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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST RICHARD KEITH ONSON, R.Ph., and MERCY MEDICAL CENTER, RESPONDENTS.	:	FINAL DECISION AND ORDER LS9212081PHM

The State of Wisconsin, Pharmacy Examining Board, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, makes the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Pharmacy Examining Board.

The rights of a party aggrieved by this Decision to petition the department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated this 9 day of NOVEMBER, 1993.

Charles H. Dinkel, R.Ph.

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST RICHARD KEITH ONSON, R. PH., and MERCY MEDICAL CENTER, RESPONDENTS.	: : : : : :	PROPOSED DECISION Case No. LS-9212081-PHM (DOE case number 92 PHM 51)

PARTIES

The parties in this matter under § 227.44, Wis. Stats. and § RL 2.036, Wis. Adm. Code, and for purposes of review under § 227.53, Wis. Stats. are:

Complainant:
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708

Respondents:

Richard Keith Onson, R. Ph.
3951 Leonard Road West
Oshkosh, WI 54904

Mercy Medical Center
Box 1100
Oshkosh, WI 54902

Disciplinary Authority:
Pharmacy Examining Board
1400 East Washington Ave.
Madison, WI 53708

FINDINGS OF FACT

1. Respondent Richard Keith Onson is and was at all times relevant to the facts of this case a registered pharmacist licensed in the state of Wisconsin, under license number 11139. Since March 19, 1988, Mr. Onson has been the director of pharmacy and managing pharmacist of co-respondent Mercy Medical Center pharmacy.

2. Respondent Mercy Medical Center is and was at all times relevant to the facts of this case a hospital pharmacy licensed in the state of Wisconsin, under license number 2021.

3. Larry Woltman, R.Ph. started working as a staff pharmacist at Mercy Medical Center a few weeks before Mr. Onson became managing pharmacist. From March 19, 1988 until he left Mercy Medical Center's employ on August 29, 1989, Mr. Woltman was supervised by Mr. Onson.

4. Mr. Woltman committed four documented dispensing errors and four documented medication errors during his employment with Mercy Medical Center:

a. On or about April 17, 1988, Mr. Woltman prepared and dispensed an I.V. which was labeled "KCl 15 mcg D5LR 1000 ml" in a D5/w 500 ml bag. The medication was apparently administered to the patient.

b. On or about May 10, 1988, Mr. Woltman prepared a heparin I.V. and mislabeled it so that it was administered for eight hours at double the correct rate.

c. On or about June 2, 1988, Mr. Woltman dispensed an I.V. containing sodium chloride for a patient who was to receive potassium chloride; the error was discovered by a nurse and corrected before it was administered to the patient.

d. On or about September 19, 1988, Mr. Woltman filled a prescription for Xanax 0.5 mg. with Xanax 0.25 mg.; the error was discovered by a nurse and corrected before it was administered to the patient.

e. On or about November 7, 1988, Mr. Woltman filled a prescription for Tocainide 400 mg. with Tolectin 200 mg.; the error was discovered by a nurse and corrected after one dose had been administered.

f. On or about July 6, 1989, Mr. Woltman dispensed a syringe of heparin 8000 units/10 ml instead of heparin 10 units/10 ml.; the error was discovered by the patient's mother before it was administered.

g. On or about July 20, 1989, Mr. Woltman received an order for doses of digoxin 17 mcg./0.068 ml. and entered the order on the pharmacy computer as .17 mg (170 mcg.) /0.068 ml. The medication was later prepared as specified on the computer and two doses were administered to the patient, causing death.

h. On or about August 19, 1989, Mr. Woltman filled an order for 50% glucose with sodium bicarbonate; the error was discovered by a nurse before it was administered.

5. The incidents in April, May and June 1988 were recorded in handwritten notes (exhibit J attached to the Second Stipulation). The other incidents were written up in one or more reports (exhibits A through E attached to the first stipulation and exhibit H attached to the second stipulation), which were prepared and maintained by Mercy Medical Center pursuant to the protocols and procedures it had established to address incidents of medication or pharmacy dispensing error. Mercy Medical Center and Mr. Onson, or their agents, had knowledge of the facts in all of the reports no later than two days after the date of the report, and they took the actions set forth in the reports in response to the errors identified.

6. Neither Mr. Onson nor Mercy Medical Center reported any of the dispensing and medication errors to the Pharmacy Examining Board.

7. The Pharmacy Examining Board has not previously imposed discipline upon any pharmacist or hospital pharmacy solely for the offense alleged here, i.e. failing to report to the board either a single error or a series of dispensing errors, under § Phar 10.03(7), Wis. Admin. Code or its predecessor rules.

