11. Assuming that compliance with small business requirements is procedural, the Administrative Law Judge is persuaded that the Board's failure to show how it considered the statutory, small business factors deprived interested persons of a meaningful opportunity to participate in the rulemaking process. The Board was required to document in its SONAR how it considered reducing the rules' impact on small business and the results of its deliberations. The Board's evaluation was required before its rulemaking notice so that small business requirements would receive good faith consideration before rules were proposed. Discussion in the SONAR was required so interested persons could review the Board's small business statement and prepare for the hearing. If the Board had articulated the factors it considered, interested persons would have had an opportunity for reasonable and meaningful comment. However, because the Board only paid lip

service to statutory, small business considerations, it is concluded that the defect was substantial and prejudicial. As a result of this defect, the Board must not extend the rules proposed to implement OBRA '90 to nonMedicaid recipients. See Findings 45, 53, 55, 64, 65, 72, 78 and 80, infra.

12. It could be argued that interested persons were not deprived of an opportunity for meaningful participation because small business could have presented methods of reducing the rules' impact on them. However, this inappropriately shifts the burden to small business to implement section 14.115. Also, the same argument could be made regarding the SONAR. If an agency does not prepare one, it could argue that interested persons could ask the agency about its rationale at the hearing and present evidence that proposed rules are unreasonable and unnecessary. Such arguments are wholly inconsistent with the purpose and intent of the rulemaking provisions of the Administrative Procedure act. If they were accepted, agencies could routinely ignore small business considerations without fear of jeopardizing their rules.

Fiscal Note

13. Minn. Stat. § 14.11, subd. 1, requires the preparation of a fiscal note when the adoption of a rule will result in the expenditure of public funds in excess of $100,000 per year by local public bodies. The notice must include an estimate of the total cost to local public bodies for a two-year period. In its Notice of Hearing, the Board stated that its proposed rules "will not result in the expenditure of public monies by local public bodies." Ex. C-1. However, Mr. Charles Cooper, Pharmacy Director of Hennepin County Medical Center (HCMC), asserted that the proposed rules would require HCMC to spend an additional $794,230 to meet the patient counseling and drug utilization review requirements in the proposed rules. HCMC arrived at that figure by multiplying 2.5 minutes per prescription for documentation and counseling, and 2.5 minutes per prescription for pharmaceutical care requirements, by 350,000 assumed prescriptions. The resultant time of 29,167 hours would require HCMC to hire 14 new pharmacists at a total cost of $794,230 annually.

14. The Board questioned HCMC's cost estimates because the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services estimated the nationwide cost of compliance with the Omnibus Reconciliation Act of 1990 (OBRA '90) -- which is implemented by these rules -- would range from $70 to $140 million annually. Mr. Holmstrom argued that it is questionable that one percent of the nationwide costs HCFA estimated would be incurred by HCMC. HCFA estimated that two to four minutes of additional time would be required under OBRA '90 at a cost of $1 to $2 per prescription. HCFA assumed that 25% of $280 million annual Medicaid prescription would involve counseling services. Ex. H. at 49486. HCFA's two- to four-minute time estimate is lower than HCMC's. However, the record as a whole indicates that the cost to local public bodies, including Hennepin County, will exceed $100,000 annually. Even if HCFA's presumptions are used for HCMC, the annual cost -- assuming counseling in 25% of the cases and two minutes' time for each prescription -- would be $79,423 following HCMC's methodology. Public Ex. 6, att. 2. This is an unlikely, rock-bottom estimate and does not include the costs incurred by other counties. If three or four minutes per prescription are used to estimate HCMC's costs, its annual costs alone would exceed $100,000 annually.

15. Group Health, Inc., while not a local public body, estimated that just the additional documentation required under the rules will take two minutes per prescription, exclusive of refills, and cost it $700,000 annually. Group Health's projections support HCMC's figures. Other commentators at the hearing mentioned estimated costs of $2.50 per prescription to implement the rule. Several years ago, the American Pharmaceutical Association estimated that patient consultation would take four minutes for each patient with a new prescription. Ex. M. at 21.

16. The Administrative Law Judge is persuaded, therefore, that the Board unreasonably and erroneously concluded that costs to local public bodies would not exceed $100,000 to implement the rule in either of the two years following its promulgation. The Board's use of HCFA's estimated costs in determining costs to local public bodies was not justified. The basis for HCFA's estimates is unknown and their accuracy is questionable. Furthermore, HCFA's estimates apply only to Medicaid patients. The Board did not adjust HCFA's estimates to reflect the fact that its rules apply to all patients and not just Medicaid recipients. Also, the Board did not consider the costs involved in establishing patient profiles and interventions, which HCFA did not estimate. Ex. H at 49406. Even if a $70 million figure is used, and it is assumed that only one percent of the costs are incurred in Minnesota, the cost of the Medicaid provisions in OBRA '90 alone would be $700,000 annually. Based on the foregoing, it is concluded that a fiscal note should have been prepared under Minn. Stat. § 14.11, subd. 1. The purpose of the fiscal note is to assure that agencies consider the cost implications of new rules and provide reasonable estimates of the cost of newly adopted rules. The statute is designed to alert persons who might be interested in commenting on the rule if the cost implications are significant and to assure that economic factors are considered before rules are proposed. Preparation of a fiscal note also may provides data that can be used in connection with the small business considerations in Minn. Stat. § 14.115, subd. 2.

17. In its Statement of Need and Reasonableness (SONAR), the Board asserted, without any discussion, its conclusion that adoption of the rules would not result in the expenditure of public monies in excess of $100,000 in either of the first two years following adoption. The Board essentially failed to consider the cost to local public bodies in implementing the rules. An agency cannot merely state, without some foundation, that costs will not exceed $100,000 annually unless such conclusion is apparent from the face of the rules. That is not the case here. The Board is expanding federal requirements for Medicaid patients to all patients in the state. It is doing so without any consideration of the cost impact or a reasonable estimate of the total cost to all public bodies in the state. It appears likely that costs to local public bodies will exceed $100,000 annually and the agency's failure to draft a fiscal note giving its reasonable estimate of the total cost to all public bodies is inconsistent with the requirements in and purposes of Minn. Stat. § 14.11. This constitutes a defect for purposes of Minn. Stat. § 14.16, subd. 2.

18. As noted before, "procedural" defects must be ignored if they did not deprive any person of an opportunity for meaningful participation in the rulemaking process or the agency has taken corrective action to cure the defect. In this proceeding, the Board's failure to consider the cost to local public bodies, if procedural, deprived them of an opportunity for meaningful

participation because some may have been mislead by the Board's assertions and others were unable to meaningfully criticize the Board's estimates because there was no relevant evidence in the record which could be challenged. Moreover, the Board took no corrective action to cure the defect. The need for expanding Medicaid requirements to all patients, which Congress itself found to be unnecessary, depends, in part, on the cost implications of the expansion and the benefits that would derive therefrom. The Board's noncompliance with the statute makes it impossible to do any rational analysis. Due to the Board's failure to consider the cost impact on the local bodies, the Board must not extend the rules adopted to implement OBRA '90 requirements to small businesses or local public bodies, it should not be permitted to do so with respect to any persons covered by the rules. See Findings 45, 53, 55, 62, 64, 72, 78 and 80.

19. The Board's failure to prepare a fiscal note is somewhat different from its failure to address small business factors. However, similar considerations apply. Because the Board initially stated that local public bodies would incur "no" additional costs, prejudice must be assumed. Although the number of local public bodies affected by the rule is unknown, those with smaller operations could very easily have been mislead by the Board's statement.

Impact on Agricultural Land.

20. Minn. Stat. § 14.11, subd. 2 (1988), imposes additional statutory notice requirements when proposed rules have a "direct and substantial adverse impact on agricultural land in the state." The statutory requirements referred to are found in Minn. Stat. §§ 17.80 to 17.84. The proposed rules will have no substantial adverse impact on agricultural land within the meaning of Minn. Stat. § 14.11, subd. 2 (1988).

Substantive Provisions

21. The Board must establish the need for and reasonableness of the proposed rules by an affirmative presentation of facts. The Board prepared a Statement of Need and Reasonableness in support of the adoption of the proposed rules and supplemented its SONAR at the hearing. Further, it explained 27 amendments proposed at the commencement of the hearing. The question whether a rule is reasonable focuses on whether it has a rational basis. The Minnesota Court of Appeals has held a rule to be reasonable if it is rationally related to the end sought to be achieved by the statute. Broen Memorial Home v. Minnesota Department of Human Services, 364 N.W.2d 436, 440 (Minn.App. 1985); Blocker Outdoor Advertising Company v. Minnesota Department of Transportation, 347 N.W.2d 88, 91 (Minn.App. 1984). The Minnesota Supreme Court has further defined the burden by requiring that the agency "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action." Manufactured Housing Institute v. Pettersen, 347 N.W.2d 238, 244 (Minn. 1984).