8. The Pharmacy Examining Board intended the rule now designated § Phar 10.03(7) to require reporting to the board of all incompetent, unprofessional or illegal practice by pharmacists. In its final revision the language of the rule was made more general so that a pharmacist would not be required to make a determination as to whether a particular unsafe act fit the legal definition of "incompetent, unprofessional or illegal practice". By broadening the language of the rule, the board created an obligation to report every dispensing and medication error made by every pharmacist in Wisconsin.

9. § Phar 10.03(7), Wis. Admin. Code is unclear and ambiguous. This is primarily due to the general and non-specific language of the rule. It is also partly due to a lack of the publicity which could be expected to attend such a significant new professional obligation.

CONCLUSIONS OF LAW

I. The Pharmacy Examining Board is the legal authority responsible for issuing and controlling credentials for pharmacists and pharmacies, under ch. 450, Stats. The Pharmacy Examining Board has jurisdiction over Mr. Onson's license and Mercy Medical Center's license.

II. The Pharmacy Examining Board has personal jurisdiction over the Respondents under §801.04 (2), Wis. Stats., based on their receiving notice of the proceeding, and their holding credentials issued by the board.

III. The Pharmacy Examining Board has jurisdiction over the subject-matter of a complaint alleging unprofessional conduct, under § 15.08(5)(c), Wis. Stats. and § 450.10, Wis. Stats.

IV. Under the rule currently designated § Phar 10.03(7), Wis. Admin. Code, Mr. Onson and Mercy Medical Center had a duty to report any incompetent, unprofessional or illegal act by a pharmacist which endangered the health, safety or welfare of a patient or the public, and they violated that rule by failing to report each of Mr. Woltman's dispensing and medication errors to the Pharmacy Examining Board.

V. § Phar 10.03(7), Wis. Admin. Code does not provide adequate notice to pharmacists of their duty to report all dispensing and medication errors.

ORDER

THEREFORE, IT IS ORDERED that the complaint in this case be dismissed.

DISCUSSION

The disciplinary complaint in this matter alleged that the respondents failed to comply with what is now administrative rule § Phar 10.03(7)[1], which requires all pharmacists and pharmacies to report to the board "any pharmacy practice which constitutes a danger to the health, safety or welfare of the public". The situation which led to this proceeding, stated in more detail in the findings of fact, is that a pharmacist in the employ of Mercy Medical Center and supervised by Mr. Onson committed a number of dispensing and medication errors[2], one of which caused the death of a patient. It is undisputed that the respondents did not report these errors to the board, and the issue in this case is solely one of legal interpretation: whether § Phar 10.03(7) creates a duty to report dispensing and/or medication errors to the board.

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[1]Though renumbered, the current text of the rule is identical to that in effect throughout the period of the events in the complaint.

[2]As defined in the Policy and Procedure Manual of Mercy Medical Center (exhibit G to the first stipulation), a "medication error" is "the administration (or omission) of a medication in a manner not prescribed by the attending physician or approved by hospital policy/procedure. Also, the dispensing of a medication to an outpatient which differs in strength, quantity, substance or any other manner from that prescribed by the physician, unless it is a pharmacy and therapeutics committee approved substitution". A dispensing error" is "a prescription which is filled inaccurately, omitted, or is incorrect, but which has not been administered to an inpatient or an outpatient who is receiving treatment at Mercy Medical Center". Mr. Woltman committed four documented dispensing errors and four documented medication errors.

To begin with, no distinction can be found in § Phar 10.03(7) between a single error and a series of errors, nor between a dispensing error and a medication error, nor between a "minor" error and an error which causes the death of a patient. The Division of Enforcement, in its trial brief, stated that the respondent violated the rule in two ways, by failing to report a "pattern of conduct" and by failing to report the error which caused a patient's death. The Division's expert, James O'Donnell, opined that dispensing errors are not reportable and a medication error is reportable only if it causes harm [transcript, pp. 31-33]. However, neither of these assertions is supported by language in any statute or rule. The only qualifying language in the rule is the phrase "that constitutes a danger to the health, safety or welfare of the public", and even the most minor dispensing error will normally satisfy that test. No other language in § Phar 10.03(7) or any other rule refers to a "pattern of conduct" or states a specific number of errors that constitutes a pharmacy practice, nor a time period within which a number of errors must be committed to be considered a pattern, nor a type of error or degree of seriousness which distinguishes some errors from others. Therefore, **if § Phar 10.03(7) imposes a duty to report errors, it is a duty to report every medication error and every dispensing error committed by every pharmacist in Wisconsin.**

In an effort to properly interpret the reporting requirement, the parties turned first to the language of the Wisconsin statutes and administrative rules, and then to the legislative history of § Phar 10.03(7) and to expert testimony on how the requirement <u>should</u> be understood and how it <u>is</u> understood.

<u>The Language of the Rules and Statutes.</u>

The parties and the expert witnesses all gave their interpretations of "pharmacy practice" and "the practice of pharmacy" as defined in the statutes and code. The complainant's position is that dispensing and medication errors should be considered a "pharmacy practice" which would make them reportable under § Phar 10.03(7). The respondent, Mr. Onson, argued that although the errors occurred in the practice of pharmacy, they do not constitute "a pharmacy practice", and he testified that his understanding of "pharmacy practice" as used in § Phar 10.03(7) covered only "fraudulent-type practices of diversion, use of unsafe drugs" [transcript, pp. 17-18]. This concept was broadened in the testimony of respondents' expert witnesses. David Brushwood interpreted "pharmacy practice" as "a system of practice or a structure of practice" [transcript, p. 103], William Herbert gave his opinion that "It's a system or process. It's the usual way of doing business" [transcript, p. 142], and Thomas Thielke stated that it means "the systems, policies and procedures, structures, that are in place in a pharmacy ... that create an environment that will protect the safety of patients" [transcript, p. 204]. All of the respondents' witnesses either explicitly or implicitly rejected the idea that dispensing and medication errors should be considered "pharmacy practice" under § Phar 10.03(7). However, none of the witnesses clearly established his interpretation as authoritative. Since the meaning of statutes and rules is a matter of the interpretation of law, I do not feel bound to follow the rationale of any of the witnesses.

Section 450.01(16), Stats. defines "The practice of pharmacy". Section 450 09, Stats. is entitled "Pharmacy Practice". Chapter Phar 7, Wis. Admin. Code is entitled "Pharmacy Practice".[3] However, attempting to resolve this issue by making distinctions between those three is to engage in unjustified hairsplitting. The items described as "pharmacy practice" in § 450.09, Stats. are completely different from those described as "pharmacy practice" in ch. Phar 7, (aside from the common mention of a medical profile record system). Further, "compounding" and "dispensing" are mentioned in both § 450.01(16) and ch. Phar 7. These differences and similarities, as well as a common-sense interpretation of language, lead to the conclusion that each section merely describes certain aspects of the same concept, and that no hard and clear distinction was ever intended between "the practice of pharmacy" and "pharmacy practice".[4] Therefore, the analysis of § Phar 10.03(7) cannot reasonably be based on a finding that it was intended only to apply to the items labeled "pharmacy practice" in § 450.09, Stats. and ch. Phar 7, and not those labeled "the practice of pharmacy" in § 450.01(16), Stats.[5]

However, even concluding after this analysis that no meaningful distinction exists between "pharmacy practice" and "the practice of pharmacy", a question remains as to whether the phrase "any pharmacy practice" in § Phar 10.03(7) was intended to cover dispensing and medication errors, which are lapses from what would be considered proper and prescribed practice. Since the rule does not give a clear answer to that question, and in light of the testimony of respondent's expert witnesses referred to below, **I find that § Phar 10.03(7) is ambiguous, and in that circumstance it is appropriate, as the parties have done here, to go beyond the text of § Phar 10.03(7) to ascertain its meaning.**[6]

The Legislative History of § Phar 10.03(7).

The rule as first proposed, prior to the public hearing, read "failing to report incompetent, unprofessional or illegal practice of any pharmacist or other health care provider to the Pharmacy Examining Board". In its revised and present form, the rule reads "failing to report to the pharmacy examining board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public" [emphases added].

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[3]The relevant texts of statutes and rules are included in Appendix I.

[4]This conclusion is reinforced by the language of § 990.001(6), Stats., which states that the titles to sections are not part of the statutes.

[5]Since § Phar 10.03(7) (then numbered § Phar 10.03(10)) was enacted before the other statutes and rules, it is even less likely that by careful choice of title the drafters of §450.09, Stats. and ch. Phar 7 intended them to be subject to the reporting requirement while the drafters of §450.01(16), Stats. did not.

[6]Doe v. American Red Cross, 176 Wis.2d 610, 616; _ N.W.2d _ (1993).

The respondent in his prehearing memorandum interpreted this change as a rejection of the requirement to report incompetent pharmacists and unprofessional conduct. In his reply brief, the interpretation offered by the attorney for the Division of Enforcement was that "the board's intent was to broaden the reporting requirement", and in the hearing he offered the testimony of Paula Possin to support this assertion.

Ms Possin was a staff attorney for the Division of Enforcement in the department at the time the rule was promulgated, who worked with the board at the time and was a member of the committee within the department which was charged with re-drafting the rule following the public hearing. Ms. Possin stated the original purpose of the proposed rule as follows:

> [T]he board was concerned about insuring that all pharmacists would have some professional and legal obligation to report unsafe practice of other pharmacists, so that the board could take proper action to safeguard the public.