22. This Report is generally limited to a discussion of the portions of the proposed rules that received significant critical comment. Because most sections of the proposed rules were not opposed and were adequately supported by the SONAR, a detailed discussion of each section of the proposed rules is

unnecessary. The need for and reasonableness of provisions not discussed in this Report have been demonstrated by an affirmative presentation of facts, and such provisions are specifically authorized by statute. The Board proposed a number of changes to the rules as published in the State Register. This Report assesses whether those changes, as well as those suggested by commentators or the Administrative Law Judge, are substantial changes. In a number of instances the Board did not make a change in the rule but stated it was willing to consider (or did not object to) the suggested change. This results in considerable uncertainty as to what rule language the Board is finally proposing. Hence, it is a practice that should be avoided. Where adopting different language would result in a defect, that has been indicated. If the Board chooses to adopt different language when the rules are finally adopted, the Board should specifically indicate where that different language is located for the Chief Administrative Law Judge's review.

Part 6800.0100 - Definitions.

23. This rule contains a number of subparts which define terms used in the rules. Previously, the Board has had only a single category of pharmacy license. In actual practice, however, various kinds of specialized pharmacies exist. The Board has decided that its licensing rules should recognize the various specialty areas and identify all licensed pharmacies. The Board also has decided that each licensed pharmacy's specialized areas should be included in its license. License fees will not be changed under the rules and a pharmacy can propose to conduct business in any or all of the specialty areas identified in the rules. Recognition of the specialty areas is necessary and reasonable because the Board will be requiring each licensed pharmacy to identify the specialty areas in which services will be offered and Board surveyors will be able to limit their inquiries and focus their attention on specialty areas identified in each pharmacy's license. Proposed subparts 2 through 6 define community/retail pharmacy, hospital pharmacy, long-term care pharmacy, nuclear pharmacy, and parenteral-enteral/home health care pharmacy. Each definition relates to a specialty area now existing within the field of pharmaceutical services. Adding these terms is needed and reasonable to keep the Board's rules relevant to changes in the provision of services by pharmacists and pharmacies, in whatever setting they are based.

24. The rules no longer contain a definition of the word "pharmacy". That definition has been replaced with a definition of a "community/retail pharmacy." A community/retail pharmacy is "an established place in which prescriptions, drugs, medicines, chemicals, and poisons, are prepared, compounded, dispensed, vended, distributed or sold to for the use of nonhospitalized patients and from which related pharmaceutical care services are provided." Linda S. Hart, RN, MPH, a quality improvement consultant for the Community Clinic Consortium, questioned the meaning of the word "distributed" in this definition. She noted that the clinic where she works does not fill prescriptions or sell over-the-counter medications but that the clinics' physicians dispense medications to patients who do not have the financial resources to have prescriptions filled at a retail pharmacy. She questioned whether dispensing medication to the clinics' patients would amount to the "distribution" of medication for purposes of the rule.

25. The Board did not specifically address Ms. Hart's comment, and her question is confusing because the dispensing of medicines is specifically included in the definition of a community/retail pharmacy. Under Minn. Stat. § 151.26, subd. 1, it appears that licensed physicians may dispense drugs to

patients. However, unless the medicines are dispensed in their original package, the physician engaged in dispensing drugs is subject to inspection by the Board. Under the plain language of the rule, however, it appears that clinics who dispense drugs not in their original package must be licensed. If this is not the Board's intention, it must clarify the rule before it is promulgated.

26. Part 6800.0100, subp. 4, defines a "long-term care pharmacy." In the definition, reference is made to "residents of a long-term care facility." Mary Absolon, Program Manager of the Survey and Compliance Division of the Minnesota Department of Health, noted that the words "long-term care facility" are vague and potentially misleading and should be replaced with the words: "a licensed nursing home, boarding care home, or supervised living facility." In the Board's April 7, 1993 comment (p. 9) it indicated that it did not object to changing the definition as proposed by Ms. Absolon. A similar change should be made in any other rule that uses the words "long-term care facility" or rules that use other inaccurate terminology such as Part 6800.6200, subp. 1, which refers to "duly licensed skilled care, intermediate care" facilities. See Department of Health comments. These amendments are all necessary and reasonable and do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1991).

27. The Board suggested a minor modification to subpart 6 to incorporate long-term care pharmacies and the term community/retail pharmacy. Subpart 6, as modified, is needed and reasonable, and the changes are not substantial. The Board should ensure, however, that the full term "community/retail pharmacy" is used in the final draft of subpart 6. The word "pharmacy" was inadvertently omitted from the Board's draft of proposed changes.

28. "Pharmaceutical care" generally is defined in subpart 7 as the responsible provision of drug therapy and other pharmaceutical patient care services by a pharmacist to cure or prevent disease, eliminate or reduce patient symptoms, or ameliorate a disease process. Many commentators urged deletion of this term throughout the rule. Brian Isetts, R.Ph., Ph.D., Director of Professional Affairs for the Minnesota Pharmacists Association, supported the inclusion of "pharmaceutical care" in the proposed rules, but suggested that a broader definition be used. Mr. Isetts suggested that the Board use the definition of "pharmaceutical care" developed by Dr. Linda Strand, a researcher at the University of Minnesota who coined the quoted phrase. The definition proposed by the Board is not significantly different than Dr. Strand's and the Board has established that its proposed definition is needed and reasonable. Mr. Holmstrom indicated, however, that the Board is willing to consider changes in the definition to more closely parallel the definition developed by Dr. Strand. Such a change, if made, would not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 and the Board is free to make it.

29. In Subpart 13, the Board has defined a "satellite pharmacy" as a "location in a licensed hospital under the direction of a licensed pharmacist that is remote from the centrally licensed pharmacy but within the same facility or location and is dependent on the centrally licensed pharmacy for administrative control, staffing, and drug procurement and that provides pharmacy services only to hospitalized patients." The definition proposed by the Board is confusing because it states that the licensed hospital must be "under the direction of the licensed pharmacist." Clearly, it was the Board's intention to state that the satellite must be under the direction of a licensed pharmacist. Moreover, use of the words "remote" and "location" create unnecessary ambiguities and could be more specific. The Administrative Law Judge recommends, therefore, that the definition be amended to read as follows:

Satellite Pharmacy. "Satellite pharmacy" means a site in a licensed hospital which is not connected with the centrally licensed pharmacy but is within the same facility or building and is dependent on the centrally licensed pharmacy for administrative control, staffing, and drug procurement. A satellite pharmacy must be under the direction of a licensed pharmacist and provide pharmacy services to hospitalized patients only."

30. It is not uncommon for large hospitals to have multiple pharmacies. In the past, the Board's position has been that these "satellite" pharmacies do not require separate licensure but must have a pharmacist in charge. Historically, many pharmacies have failed to identify a pharmacist in-charge for each satellite pharmacy within a hospital and, in many cases, the Board is unaware of the number and location of satellite pharmacies. Because the Board has now decided to identify and regulate satellite pharmacies, a definition is needed and reasonable.

31. Several commentators objected to the definition of "satellite pharmacy" set out in subpart 13. David Fuhs of United and Children's Hospitals urged the Board to permit satellite pharmacies to provide services to patients treated by a hospital, and not merely to "hospitalized patients" as the proposed definition states. Mr. Fuhs noted that as pharmacy services expand, satellite pharmacies provide services to patients that are not hospitalized. Included among them are satellite pharmacies in oncology clinics, day-surgery centers, and emergency rooms. Rayburn B. Vrabel, Pharm.D., Director of Pharmacy-Central Supply for Rochester Methodist Hospital, also noted that due to the shift from inpatient to outpatient care, pharmaceutical care is provided in a variety of "nontraditional" satellites. Consequently, he recommended that the Board amend the definition of satellite pharmacies by replacing the word "hospital" with the words "institutional practice setting" and replacing the words "hospitalized patients" with the words "a limited, defined patient population." Kristin Young, R.Ph., Pharmacy Administrator of Clinic Operations for Group Health, Inc. (GHI), suggested that the rule should recognize satellite pharmacies located in licensed hospitals and satellite pharmacies located in a health maintenance organization (HMO). She noted that GHI has two pharmacies at the Riverside Clinic. One would meet the proposed definition of a satellite pharmacy if it were located in a hospital.