[transcript, pp. 174-175]. Ms. Possin then described the notes she took during the public hearing and stated that

> the way the rule was originally proposed was perhaps too categorical and difficult for pharmacists to interpret, and perhaps ... that pharmacists wouldn't fully comply with the rule as worded because of practices within their own health care institution that would allow them to work around these specific terms: incompetent, unprofessional or illegal.

[transcript, p. 176]. She stated that

> the rule as finally adopted represents a broader standard than the one that was proposed for public hearing. And I believe it was the intent of the committee to overcome options for pharmacists to find loopholes and ways to circumvent the intent of the board to have pharmacists report unsafe practice based on institutional policies. That this standard of -- contained in the existing rule is broader and informs all pharmacists adequately of the standard for reporting being that conduct which constitutes a danger to health, safety or welfare of patient or public. This would not require pharmacists to have a legal understanding of what is meant by unprofessional conduct, in a way that would allow them to say they weren't in violation of the rule because they didn't understand the conduct that was subject to reporting.

[transcript, p 179].

Although Ms. Possin was not a member of the Pharmacy Examining Board and did not claim to know the minds of the board members who voted for the rule, her opinion as to the reason for the change is consistent with the language of the draft rules and the notes taken. In

the absence of an equally plausible explanation for the drafting changes, her testimony established by the greater weight of the evidence that **the rule was intended to require reporting of any unsafe conduct, including incompetent, unprofessional and illegal practices.** Her testimony further established that **the intent of the more inclusive language was to require pharmacists to report unsafe practices without attempting to second-guess whether they were incompetent, unprofessional or illegal.**[7]

Since an argument can be made that every one of Mr. Woltman's dispensing and medication errors demonstrated incompetence[8], **Mr. Onson and Mercy Medical Center had an obligation to report every one of Mr. Woltman's errors to the board under the rule as interpreted.**

How The Rule Should Be Interpreted Versus How It Is Interpreted.

Even though the testimony of Ms. Possin supported by various documents can be taken to establish the intent of the rule, the rule as written simply does not succeed in conveying that meaning.

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[7]The evidence was not, however, clear and convincing. This could have led to a complication had the complaint been charged differently. The burden of proof which must be met by the Board in disciplinary hearings has alternated over the past few years between "clear and convincing" and "a preponderance of the evidence". Prior to January 1, 1986 it was "clear and convincing". From January 1, 1986 to June 30, 1989 it was "a preponderance of the evidence". From July 1, 1989 to August 8, 1989 it was "clear and convincing". And since August 9, 1989 it has been "a preponderance of the evidence". Two of the errors, including the one which resulted in a patient's death, occurred during the period when the burden of proof on the board was higher, and even though an argument can be made that the reporting requirement continues regardless of when the unsafe pharmacy practice occurred, if each of the eight errors had been issued as a separate charge against the respondents, the two which occurred between July 1, 1989 and August 8, 1989 might have required dismissal due to the higher, and unmet, burden of proof.

[8]Mr. Thielke's testimony regarding the normal rate at which a pharmacist can be expected to err [transcript, p. 209] established that Mr. Woltman's errors cannot be considered incompetent per se and that he may not have even violated the standard of care for pharmacists. Mr. Thielke testified that pharmacists make errors at a statistically predictable rate, and that quality assurance systems are established to cope with this fact. Under his analysis, simply making an error does not violate the standard of care to be expected of all pharmacists. However, § Phar 10.03(7) as written and interpreted is not limited to acts which violate the standard of care.

Both parties offered expert testimony on the meaning of the rule as it appears on the books.[9]

Complainant's expert witness was James O'Donnell, a licensed pharmacist in Illinois and a faculty member at Rush Medical School where he teaches anatomy, micro-anatomy and embryology to medical students. Mr. O'Donnell has never been licensed in Wisconsin. He was an assistant director of pharmacy at Cook County Hospital in Chicago from 1971 to 1976 and assistant director of pharmacy at Rush Presbyterian - St. Luke's Medical Center from 1976 to 1988, though he has been without supervisory responsibilities since 1980. He is also editor-in-chief of the Journal of Pharmacy Practice, and a private consultant who spends 75% of his time and generates 85% of his income as a witness. Mr. O'Donnell stated that a competent pharmacist in Wisconsin would interpret § Phar 10.03(7) to require reporting a pharmacist in Mr. Woltman's situation to the board [transcipt, p. 31]. I have found that such a requirement exists, but I do not agree with Mr. O'Donnell's statement that a competent pharmacist in Wisconsin should be expected to so interpret the rule, especially in light of the following testimony.