32. The Board has not opted to change its definition of satellite pharmacies as suggested by these commentators. In its initial post-hearing comment (p. 19.) the Board noted that hospitals have been expanding their services to many areas that are not associated with the hospital itself and have established for-profit subsidiaries, retail pharmacies, and other species of service arrangements. The Board is not willing to permit hospitals to operate an unlimited number of pharmacies under a single license. That decision is necessary and reasonable. Requiring satellite pharmacies to be located in a licensed hospital is a rational method for identifying satellite pharmacies that need not be separately licensed. Moreover, the proposed rule can be easily applied and administered.

33. The rules on satellite pharmacies are intended to allow a central pharmacy to offer pharmacy services in more than one location without requiring an additional license. Limiting satellite pharmacies to licensed hospitals retains the additional protection of clearly defined facility boundaries. Where pharmaceutical services are being offered apart from the facility containing the central pharmacy, the Board would insist on licensing that service as a separate pharmacy. Under Minn. Stat. § 151.19, the Board is required to license every pharmacy in the state. In determining what is a pharmacy that must be licensed, the Board has recognized that in large medical institutions, such as major hospitals, pharmacy services may be provided from more than one location. The Board is willing to consider the multiple pharmacies within a hospital as satellites not requiring separate licensure. However, it is not willing, as GHI proposed, to permit multiple pharmacies not serving inpatients to operate under one license. The distinctions it has made are necessary and reasonable.

Part 6800.0350 - License Categories.

34. Proposed rule 6800.0350 establishes five categories of pharmacy licenses. They correspond to the types of pharmacies set out in the definitions. Licensing the same pharmacy in different categories is accomplished by the same form and only one application fee is charged. Only services available under the categories for which the pharmacy is licensed may be offered by that pharmacy. As originally proposed, one category was entitled "nursing home [pharmacy]." At the hearing, the Board modified that category to "long-term care [pharmacy]." The words "nursing home" while commonly used by lay persons, are seldom used in the regulatory context. Consequently, using the words "long-term care" instead is necessary and reasonable. Clarifying changes in definitions do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1991).

35. GHI suggested that the Board recognize staff-model HMO pharmacies as a separate licensing category. In its view, HMO's, like Group Health, do not fit squarely into any of the licensing categories proposed by the Board. In its March 30, 1993 post-hearing response (p. 17), the Board indicated that it is willing to develop an appropriate definition for health maintenance organization pharmacies. However, no specific language changes were proposed. At this time, the five licensing categories recognized in the proposed rules were shown to be necessary and reasonable. If the Board proposes a new licensing category for HMOs in this proceeding, its proposed language must be submitted to the Chief Administrative Law Judge for approval.

Part 6800.0700 - Pharmacy, Space, and Security.

36. The existing rule regarding the physical space required of pharmacies is modified significantly by the amendments proposed in this proceeding. The requirement of reasonable public access is deleted. The maximum space of 12,500 square feet is deleted and a minimum space of 400 square feet is added. The existing requirement for a continuous wall from the floor to the ceiling is clarified by requiring extension to the "permanent" ceiling. The Board also added item C, which requires community/retail pharmacies to have "an area where consultation between the patient and the pharmacist can be conducted with a reasonable expectation of privacy." Item C becomes effective on January 1, 1994. The "continuous wall" requirement was questioned by a commentator at the hearing. The Board indicated that the rule is intended to enhance security for pharmacies and render theft of controlled substances more difficult. This requirement is necessary and reasonable because suspended ceilings, for example, provide no security.

37. Judy Cook, representing the Minnesota Retail Merchants Association, objected to the requirement for a "consultation area." Public Ex. 2. The Board indicated that no physical changes are necessarily required by the rule, so long as some area within the pharmacy provides a location where privacy can be maintained. Ms. Cook and Ronald L. Broekmeier, R.Ph., asserted that merely requiring a "reasonable expectation of privacy" is too vague. Mr. Broekmeier suggested the addition of minimum construction standards while Ms. Cook suggested that the requirement be eliminated.

38. As noted in the Board's SONAR (p. 3.) discussions between a pharmacist and a patient regarding the patient's drug therapy involve matters of a private and confidential nature. These conversations should not be conducted in a public area. Consequently, even though OBRA '90 does not specifically require that consultation with patients be undertaken in an area that affords a "reasonable expectation of privacy", it is reasonable for the Board to adopt such a requirement. A person's medical treatment is an extremely private matter and communications regarding a patient's treatment for depression, anxiety, HIV, or even more mundane ailments, should be protected. The Board's attempt to protect these confidential and private matters is necessary and reasonable. It is also concluded that the standard proposed is reasonably clear and capable of application to a variety of situations. The Board is not required to adopt minimum construction standards to assure privacy. It is reasonable for the Board to give pharmacies as much leeway as possible in tailoring the patient counseling area to the needs and physical layout of each site. The minimal requirement proposed by the Board gives pharmacies flexibility and was shown to be necessary and reasonable. It is immaterial that OBRA '90 does not require the protection of patient confidences. A patient's privacy rights and interests, like patient privileges, are frequently matters of state, rather than federal law. Moreover, the Board's rulemaking authority is not limited to the implementation of federal laws.

39. One or more commentators suggested that the effective date of subpart 1C -- regarding an area affording a reasonable expectation of privacy -- should be extended. Presently the rule is effective January 1, 1994. There is no evidence in the record that an effective date of January 1, 1994 is unnecessary or unreasonable. In fact, due to the flexibility given to pharmacists in complying with the rule, it is concluded that the proposed effective date is necessary and reasonable. In the event that the Board has any doubt about a pharmacy's ability to comply, the Board can consider adopting a variance provision under Minn. Stat. § 14.05, subd. 4.

Part 6800.0800 - Location, Dimension, and Security Changes.

40. The existing rule regarding changes to the location or physical space of a pharmacy requires prior application to the Board, with information included on the changes. Minor changes are proposed for subparts 1 and 2, governing changes in location, dimension, and security; and a new subpart 3 is proposed to regulate the establishment of satellite pharmacies. At least 60 days before satellite pharmacies are established, documents and plans for the satellite must be filed with the Board. The Board has 60 days to approve or reject the satellite pharmacy. Failure to respond in writing within the 60 days results in approval of the satellite pharmacy. No commentators objected to this provision. The Board has shown that the oversight of satellite pharmacies in proposed rule part 6800.0800 is needed and reasonable.

Part 6800.0910 - Patient Access to Pharmacist.

41. Subpart 1 of proposed rule 6800.0910 requires pharmacies to develop and maintain written procedures for direct, oral consultation between pharmacists and patients. At the hearing, the Board amended the proposed rule to limit the scope of subpart 1 to those pharmacies which are required to provide patient counseling under the rule. Subpart 1 works in tandem with subpart 2, which requires pharmacists to "attempt to consult with the patient . . . and inquire about the patient's understanding of the use of the medication." The subpart goes on to require a pharmacist to personally initiate discussion of matters necessary to optimize the use of prescribed medication and sets forth the elements of appropriate patient counseling. For refill prescriptions, the pharmacist must inquire about reactions to the medication, outcomes obtained, proper use of the medication, and any additional over-the-counter medications used since the prescription was filled. Latitude is granted pharmacists to withhold information, if in the patient's best interest, but any information withheld must be noted on the prescription, in the patient's records, or both. Personal communication is not required in hospitals or other inpatient institutions or where the patient has refused consultation. When prescriptions are filled by mail, consultation may be accomplished by telephone. The language proposed in part 6800.0910 and other sections of the rule is based on model language developed by the National Association of Boards of Pharmacy to meet the requirements of OBRA '90.

42. The Board described patient consultation as "rapidly becoming one of the keystones of pharmacy practice." SONAR at 15. The chief benefit cited is optimization of drug therapy. Id. The present rule, Minn. Rule 6800.2250, subpart 1 F, makes refusal to consult with a patient on a prescription unprofessional conduct. The proposed rule takes that professional obligation one step further and requires pharmacists to initiate patient consultation. This requirement has become known as the "offer to counsel." Of course, the patient may refuse consultation with the pharmacist.

43. The requirement for offers to counsel arises from the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), amending section 1927(g) of the Social Security Act, Title XIX, codified as 42 U.S.C. § 1396r-8(g). OBRA '90 requires a drug use review to be initiated for Medicaid recipients. One element of the drug use review program states as follows:

> (I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practical, or through access to a telephone service which is toll-free for long distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant ...

Section 1927(g)(2)(A)(ii)(I). Following the quoted language the Act lists specific items to be discussed. These items are reproduced in subpart 2 of the proposed rules with only minor differences.

44. OBRA '90 applies only to Medicaid recipients. The Board decided, however, to impose similar requirements on all other patients. It seems clear that the Board's expansion of the requirements in OBRA '90 is reasonable to avoid or limit adverse drug reactions. The Federal Food and Drug Administration (FDA) has estimated that there are 27 to 28,000 reported adverse reactions to medications annually with hospitalization or death resulting in 19% of those cases. Ex. J(2) at 9. Also, the incidence of mismedication among older adults is relatively high. Pharmacists can play a critical role in managing drug therapy for older adults who frequently have complex drug regimens prescribed by more than one physician. Ex. J(1) at 1. One commentator suggested that 10 to 20 percent of all hospital admissions are due to adverse drug reactions and that those admissions as well as lost days of productivity due to the misuse of medications can be limited through the pharmacist's intervention. Public Ex. 1 at 2. Patients who do not follow prescription directions and skip dosages or prematurely stop taking drugs frequently pay with their health. Moreover, noncompliance contributes to premature deaths, prolonged illnesses and preventable hospitalizations. In economic terms, noncompliance has been estimated to cost billions of dollars annually. Ex. M. at 22.

45. Because patient consultation and drug use review is required by all Medicaid patients under OBRA '90, the Board decided to apply those requirements uniformly to all patients. In the Board's view, the proposed rule recognizes the important role pharmacists play in maximizing the effectiveness of drug therapy. In addition, the Board pointed out that it does not make good sense to have pharmacists engage in drug use review and patient counseling for only one segment of their patient population. The Board's decision to apply the requirements of OBRA '90 to all patients seems to be a reasonable health measure. Nonetheless, due to the Board's failure to prepare a fiscal note or undertake a meaningful consideration of the impact of its rules on small businesses, the Board cannot extend the requirements in OBRA '90 to all patients at this time. It can, however, enact the rules proposed, unless otherwise noted herein, and apply them to Medicaid patients because that is a requirement of federal law. Part 6800.0910 must be amended accordingly. In addition, long-term care facilities must be exempted from prospective drug reviews pursuant to 42 C.F.R. § 456.703(b)(1992).

46. The Minnesota Retail Merchants Association; Mr. Vrabel; and Roy Bussewitz, R.Ph., J.D., Vice President of the National Association of Chain Drug Stores (NACDS), argued that the pharmacist should be able to delegate the responsibility for making the offer to counsel to a pharmacist's assistant. For situations where the prescription is mailed or delivered, GHI, and Gerald A Christenson, R.Ph., Rochester Medical Products Coordinator of the Mayo Pharmacy, suggested that the offer to counsel be made in writing and a toll-free number be provided for the patient. C. A. Catizone, M.S., R.Ph., Executive Director of the National Association of Boards of Pharmacy supported the proposed rule.

47. The Board maintains that the plain language of OBRA '90 requires the pharmacist to personally make the offer to counsel to Medicaid patients, whenever practical and that the federal legislation provides only a few carefully limited exceptions. The objecting commentators argue that the legislative history of OBRA '90 does not clearly indicate who must make the offer to counsel. These commentators maintain that the federal statute permits delegation of the offer to counsel.

48. In implementing the counseling requirements of OBRA '90, many states have adopted rules requiring pharmacists to make the offer to counsel. However, about half the states permit a designee to make the offer on the pharmacists behalf. HCFA has made inconsistent pronouncements regarding the permissibility of having the offer to counsel made by a designee of the pharmacist. On October 26, 1992, HCFA mailed written guidelines to State Medicaid Directors which specifically state that pharmacists may have ancillary personnel make the offer to counsel. Public Ex. 2., att. Ex. C at 3. NACDS also cited a September 23, 1992 letter from HCFA which states that "ancillary personnel ... may extend the offer to receive counseling if pharmacists choose not to make the offer directly." This HCFA letter changed the agency's position on this issue from an earlier letter dated September 1, 1992. The earlier letter states "the statutory language would not permit delegation by the pharmacist of responsibilities to offer to counsel, conduct counseling or to obtain patient profile information."

49. The Board relies upon the language of OBRA '90, which states that "the pharmacist must offer to discuss ...." and the expressed opinion of U.S. Senator David Pryor in a letter to Dr. Louis Sullivan, then Secretary of Health and Human Services, that "the Congressional intent which, at a minimum, should define the 'offer to counsel' as being made orally (face to face) by the pharmacist to the Medicaid patient." Exhibit P(1) at 2. The opinion of Senator Pryor regarding the meaning of OBRA '90 are immaterial and cannot be considered. Matter of State Farm Mut. Auto Ins. Co., 392 N.W.2d 558, 569 (Minn. App. 1986).

50. On November 2, 1992 HCFA issued interim regulations implementing OBRA '90. Ex. H. The regulations, codified at 42 C.F.R. § 456.700 et seq., do not clearly state who must make the offer to counsel. Instead, the regulations repeat statutory language stating, in part:

> Drug Counseling. As part of the prospective drug review program, the standards for counseling by pharmacists of recipients or the recipients caregivers must be established by State law or other method that is satisfactory to the State. State law must specify how counseling requirements apply to mail order pharmacies. The standards must meet the following requirements:
>
> (1) They require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription . . . ."

42 C.F.R. § 456.705(c).

51. Neither the cited regulation nor OBRA '90 itself require the pharmacist to personally offer counseling. Instead, they require the counseling to be "in person." The quoted words modify the phrase "to counsel", not the phrase "to offer." This is clear from the language of the Act. See Finding 43, supra. Hence, the only basis for arguing that a pharmacist must make the offer is the language of the Act stating the "pharmacist must offer to discuss" significant matters. Although the Act

refers to pharmacists, there is no known legal principle or law which would require the pharmacist to personally make the offer or prohibit delegation of the pharmacist's statutory duty. On the contrary, HCFA's most recent pronouncements indicate that the offer to counsel may be delegated. That pronouncement should be accepted.

52. A distinction between an offer to counsel and counseling was made by several commentators, with the former being delegable and the latter being the sole responsibility of the pharmacist. Twenty-six states allow a designee to make an offer to counsel to the patient. The Board has expressed its concern that delegation of the offer to counsel will result in barriers to face-to-face counseling. These fears may be well-founded. One can envision situations where the prescription is prepared by the pharmacist and obtained by the patient from a pharmacist's assistant. If the pharmacist is unavailable, the patient must either come back, telephone, or forego counseling. Even if the pharmacist is present at the pharmacy, a possibility exists that the pharmacist will be otherwise engaged and the patient will be told to wait for counseling. Nonetheless, permitting the pharmacist's designee to make the offer was not shown to be infeasible.

53. The Administrative Law Judge is persuaded that the Board's interpretation of OBRA '90 with respect to offers to counsel is incorrect. However, the Board expressed misgivings regarding the efficacy of having offers to counsel made by clerks or other subordinates. If pharmacists are not required to personally make the offer, pharmacists may not be available in sufficient numbers to offer timely consultation. This would dissuade patients from obtaining desired information. Moreover, clerks or other subordinates could make the offer to counsel in such way as to invite rejection. For these reasons, the Administrative Law Judge is persuaded that the proposed rule regarding personal, face-to-face offers to counsel is a reasonable one even though it is not required by OBRA '90. Due to the Board's failure to address small business considerations or prepare a fiscal note, however the Board cannot, require that the offer to counsel be personally made. Such a requirement exceeds minimal OBRA '90 requirements. Under Minn. Stat. § 14.115, subd. 3, agencies must incorporate feasible methods of reducing the impact of their rules on small business. In this proceeding it has failed to show that rules permitting a pharmacist's designee to make the offer to counsel are not feasible. Hence, even if reasonable, the Board's proposed requirement cannot be promulgated in this proceeding.

54. The Conference Report accompanying OBRA '90 states:

> Counseling is to include at least a reasonable effort by the pharmacist to provide face-to-face counseling to discuss matters concerning the medication.