Respondents' first expert witness was David Brushwood, a pharmacist licensed in Kansas, though now residing in Florida and teaching full-time as a professor at the University of Florida. Mr. Brushwood is also an attorney licensed in Kansas, and as part of his curriculum he teaches pharmaceutical law. He was president of the American Society for Pharmacy Law from 1986 to 1988. He is not licensed as either a pharmacist or an attorney in Wisconsin. Mr. Brushwood expressed his opinion that a minimally competent pharmacist could not know that § Phar 10.03(7) requires reporting of dispensing errors of a pharmacist [transcript, p. 102]. Mr. Brushwood also pointed out that North Carolina promulgated an administrative rule in early 1992 requiring pharmacists to report to the Pharmacy Examining Board any incident in which "there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer", and that this was noted in the literature of pharmacy law at the time as the first such reporting requirement in any state.

Respondents' second expert witness was William J. Herbert, a pharmacist licensed in Wisconsin and currently employed as director of pharmacy at Meriter Hospital in Madison. Mr. Herbert served as president of the Wisconsin Society of Hospital Pharmacists from 1991 to

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[9]This testimony was received with a certain reluctance. As stated by the Court of Appeals in East Troy v. Town & Country Waste Service, 159 Wis.2d 694, fn. 7, p. 707; 465 N.W.2d 510 (Ct. App., 1990), "We question whether an expert is qualified to give testimony on the meaning of a statute or an administrative rule. This is an exercise for judges and lawyers; not others." However, this statement is oblique dicta in a footnote and, given the gravity of the issue to be decided in this case, I agreed to accept more rather than less evidence into the record. It turned out that the testimony was not helpful in determining the meaning of the rule, but it was invaluable in establishing the rule's ambiguity.

1992. Mr. Herbert stated "It's my conclusion, both personally as well as collectively by talking with other individuals within the profession in Wisconsin, that pharmacists are under no obligation to report medication errors to the board based on that administrative code." [transcript, p.141].

Respondents' final expert witness was Thomas Thielke, a pharmacist licensed in Wisconsin and currently the director of pharmacy at University of Wisconsin Hospital in Madison. Mr. Thielke served as president of the Wisconsin Society of Hospital Pharmacists from 1976 to 1977, and president of the American Society of Hospital Pharmacists from 1989 to 1990. Mr. Thielke stated his opinion that § Phar 10.03(7) does not require the reporting of a medication error or a dispensing error or a series of such errors [transcript, p. 201].

The testimony of the four expert witnesses was split and, while I have decided above that respondents' witnesses are incorrect in their interpretation of "pharmacy practice" versus "the practice of pharmacy", their testimony is nevertheless eloquent evidence of the rule's ambiguity. When pharmacists of the stature of Mr. Herbert and Mr. Thielke, who have served as president of the Wisconsin Society of Hospital Pharmacists, state that they interpret the rule in a way which differs from the intent of the board in promulgating it, the respondent has proved beyond a reasonable doubt that the rule is unclear, and that a reasonable pharmacist in Wisconsin could not know that the rule should be interpreted to require reporting all dispensing and medication errors to the board.

As courts have said, "A statute is ambiguous if reasonable persons can understand it differently ...."[10], and "'a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process law.' This rule applies to administrative regulations affecting conditions of governmental employment in the same manner as it applies to penal statutes. '[T]he root of the vagueness doctrine is a rough idea of fairness.'"[11]

Although, as stated above, the rule was intended to create a reporting requirement, the actual language of the rule fails to convey that intent. The changes which were made following the public hearing may have been intended to "broaden" the rule, or close a loophole of interpretation, but the language which was chosen for the final version of the rule was subject to misunderstanding. As such the rule is unclear and ambiguous, and I consider it to be

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[10] Limjoco v. Schenck, 169 Wis.2d 703, pp. 710-711; 486 N.W.2d 567 (Ct. App., 1992).

[11] Kalt v. Milw. Bd. of Fire Com'rs, 145 Wis.2d 504, 510; 427 N.W.2d 408 (Ct. App., 1988). [citations omitted].

unenforceable as a matter of fairness to the respondents.[12]

Compounding the inherent ambiguity in the language of the rule is the fact that the reporting requirement was imposed without any further notice to the professional community on which the requirement falls.

As mentioned above, no other state in the Union had such a reporting requirement at the time, and even today the only state which is commonly known to have such a requirement is North Carolina. Such a departure from previous practice as the Wisconsin rule was intended to be could be expected to have been attended by some fanfare, publicity, and even controversy, none of which occurred.

The rule as intended could be expected to lead to volumes, if not reams, of reported violations. The addition of staff in the department, or the creation of policies for handling the incoming reports, or the creation of a special reporting form for pharmacies and pharmacists would have given more notice of the new requirement.