OBRA '90 requires that counseling must be "in-person" whenever "practicable." The word "practicable" is essentially synonymous with the words "feasible" or "possible." It follows that under OBRA '90 it was intended that pharmacists will personally counsel a patient if it is possible to do so. The only recognized situation where personal counseling is not "practicable" is when prescriptions are mailed or delivered to the patient. No other situations were mentioned in the federal regulations which would make personal counseling impracticable. Exceptions apparently were not contemplated for staff shortages, high volume, or other factors. This is reflected in the plain language of the regulations proposed to implement federal requirements.

55. GHI suggested that the Board exempt health maintenance organizations (HMOs) from patient counseling requirements because OBRA '90 exempts HMOs from its requirements in that area. The Board has developed its standard based upon OBRA '90, but proposes to expand on minimum federal standards to provide a higher standard of care in providing pharmaceutical services directly to patients. Generally speaking, the Board's regulatory authority would not be limited by the terms of a federal act, like OBRA '90, and the Board would have authority to extend patient counseling to private pay patients and others. No exemption in OBRA '90 would necessarily control the Board's choices in establishing standards of pharmaceutical care. In fact, the implementing regulations specifically authorize the State to regulate HMOs. 42 C.F.R. § 456.703(b). Although it is unlikely that any HMO is a small business, it is concluded that it would be unreasonable to require HMOs to provide prospective drug use review to any patients but Medicaid patients at this time. The Board's failure to comply with small business considerations generally precludes it from extending OBRA '90 to nonMedicaid patients. HMO's should not be placed in a different position.

56. At the hearing, the Board proposed four changes in subpart 2 of proposed rule part 6800.0910. The changes clarify that the pharmacist must initiate patient counseling where new prescriptions for medication not previously taken by the patient are filled. Where a subsequent prescription is unchanged, the offer to counsel is expressly allowed to be delegated. Also, pharmacists are expressly allowed to charge their for these additional services. The changes respond to specific recommendations of commentators and were shown to be needed and reasonable. Although the Board has allowed pharmacists to charge for the additional services required by the rules, it is questionable whether obtaining reimbursement is feasible. The Board does not establish reimbursement rates for public assistance recipients or third-party payors. Hence, at this time, it appears likely that the additional costs may go largely unreimbursed. The Board did not consider delaying the effective date of its rules or other measures to address this problem.

57. When the Board's rules were initially published, pharmacists were required to personally offer to counsel with a patient about refill prescriptions, and the pharmacist was required to obtain current information on which to base patient advice. At the hearing, the Board proposed to modify the rule for prescription drugs previously dispensed to a patient. In such cases, either the pharmacist or a pharmacist's designee must attempt to determine: (1) if the patient has experienced any unexpected or unusual reaction or changes in health; (2) if the patient has experienced a favorable outcome; (3) if the patient is using the medication as prescribed; and (4) whether the patient has been using any over-the-counter or prescription drugs not in the patient's record since the patient's last visit. If a review of the patient's record or discussions with the patient show that the patient has improperly used the medication; therapeutic duplications, contraindications, or potentially harmful interactions exist; or incorrect drug dosages or treatment durations have been prescribed; the rule states that "the pharmacist shall orally counsel the patient or caregiver accordingly, in person, whenever practicable."

58. It is necessary and reasonable to allow a pharmacist or the pharmacist designee to obtain current information. It is also necessary and reasonable to require the pharmacist or his designee to offer to counsel a

patient when it appears, based on the information gathered, that consultation is necessary. However, the Board should amend the rule to make it clear that the pharmacist must review the patient's record and that the pharmacist or the pharmacist's designee need only make an offer to counsel the patient when it appears necessary. The sentence proposed by the Board reads as follows:

> If a review of the patient's record or discussions with the patient reveal any of the conditions listed in Minn. Rules, pt. 6800.3100, subpart 4, the pharmacist shall orally counsel the patient or caregiver accordingly, in person, whenever practicable.

It is suggested that the sentence be amended to read as follows:

> If the pharmacist's review of the patient's record or discussions with the patient reveal any of the conditions listed in Minn. Rules, pt. 6800.3110, subpart 4, the pharmacist or the pharmacist's designee must offer to counsel the patient or the patient's agent or caregiver regarding those conditions or other problems. The consultation must be in person whenever practicable.

59. The Board has also proposed a new paragraph which dispenses with the consultation requirement when certain refill prescriptions are involved. The new language states:

> If a prescription drug has been previously dispensed to a patient and the patient's record shows no change in the dose, dosage form, strength, or directions for use, and if none of the conditions listed in Minn. Rules, pt. 6800.3100, subpart 4 are present, the pharmacist or the pharmacist's designee shall offer counseling to the patient or caregiver.

This is a necessary and reasonable amendment. Although OBRA '90 does not differentiate between new and refill prescriptions, it must be given a practical construction. Moreover, Minn. Stat. § 151.06, subd. 1(c) refers only to "new" prescriptions. It is unlikely that Congress intended to require pharmacists to personally offer consultation services when a patient has been previously offered the opportunity for consultation or actually has been consulted by a pharmacist. Therefore, it is concluded that the amendments proposed by the Board regarding refill prescriptions are necessary, reasonable and authorized. In addition, it is concluded that the amendments do not constitute substantial changes for purposes of Minn. Rules, pt. 1400.1100 (1991).

60. The personal discussion pharmacists must have, when practicable, must include appropriate elements of patient counseling. The rule identifies the elements that should be covered, when necessary. Mr. Vrabel criticized the language of the rule which requires the consultation to include appropriate elements of patient counseling and lists some of the elements that are included. In his view, the rule appears to dictate that all elements be discussed with every patient requesting counseling for every prescription. He argued that this is impractical and does not reflect the pharmacist's ability to use professional judgment. As noted by the Board, the proposed rule does

not require pharmacists to address all the elements for each patient. The rule clearly states that pharmacists must initiate discussion of matters which "in the professional judgment of the pharmacist" will enhance or optimize drug therapy. It is concluded that the language proposed by the Board with respect to the elements of patient counseling is necessary and reasonable.

61. Charles Cooper, Director of Pharmacy at Hennepin County Medical Center, suggested that discharge prescriptions be exempted from the counseling requirements in the rules. He noted that patients being discharged from the Hennepin County Medical Center are not ambulated to the pharmacy upon discharge. Instead, their prescriptions are sent to the patient's primary care nurse who coordinates all discharge activities for the patient. In his view, coordinating patient discharges with a pharmacist at the time of discharge would be logistically impossible. He noted further that North Dakota has taken the position that direct patient counseling does not apply to hospital discharge prescriptions. Public Ex. 6.

62. Hospitals, unlike HMOs and nursing facilities, are not specifically exempted from the requirements in OBRA '90. However, OBRA '90 applies only to covered outpatient drugs. Whether a discharge prescription is an "outpatient" or "inpatient" drug is not addressed in federal regulations and was not adequately discussed by the parties. Assuming that they are "outpatient drugs", however, "covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements in OBRA '90. See, 42 C.F.R. § 456.703(c) (1992). There is no evidence that the Hennepin County Medical Center is or is not within the provisions of that regulation. Therefore, it cannot be concluded that the Board's rule is unauthorized in its application to Hennepin County Medical Center. The Board must, however, examine the language of the regulation and draft a provision implementing it because no costs can be placed on Hennepin County in this proceeding that are not required by OBRA '90.

63. At least two commentators addressed consultation with patients whose prescriptions are mailed or delivered to them. Pertinent language is found in the last paragraph of part 6800.0910, subpart 2. The pertinent provisions of that paragraph, as amended at the hearing, state:

> ". . . When a new prescription or a refilled prescription for which counseling is required, is being mailed or delivered to the patient by common carrier or delivery services, the pharmacist shall initiate counseling by telephone. If the counseling cannot be completed by telephone, the pharmacist may use alternative forms of communication.

As initially published, the rule stated that consultation could be accomplished by telephone or in writing. When prescriptions are mailed or delivered to a patient, face-to-face consultation is impracticable. Hence, federal regulations require that states specify how counseling requirements apply to mail order pharmacies. 42. C.F.R. § 456.705(c) (1992). GHI suggested that requiring pharmacists to make a telephone offer of counseling will result in pharmacists spending an inordinate amount of time attempting to track a patient down and that such a requirement does not provide the best use of professional resources. Mr. Christenson of the Mayo pharmacy made similar

arguments. He also noted that the date and time of the delivery of the prescription would not be known to the pharmacist. GHI recommended that the rule be amended to permit the offer to be made by telephone or in writing. Mr. Christenson suggested, alternatively, that pertinent printed material be required to be included with each mailed or delivered prescription which would contain a toll-free telephone number for long-distance calls.