Respondent argued that a reporting requirement would be in conflict with the language of § 450.10(3), Stats., which provides immunity to health care professionals who report violations of chapters 450 and 161 to other certain other health care professionals, not including the board. The omission of the board is hardly conclusive on this point, because § Phar 10.03(7) obviously imposes a duty to report something to the board, and because § 450.10(3), Stats. is directed only to facilitating the sharing of information about drug abusers. Nevertheless, this is another missed opportunity; if the board had wished to impose an unambiguous duty to report all errors, the addition of itself to this statute would have helped clarify that duty.[13]

Finally, the profession would have received much more effective notice if the requirement had not been phrased only in the negative. A disciplinary rule which speaks of "failing to report" could easily have been coupled with a practice rule which imposes a positive duty to

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[12]The rule's ambiguity may also raise a question of "vagueness", which could be a violation of constitutional due process, but that issue cannot be decided in this forum. Kmiec v. Town of Spider Lake, 60 Wis.2d 640, 645-646; 211 N.W.2d 471 (1973). The issue was raised by the respondents in their prehearing memorandum dated June 18, 1993, and it is preserved for appeal.

[13]Respondent argued in his prehearing memorandum that the interpretation urged by the Division of Enforcement would "impermissibly stretch the regulatory requirements beyond the board's authority, as set forth in chapter 450 of the Wisconsin Statutes". The argument focused specifically on the proposed interpretation's conflict with the discretionary reporting requirement in § 450.10(3), Stats. As stated, the argument is not on point, and no showing was made that the board lacks the authority to have promulgated a rule such as § Phar 10.03(7).

report, but this was not done. All of these overlooked opportunities to give the profession notice of the new reporting requirement left the rule in its ambiguity.

Recommended Disposition.

The respondents in this case did violate what the drafters of § Phar 10.03(7) intended it to mean, but it would be unfair to enforce it against them. This is because § Phar 10.03(7) is unclear and ambiguous. The respondents had no adequate notice, either through the plain text of the rule or through other actions by the board which would have explained the rule, of the interpretation which lay behind the words. **I therefore recommend that this complaint be dismissed and that the Board consider redrafting the rule to clarify it.**

If the Board decides that no clarification of the rule is necessary, and chooses to enforce it as interpreted here, I would then recommend that a conclusion of law be made to that effect, but that neither discipline nor costs be imposed, not even a reprimand. Ignorance of law cannot be a defense to a legal conclusion that a violation occurred, but it should be a factor in the imposition of a penalty or discipline, and the only practical purpose of discipline to be served here is notice to the other members of the profession.[14] Discipline would not alter the effects of Mr. Woltman's past errors, and the protection of the public in the future will be sufficiently guaranteed by a published conclusion of law, because all pharmacists and pharmacies, including Mr. Onson and Mercy Medical Center, can be expected to comply with a rule as long as its meaning is clear. I accept Mr. Brushwood's statement that "That's what pharmacists do. Pharmacists try to comply with the law. And if told what it is they're supposed to do, then they will do it. But it must be told to them in sufficiently plain language that they can understand what the requirement is." [transcript, p. 107].

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[14]The purposes of professional discipline have been set forth in various attorney discipline cases, including Disciplinary Proc. Against Kelsay, 155 Wis.2d 480, 455 N.W.2d 871 (1990). In that case the Wisconsin Supreme Court stated "discipline for lawyer misconduct is not intended as punishment for wrongdoing; it is for the protection of the public, the courts and the legal profession from further misconduct by the offending attorney, to deter other attorneys from engaging in similar misconduct and to foster the attorney's rehabilitation." That reasoning has been extended by regulatory agencies to disciplinary proceedings for other professions. Rehabilitation in this case amounts to nothing more than understanding the rule.

Dated September 30, 1993.

John N. Schweitzer
Administrative Law Judge
Department of Regulation and Licensing

APPENDIX I

APPLICABLE RULES

Chapter Phar 7 PHARMACY PRACTICE

Phar 7.01 Minimum procedures for compounding and dispensing. ... a pharmacist or pharmacist-intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. ...

Phar 7.02 Prescription label; name of drug or drug product dispensed. No prescription drug shall be dispensed unless the prescription label discloses the brand name and strength, or the generic name, strength, and manufacturer or distributor of the drug or drug product dispensed unless the prescribing practitioner requests omission of the above information.

Phar 7.03 Prescription renewal limitations. A prescription order for any drug other than controlled substances, which bears renewal authorization permitting the pharmacist to renew the prescription as needed (PRN) by the patient, shall not be renewed beyond one year from the date originally prescribed. No prescription order containing either specific or PRN renewal authorization is valid after the patient-physician relationship has ceased.