64. The rule proposed by the Board, as amended at the public hearing, even if necessary and reasonable, must be amended to permit a pharmacist's designee to make the offer to counsel. See Finding 53. Alternatively, it can be amended to permit the offers to counsel to be made in writing and a toll-free number provided for long-distance calls. Also, as suggested by GHI, if an attempt to telephone a patient is unsuccessful or the patient refuses counseling, the rule should specify the information that must be documented and specifically authorize recording that information in the patient's record or in a specially developed log.

65. The Long-Term Care Pharmacy Group suggested that long-term care pharmacies directing prescriptions to long-term care residents should be exempted from the requirements in part 6800.0910, subpart 2 because they are exempted under federal regulations. Ex. E. The last paragraph of subpart 2 states:

> Personal communication by the pharmacist is not required for inpatients of a hospital or other institution where other licensed health care professionals are authorized to administer the drugs. . . .

It is unclear if the Board intends to include long-term care facilities within the phrase "other institution." This must be clarified. The Board could, for example, add the words "such as a long-term care facility" after the words "other institution" in the last paragraph of subpart 2. Because of the Board's failure to properly follow small business requirements, it cannot require long-term pharmacies exempt from OBRA '90 under 42 C.F.R. § 456.703(b) (1992) to comply with the prospective and retrospective drug use reviews in the Act. Hence, the federal exemption must be incorporated into the rule.

Part 6800.1050 - Required Reference Books and Equipment for Pharmacies.

66. Subpart 1 of proposed rule 6800.1050 requires that pharmacies keep certain reference works, or equivalent works approved by the Board, on hand. John Stevens, R.Ph., a community pharmacist in Lake City, speaking on behalf of the Minnesota Pharmacists Association objected to this requirement as an unreasonable intrusion into a pharmacist's professional judgment. However, the requirement is not new. The proposed rule merely updates some of the reference works required and adds several new ones. Because equivalent works, approved by the Board can be used, the proposed subpart is a reasonable means of ensuring that information is available to the pharmacist in carrying out the preparation and dispensing of medications.

67. Mr. Stevens also suggested that pharmacists should have the discretion to use electronic references rather than having tangible reference books on site. The Board should consider specifically stating that if the

required references are electronically accessible by its pharmacists, the pharmacy is not required to have tangible reference books on site. Requiring pharmacies to purchase books, when the same information is readily available through a computer, is obsolete.

68. Mr. Vrabel objected to the use of "sterile" in subpart 3(c) (referring to gloves, masks, and gowns), and suggested that the term be added to item b (referring to filters, needles, and syringes). The Board apparently agrees with this change. The modification clarifies the rules and does not constitute a substantial change. Proposed rule 6800.1050, as modified, is needed and reasonable.

Part 6800.1500 - Continuing Education.

69. Continuing education for pharmacists is required by proposed rule 6800.1500. The Board's language alters subpart 2 to make some grammatical changes and require each pharmacist to keep records of that pharmacist's attendance at continuing education. Mr. Stevens, suggested that attendance at live presentations be required. Joe Meese, R.Ph. suggested that the number of continuing education hours be increased. The Board suggested that such requirements would impose too great a burden on pharmacists, particularly in rural areas, and the change would constitute a substantial change. Many pharmacists attended the hearing and were, therefore, available for comment on this issue. No support for the need to make either change was forthcoming. Even if the changes proposed by these commentators are not substantial changes, they need not be addressed. Subpart 2 is needed and reasonable as proposed.

Part 6800.2250 - Unprofessional Conduct.

70. Mr. Vrabel requested clarification of the prohibition against drug diversion in proposed rule 6800.2250, subpart 4. He suggested that the Board add language to ensure that pharmacists who participate in "hospital buying groups" are expressly excluded from the prohibition against drug diversion. The Board indicated that Minn. Stat. §§ 151.44 and 151.46 expressly authorize the activities of buying groups, and that it does not object to adding language to incorporate the statutory exemption. The Administrative Law Judge suggests the Board use the following language in a new item in subpart 4:

> D. the sale, purchase, or trade of a drug or the offer to sell, purchase or trade a drug between members of a group purchasing organization as defined in Minn. Stat. § 151.44(a)(2).

The suggested language is needed and reasonable and would not constitute a substantial change, if the Board chooses to add that language.

Part 6800.3000 - Acceptance of Order and Distribution of Medication; Fax Transmission of Prescriptions.

71. Proposed rule 6800.3000 is altered by adding subpart 2, which permits use of facsimile transmission machines (fax) for transmitting certain prescriptions or drug orders. At the hearing, the requirement that pharmacies adopt written procedures for facsimile transmissions before accepting them was

deleted. Mr. Fuhs, on behalf of Bruce Scott, Director of Pharmacy for United Hospital and Children's Hospital, suggested that the prohibition against filling Schedule II-IV prescriptions by fax be replaced by a requirement that U.S. Drug Enforcement Agency (DEA) regulations must be followed for fax prescriptions. The Board made that change in order to avoid the need to change its rules if DEA regulations are changed. Prescriptions directly from the patient cannot be filled by fax. A copy of the prescription must be legible for five years or the hard copy must be sent, and prescriptions transmitted from within the facility must have a method of identifying the sender. Mr. Stevenson and Mr. Fuhs objected to the five-year requirement and suggested two years as the appropriate standard. The Board indicated that the five-year requirement is based on the U.S. Food and Drug Administration inspection standards. The five-year requirement is needed and reasonable. Proposed rule 6800.3000, as modified, is needed and reasonable. The changes do not constitute substantial changes.

Part 6800.3110 - Patient Medication Profiles

72. The existing rule part, Minn. Rule 6800.3100, subpart 2, requires certain patient information to be recorded. This information identifies the patient and includes all prescriptions filled at that pharmacy within the last two years. The information required under the new rules retains the patient identification provisions and adds the patient's medical history, where significant, and the pharmacist's comments about the patient's drug therapy. The two-year provision is deleted. At the hearing, the Board modified the proposed rule to require that the medical history of the patient be reviewed with the patient if that information is obtained by someone other than the pharmacist. Mr. Stevens suggested that delegation be permitted for recording the information other than the medical history and pharmacist's comments. The Board acknowledged that such a delegation would be permissible, but did not propose a change in the rule language. The Administrative Law Judge suggests that the word "pharmacist" be replaced with the word "pharmacy" in the first line of subpart 2 to accomplish the commentator's intent. This language change is not required, but will accomplish the Board's intent without adversely affecting patient care. Subpart 2, as modified, is needed and reasonable, and none of the changes discussed in this Finding constitute a substantial change. However, the new language, if adopted, can be applied only to Medicaid recipients.

73. Subpart 3 replaces a requirement that pharmacists document allergies and other drug utilization information with three specific requirements. As amended at the hearing, subpart 3 will read as follows:

> Documentation. In meeting the requirements of subpart 2, item C, the pharmacist shall document:
>
> A. the pharmaceutical care needs of the patient;
> B. the services rendered by the pharmacist; and
> C. the pharmacist's impression of the patient's drug therapy.
>
> This documentation is not required for residents of a long-term care facility where a consultant pharmacist is performing regular drug regimen reviews.

Subpart 3 is one of the most controversial provisions proposed by the Board and was the subject of a significant amount of public comment. William J. Nelson, Pharmacy Director of Pilot City Health Center (Pilot City), objected to the documentation requirements of subpart 3 on the ground that the Board's rule is not reasonable. Pilot City maintains that the rule requires all prescriptions to be documented, while under OBRA '90, only 25% of prescriptions would require documentation. Owing to changes in the computer processing system that would be required, Pilot City estimates an initial cost of $30,000 to implement compliance and an annual cost of $20,000 thereafter.

74. Other commentators discussed the cost of complying with the documentation requirements in subpart 3. Ms. Young, speaking on behalf of GHI, estimated that the documentation requirements in subpart 3 will add two minutes time to process a prescription. Since GHI fills over 700,000 prescriptions annually, GHI estimated that its operating expenses would increase by $500,000 annually to comply with the rule. She stated that the documentation requirements will not improve patient care and will require large expenditures for unnecessary clerical functions that must be performed by pharmacists. Darwin Zaske, Director of Pharmacy for St. Paul-Ramsey Medical Center, made similar comments. He stated that the documentation requirements in subpart 3 will essentially require the regeneration of a patient's medical record and result in inordinate costs. He stated that the extent of the documentation required should be based on the professional judgment of the pharmacist in order to eliminate unnecessary documentation. Mr. C.F. Richards, Senior Associate Administrator of the Hennepin County Medical Center, also argued that subpart 3 should be deleted to eliminate unnecessary cost increases having little or no benefit to patients.