Phar 7.04 Return or exchange of drugs prohibited. No drugs, medicines, or items of personal hygiene, after taken from a pharmacy where sold, distributed or dispensed, may be returned except a health care facility may return them to the pharmacy provided they are in their original containers and the pharmacist determines the contents are not adulterated or misbranded.

Phar 7.05 Prescription records. A record of all prescriptions dispensed shall be maintained for a period of 5 years after the date of the last renewal. ...

Phar 7.06 Complete pharmaceutical service. Complete pharmaceutical service, including compounded prescriptions, shall be available to the public normally served by the pharmacy.

Phar 7.07 Medication profile record system. (1) Within 3 years of February 1, 1989, an individual medication profile record system shall be maintained in all pharmacies for persons for whom prescriptions, original or renewal, are dispensed for outpatient use.

...

(3) The pharmacist shall be responsible for attempting to ascertain and record any patient allergies, adverse drug reactions, drug idiosyncrasies, and any chronic conditions which may affect drug therapy as communicated by the patient or agent of the patient. If none, this should be indicated.

(4) At the time a prescription order is reviewed by the pharmacist for dispensing, the pharmacist shall review the medication profile record of the patient for the previously dispensed medication history and shall determine whether the prescription order presented should be dispensed.

...

Phar 10.03 Unprofessional Conduct. The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct in addition to those grounds specified under s. 450.10(1), Stats.:

...

(7) Failing to report to the pharmacy examining board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public;

....

450.01 Definitions. In this chapter:

...

(16) "Practice of pharmacy" means any of the following:

(a) Interpreting prescription orders.

(b) Compounding, packaging, labeling, dispensing and the coincident distribution of drugs and devices.

...

450.10 Disciplinary proceedings; immunity; orders.

...

(3) (a) In this subsection, "health care professional" means any of the following:

1. A pharmacist licensed under this chapter.
2. A nurse licensed under ch. 441.
3. A chiropractor licensed under ch. 446.
4. A dentist licensed under ch. 447.
5. A physician, podiatrist or physical therapist licensed or occupational therapist or occupational therapy assistant certified under ch. 448.
6. An optometrist licensed under ch. 449.
7. An acupuncturist certified under ch. 451.
8. A veterinarian licensed under ch. 453.
9. A psychologist licensed under ch. 455.
10. A social worker, marriage and family therapist or professional counselor certified under ch. 457.
11. A speech-language pathologist or audiologist registered under subch. III of ch. 459 or a speech and language pathologist licensed by the department of public instruction.

(b) Any health care professional who in good faith provides another health care professional with information concerning a violation of this chapter or ch. 161 by any person shall be immune from any civil or criminal liability that results from any act or omission in providing such information. In any administrative or court proceeding, the good faith of the health care professional providing such information shall be presumed.

..

450.09 Pharmacy practice. (1) MANAGING PHARMACIST. . . The managing pharmacist shall be responsible for the professional operations of the pharmacy. ...

(2) PRESENCE OF PHARMACIST. No pharmaceutical service may be provided to any person unless a pharmacist is present in the pharmacy to provide or supervise the service.

(3) PHARMACEUTICAL EQUIPMENT. Every pharmacy shall be equipped with proper pharmaceutical utensils for compounding and dispensing prescriptions. The board shall prescribe, by rule, minimum standards of professional and technical equipment.

(4) CONDITION OF PHARMACY. The pharmacy shall be maintained in a clean and orderly manner and the professional service area shall be equipped with proper fixtures and equipment for sanitation.

(5) DISPLAY OF LICENSE. ...

(6) MEDICATION PROFILE RECORD SYSTEM. Every pharmacy shall maintain a medication profile record system of all drug products dispensed for a particular patient according to the minimum standards for such systems established by the board by rule. ...

(7) SELECTION OF DRUGS. Drug products purchased for subsequent sale and dispensing at a pharmacy shall be selected for purchase by a pharmacist.

(8) PENALTIES. ...

990.001 Construction of laws: rules for. In construing Wisconsin laws the following rules shall be observed unless construction in accordance with a rule would produce a result inconsistent with the manifest intent of the legislature:

...

(6) STATUTE TITLES AND HISTORY NOTES. The titles to subchapters, sections, subsections, paragraphs and subdivisions of the statutes and history notes are not part of the statutes.

...

APPENDIX II

PROCEDURAL HISTORY

A. This case was initiated by the filing of a complaint with the Pharmacy Examining Board on December 8, 1992. A disciplinary proceeding (hearing) was scheduled for February 2, 1993. Notice of Hearing was prepared by the Division of Enforcement of the Department of Regulation and Licensing and sent by certified mail on December 8, 1992 to Richard Keith Onson, who received it on December 11, 1992. Notice of Hearing was prepared by the Division of Enforcement of the Department of Regulation and Licensing and sent by certified mail on December 8, 1992 to Mercy Medical Center, which received it on December 9, 1992.