75. Clayton K. Whitehead, Manager of Pharmacy Operations for Snyder Drug Stores, Inc., and others, objected to the Board's approach to pharmacist's services in requiring documentation of "pharmaceutical care" in subpart 3A. The commentators maintained that pharmaceutical care is a relatively new concept in the practice of pharmacy and has not been validated by research. The objections to pharmaceutical care and documentation are that these requirements will impose costs not required by OBRA '90 and have not been demonstrated to be necessary. However, many pharmacists are incorporating pharmaceutical care into their practices and no one suggested that such practices are inappropriate for pharmacists. Where a physician has diagnosed a patient's condition and prescribed medication, most patient pharmaceutical care needs will be accurately reflected in the prescription itself. However, a significant number of patients will exhibit needs directly related to the prescribed drug therapy which require the attention of a professional attuned to the interaction of medications, or the impact of one specific medication. In such instances, requiring documentation of pharmaceutical care needs promotes the patient's best interest.

76. Bruce Scott, President of the Minnesota Society of Hospital Pharmacists (MSHP); Mr. Broekemeier; Richard J. Streit, R.Ph., M.S., Director of Pharmacy Services for Saint Mary's Hospital; and Mr. Christenson, suggested that documentation by exception be adopted. Under this approach, the documentation requirements would only apply where the purpose for the prescription is not obvious or unique factors are encountered. The Board expressed a willingness to "develop appropriate language to require documentation only of deviations from the established policies and procedures [i.e. documentation by exception]." Board's April 7, 1993 Comment, at 3. The Board did not suggest any language in its comment.

77. The Board's failure to indicate the language it is proposing to address comments regarding documentation by exception makes it impossible to determine the appropriateness of the language it proposes to add to the rules. In an agency's post-hearing comments, if the agency is willing to adopt changes, the specific language it is willing to enact should be proposed so that interested persons can comment on it and the Administrative Law Judge is in a position to review it. Hence, when the Board submits its final version of the rules to the Chief Administrative Law Judge, the language it proposes to authorize documentation by exception will be reviewed for need and reasonable at that time.

78. Although there may be some benefit in requiring the detailed documentation mandated under subpart 3, the documentation requirements in the rule far exceed the requirements in OBRA '90. Federal regulations adopted to implement that act state as follows:

> Profiling. The state must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(3) of this section.
>
> (1) Name, address, telephone number, date of birth (or age), and gender of the patient.
>
> (2) Individual medical history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
>
> (3) Pharmacist's comments relevant to the individual's drug therapy.

42 C.F.R. § 456.705(d) (1992)

As noted by Mr. Zaske, the documentation required under subpart 3 far exceeds the requirements of OBRA '90. Because the Board did not adopt a fiscal note dealing with the increased costs of extending OBRA requirements to all prescriptions or the impact its expanded rules will have on small businesses, subpart 3 cannot be adopted as proposed by the Board. The Board may, however, implement its proposed requirements consistent with minimally required federal standards which the state must adopt in spite of financial and economic considerations. Hence, subpart 3 must be amended to parallel the language in OBRA '90 and implementing federal regulations cited above.

79. Rochester Methodist Hospital and Mr. Fuhs suggested that subpart 3 be deleted and subpart 2 be expanded and clarified by moving subpart 3A, B, and C to subpart 2C and prefacing them with the words "Where appropriate, this may include the documentation of the following for each prescription:" That language, with the substitution of "shall" for "may," would accomplish the intended result. The other method of altering the rule requirement without resulting in a substantial change is to interpret the requirement of subpart 2C, that pharmacists record "comments relevant to the individual's drug therapy", to mean that only comments which add to the prescription itself are required. If this interpretation is acceptable to the Board, it should so indicate when the rule is adopted. Both approaches are needed and reasonable. The changes to subpart 3, if adopted, are not substantial changes.

80. Subpart 4 establishes a drug use review requiring prospective analysis of prescribed medications to determine whether proper utilization, unnecessary duplication, contraindications, interactions, or abuse are occurring. Computer review of drug use profiles is expressly permitted, with some changes to that language proposed at the hearing. OBRA '90 expressly requires drug utilization review for Medicaid patients and the Board has extended that requirement to all patients. The proposed rule, as modified, is needed and reasonable. However, due to the Board failure to prepare a fiscal note regarding the impact of its rules on local governmental bodies and its failure to follow the small business requirements in the Administrative Procedure Act, the provisions of subpart 4 must be limited to Medicaid prescriptions.

Part 6800.3300 - Bulk Compounding

81. Proposed rule 6800.3300 modifies an existing rule which allows bulk compounding, by limiting the medications compounded to the pharmacy's own use. In addition, the information required on the medications compounded is increased, raw materials must be obtained from sources approved by the U.S. Food and Drug Administration (FDA), and only a three-month supply of bulk compounded medications may be prepared per batch, based upon the historical dispensing records of the pharmacy. Mike Jones of Gallipont Labs objected to the requirement that raw materials be obtained from FDA-approved sources, on the ground that the FDA does not approve those facilities. The Board concurred with the objection and modified the rule to require raw materials be obtained from FDA-inspected sources, when possible. At the hearing, the Board modified the rule to require pharmacists to "receive, store, or use" drug components from FDA-inspected sources and use drug components that meet the official compendia requirements. Only if neither of those requirements can be met can pharmacists then use their professional judgment to obtain alternatives. This modification meets the objection of the commentator, recognizes that pharmacists are occasionally forced to use alternative supplies, and establishes an order of use consistent with the best interests of patients. These changes do not constitute substantial changes. The proposed rule is needed and reasonable, as modified.

Part 6800.3350 - Expiration Dates

82. The Long Term Care Pharmacy Group objected to subpart 3 of proposed rule 6800.3350 which requires blister card-packaged medications to carry an expiration date of not more than one-quarter of the time from the date of compounding to the manufacturer's expiration date. It maintained that this provision unduly limits the shelf life of blister card-packaged medications. The Board responded that both the U.S. Pharmacopeia and the FDA maintain the standard used in the rule. The Board has shown that its rule is needed and reasonable to conform to a national standard.

Part 6800.3450 - Labeling of Outpatient Intravenous Admixture Drugs

83. Part 6800.3950, subp. 3 requires that pharmacies engaged in dispensing outpatient intravenous admixtures must develop a "permanent" audit trail system which will identify the dispensing pharmacist for each unit dispensed. Several speakers questioned the reasonableness of requiring a

"permanent" audit trail. Requiring a permanent trail is, of course, unreasonable. The Board recognized this and has proposed to require that the audit trail be limited to a period of five years. An amendment to the rule containing a five-year limitation, which is consistent with other state and federal regulations, is reasonable and amendment does not constitute a substantial change for purposes of Minn. Rules, pt. 1400.1100 (1991).

Part 6800.3850 - Supportive Personnel

84. Over the past years, the Board has periodically received information from pharmacists that technicians have been involved in diverting drugs from pharmacies. At the present time, the Board has not required pharmacists to identify the technicians who are involved in drug thefts. Consequently, these technicians are frequently rehired by another pharmacy where they may again become involved in drug thefts. The Board has determined that it should keep track of these individuals and has adopted new rules to do so. Subparts 10 and 11, which contain all new language, state:

> Subp. 10. Pharmacists-in-charge to report. The pharmacist-in-charge of a pharmacy where a supportive person, or technician, is found to have diverted or misappropriated drugs shall immediately report that fact and the identity of the individual involved to board.
>
> Subp. 11. Registration of technicians. The Board shall maintain a record of individuals employed as pharmacy supportive personnel, or pharmacy technicians, and of individuals reported to the board in accordance with subpart 10. The board shall provide to pharmacists who inquire any information in its possession regarding specific supportive personnel.

Ms. Young, speaking on behalf of GHI, properly questioned these rules. She suggested that the Board strike subp. 11 and clarify the words "is found to have diverted or misappropriated drugs" in subp. 10. In response to her comments the Board has not offered any clarifying language.