B. A companion complaint was filed and notice was mailed at the same time to Dale R. Prey, R. Ph. That case was resolved without a hearing.

C. Another companion complaint was filed and notice was mailed at the same time to Larry Woltman, R. Ph. That case was not resolved by the time of the hearing in this matter.

D. On December 17, 1992 an answer was filed on behalf of Richard Keith Onson and Mercy Medical Center by Attorney Jonathan M. Menn of Menn, Nelson, Sharratt, Teetaert & Beisenstein, S.C., 222 North Oneida Street, Appleton, WI 54912-0785.

E. On December 24, 1992 an answer was filed on behalf of Dale Prey, Richard Keith Onson, and Mercy Medical Center by Attorney Daniel F. Miller, of von Breisen & Purtell, S.C., 411 East Wisconsin Avenue, Suite 700, Milwaukee, WI 53202-4470. The answer contained a request that the complaint be dismissed.

F. A prehearing conference was held on January 21, 1993. The parties requested that the hearing be rescheduled to allow time to develop expert testimony, to agree on facts that could be stipulated, and to investigate the possibility of settlement. The hearing was rescheduled to April 28, 1993.

G. On February 26, 1993 a Consent to Substitution of Attorneys was filed whereby Mr. Miller was substituted for Mr. Menn as attorney for Richard Keith Onson and Mercy Medical Center.

H. A prehearing conference was held on March 3, 1993, at which a schedule was set for preparing a stipulation of facts and identifying expert witnesses.

I. A prehearing conference was held on April 6, 1993. Neither the stipulation of facts nor the identification of witnesses was completed.

J. A prehearing conference was held on April 20, 1993. Expert witnesses were identified. The stipulation of facts was not completed. Additional discovery was identified and a deadline set for all discovery. A schedule for trial briefs was set. The hearing was rescheduled to July 7, 1993.

K. A stipulation of facts was filed on May 7, 1993. Trial briefs and responses were filed on June 18th and June 25th, 1993.

L. A prehearing conference was held on June 29, 1993. A ruling was made denying the motion for dismissal contained in the respondent's answer. Both parties requested additional time to depose witnesses and develop the legislative history of § Phar 10.03(10), Wis. Admin. Code, an issue which was raised for the first time in the trial briefs. The hearing was rescheduled to August 11, 1993.

M. All time limits and notice and service requirements having been met, the disciplinary proceeding was held as scheduled on August 11th and 12th, 1993. Richard Keith Onson appeared in person and represented by Attorney Daniel F. Miller. Mercy Medical Center appeared by Mr. Miller. The Pharmacy Examining Board was represented by Attorney Arthur Thexton of the Department's Division of Enforcement. The hearing was recorded, and a transcript of the hearing was prepared and delivered on September 14, 1993. Mr. Miller requested the opportunity to file a legal brief on the issues raised in the hearing, and both attorneys were directed to file briefs simultaneously by September 3, 1993. The testimony and exhibits entered into evidence at the hearing form the basis for this Proposed Decision.

BDLS2-2802

NOTICE OF APPEAL INFORMATION

(Notice of Rights for Rehearing or Judicial Review, the times allowed for each, and the identification of the party to be named as respondent)

The following notice is served on you as part of the final decision:

1. Rehearing.

Any person aggrieved by this order may petition for a rehearing within 20 days of the service of this decision, as provided in section 227.49 of the Wisconsin Statutes, a copy of which is attached. The 20 day period commences the day after personal service or mailing of this decision. (The date of mailing of this decision is shown below.) The petition for rehearing should be filed with the State of Wisconsin Pharmacy Examining Board.

A petition for rehearing is not a prerequisite for appeal directly to circuit court through a petition for judicial review.

2. Judicial Review.

Any person aggrieved by this decision has a right to petition for judicial review of this decision as provided in section 227.53 of the Wisconsin Statutes, a copy of which is attached. The petition should be filed in circuit court and served upon the State of Wisconsin Pharmacy Examining Board

within 30 days of service of this decision if there has been no petition for rehearing, or within 30 days of service of the order finally disposing of the petition for rehearing, or within 30 days after the final disposition by operation of law of any petition for rehearing.

The 30 day period commences the day after personal service or mailing of the decision or order, or the day after the final disposition by operation of the law of any petition for rehearing. (The date of mailing of this decision is shown below.) A petition for judicial review should be served upon, and name as the respondent, the following: the State of Wisconsin Pharmacy Examining Board.

The date of mailing of this decision is November 11, 1993.