85. The language in subp. 10 is not sufficiently specific. The words "found to have diverted or misappropriated drugs" are unclear and do not identify who must make a finding of misappropriation or diversion or what constitutes a finding of misappropriation or diversion. Furthermore, the language in subpart 11 is unreasonable because it creates a blacklist. It sounds like the Board is attempting to require pharmacies to report the name of any technician suspected of diverting or misappropriating drugs and that the names of those persons will be disclosed to other pharmacies if an inquiry about the individuals is made. Such a proposal offends due process requirements. The individual's interest in employment, as well as in the individual's reputation, cannot be impaired on the basis of mere suspicions. It is concluded, therefore, that the need and reasonable of subps. 10 and 11 has not been established with an affirmative presentation of fact. The Board may need a procedure for identifying persons who have been convicted of diverting or misappropriating drugs. To that end, it may wish to require pharmacies to report these suspected thefts of drugs to the police and to it.

However, the Board must spell out in detail who must report drug thefts to the police or to the Board and how information regarding convictions will be gathered and maintained. The Board cannot merely maintain a list of individuals suspected of drug thefts and disseminate that information in the absence of a conviction or some opportunity by the individual to obtain a hearing.

Part 6800.3950 - Electronic Data Processing; Computer Usage

86. As originally proposed, part 6800.3950, subpart 2D(1) required that patient profile records be kept for hospitalized patients until discharge. Mr. Vrabel suggested that the records be kept for a minimum of two years. The Board concurred, but did not suggest language to effectuate this change. The Administrative Law Judge suggests that item D(1) be amended by adding the following language:

> After a patient's hospital discharge, the records shall be kept in the computer system or on hard copy and be immediately retrievable for two years.

The new language does not constitute a substantial change. The Board has shown the rule, as modified, to be needed and reasonable.

87. The Minnesota Pharmacists Association objected to the requirement of subpart 5 that the Board be notified if dispensing information is lost by computer system interruption (a computer "crash"). The Board has received inquiries from patients about lost prescription information and must be in a position to respond to these inquiries. Further, if a pharmacy is using unreliable equipment or improper computer processing techniques, the Board has an interest in that information. Requiring reporting of the loss of dispensing information within 72 hours has been shown to be needed and reasonable.

88. Subpart 6 requires computer generated labels, receipts, duplicate prescriptions or other printed matter which will be attached to the hard copy prescription must be affixed so the face of the prescription is unobstructed. Rich Braun, District Manager for Shopko and Cub Pharmacies, took this requirement to mean that nothing could overlay the prescription and objected since the system used in his pharmacy creates a "hinge" for other printed information to lay across the front of the prescription. The Board explained at the hearing that overlaying the prescription was not prohibited, so long as the obscuring addition could be moved to enable the prescription to be read. Thus, attaching a document to the top of the prescription with a staple or tape is acceptable, but using adhesive over the full back side of the added document is prohibited. Subpart 6 is needed and reasonable, as proposed.

Part 6800.4500 - Controlled Substance Samples

89. The Minnesota Pharmacists Association urged that distribution of samples of controlled substances be prohibited to prevent misuse of those drugs. The Board declined to change the rule because it would be controversial and interested persons did not have notice that such a rule was being considered. The existing rule is necessary and reasonable.

Part 6800.4600 - Perpetual Inventory

90. The Minnesota Pharmacists Association suggested that reconciliation of Schedule II drugs be performed biennially rather than using the perpetual inventory required under proposed rule 6800.4600. The Association cites DEA requirements for an inventory every two years as being the only needed inventory. The Board explained that the DEA inventory is used for audits and was not required to be reconciled. The Board pointed out that a perpetual inventory is now in use in three large pharmacy systems and in every major hospital in Rochester, Minneapolis, St. Paul, and Duluth. All of these inventories are reconciled at least monthly. The Board cites the added advantage of detecting missing controlled substances in a timely fashion as supporting use of a perpetual inventory system. The Board has shown that rule 6800.4600 is needed and reasonable as proposed.

Part 6800.5350 - Preceptors

91. As part of its oversight responsibilities, the Board has proposed standards for pharmacists who seek to be preceptors. These pharmacists supervise interns to ensure that the interns are exposed to the practice of pharmacy while protecting patients. Mr. Vrabel objected to the standards for being a preceptor as too restrictive, particularly for a pharmacist with experience in another state. The Board reduced the required standards from a full-time pharmacist to a half-time pharmacist. The Board also stated that "some practice in Minnesota, under Minnesota laws and rules, should be required before the pharmacist can act as a teacher for pharmacy students, perhaps one year or 2,000 hours of such practice might be acceptable." The Board did not suggest any language to carry out this modification. If the Board chooses to modify the rule further, the Administrative Law Judge suggests the following language:

> B. they have completed at least 4,000 hours of pharmacy practice after licensure, with at least 2,000 hours of that pharmacy practice after licensure as a pharmacist in Minnesota.

The Board cannot use one year as a measure, since that amount of experience is vague. A pharmacist could work part-time and amass significantly less experience than the required 2,000 hours. The rule has been shown to be needed and reasonable. The modifications proposed and suggested do not constitute substantial changes.

Part 6800.6500 - Consultative Services to Long-Term Care Facilities

92. At the hearing, Mr. Vrabel questioned the intent of the language proposed for subpart 2H of part 6800.6500. Subpart 2H allows preparation of a 72-hour supply of medications for residents spending time away from long-term care facility. The commentator questioned whether a 72-hour supply meant for one patient, all patients, or something in between. The Board responded that the 72-hour supply was per patient, and as many kits could be prepared as needed. The proposed rule is not unduly vague. Subpart 2H is needed and reasonable, as proposed.

Part 6800.6700 - Drugs for Use in Emergency Kits

93. Emergency kits are supplies of medications which, in the experience of long-term care facilities, are needed to care for patients in life-threatening situations. The existing rule for these kits, part 6800.6700, is modified in the proposed rules to give quality assurance and assessment committees in these facilities more latitude in determining the contents of these kits. Mary Absolon, Program Manager of the Survey and Compliance Division of the Department of Health, objected to the term "quality assurance and assessment committee" since that term is not used by the Department of Health. The Board explained that while the term is not required under any rule each facility has such a committee under one name or another, and these committees have dealt with the issues in the rule parts where these committees are mentioned. Proposed rule 6800.6700 is needed and reasonable with the minor modification made at the hearing (changing "pharmacist" to "pharmacy"). The change is not a substantial change.

Part 6800.7200 - Administration

94. The use of hoods to prepare intravenous solutions (IVs) was questioned by Mr. Vrabel. He suggested that IVs should be prepared in hoods, except those which were to be used immediately. Mr. Vrabel maintains that IVs used immediately did not provide an opportunity for contaminants to interact and cause harm to the patient. The Board agreed that the risk of contamination was low, and at the hearing, it modified the rule to require use of hoods "whenever possible." The change gives pharmacists discretion in emergencies and does not constitute a substantial change. The rule, as amended, is necessary and reasonable.

Part 6800.9950 - Dispensing by Practitioners

95. Mr. Stevens urged the requirements for patient counseling and drug utilization review be imposed upon nonpharmacists who dispense medications. The Board noted that OBRA '90 is limited by its terms to pharmacists. Requirements for patient counseling and drug utilization review contained in the rules are based upon the OBRA '90 requirements. The rules as proposed in the State Register did not suggest that practitioners would be required to comply with the patient counseling or drug utilization review provisions. This lack of notice would adversely affect practitioners who would reasonably have been expected to participate in the rulemaking process. This lack of notice violates Minn. Rule 1400.1100, subpart 2. Making the suggested change would result in a rule substantially different from the rule published in the State Register and constitute a defect in the proposed rule.

Part 6800.9953 - Labeling

96. Neil Thompson, a community pharmacist, objected to proposed rule 6800.9953 to the extent that unit doses are excluded from the general labelling requirement. The Board has previously cited the statutory provision allowing samples and has not suggested any change to this rule part. The exemption of samples from the labelling requirement is needed and reasonable. Samples are prepared by the manufacturer and only limited information need be provided to ensure proper use of the sample medication.

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

CONCLUSIONS

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

2. That the Minnesota Board of Pharmacy 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.

3. That the Minnesota Board of Pharmacy 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 9 and 17.

4. That the Minnesota Board of Pharmacy 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 Finding 85.

5. That the amendments and additions to the proposed rules which were suggested by the Minnesota Board of Pharmacy 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 11, 18, 45, 53, 55, 62, 64, 65, 72, 78, 80 and 85.

7. That due to Conclusions 3, 4 and 6, 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 Minnesota Board of Pharmacy 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 26th day of May, 1993.

Jon L. Lunde by GAB

JON L. LUNDE
Administrative Law Judge

Reported: Taped, no transcript prepared.