

September 20, 2005

Ann E. Mowery
Executive Director
Board of Medical Examiners
400 S.W. Eighth St., Suite C
Des Moines, IA 50309-4686

RE: Physician-Pharmacist Collaboration -- ARC 4447B

Dear Ann:

Thank you for the opportunity to comment on proposed rules of the Iowa Board of Medical Examiners (BME) establishing protocol requirements for physician-pharmacist collaboration on patient drug therapy management. The Iowa Medical Society (IMS) appreciates the persistence of the BME on this issue as well as the BME's cooperation with the Iowa Board of Pharmacy Examiners (BPE) in developing this draft. The proposed rules represent an excellent base for further discussions on how best to assure effective, high quality collaboration between physicians and pharmacists in co-management of a patient's course of drug therapy.

Supervising physician. The proposed rules address a collaborative relationship between a "supervising" physician and an "authorized" pharmacist. Rule 653-13.4 clarifies that the supervising physician retains ultimate responsibility for the care of the patient. IMS agrees with this statement.

IMS is concerned, however, with the definition of a "supervising physician" set forth in proposed subrule 13.4(1)(i). That definition says in pertinent part that a supervising physician is the physician *responsible for the overall management and supervision of the activities of the pharmacist as they are directly related to patients receiving medications or disease management services under the protocol*. This definition applies to supervising physicians both in the hospital and in the community practice setting.

Physicians and pharmacists both bear professional responsibility in their respective spheres of practice consistent with the collaborative protocol required by the proposed rules. The supervising physician is not in a position to actually manage the pharmacist in performing the pharmacist's role in drug therapy management. Certainly the physician remains the medical decision maker in the event information from the pharmacist

indicates that shifts in the patient's course of drug therapy are required. The language cited above, however, implies a direct supervisory relationship akin to supervision provided in an office setting. This level of supervision is not feasible. IMS suggests that the italicized language be stricken from the proposed definition.

IMS believes the better and more accurate definitional approach is one like the definition of "supervision" in the BME's rule on "Supervision of Pharmacists Who Administer Adult Immunizations." Ia. Admin. Code r. 653-13.3(2) That definition addresses specific factors the physician must satisfy as a supervising physician (i.e., establish that the pharmacist is appropriately trained; provide written protocol consistent with the rule; and be available for consultation, direction, assistance). The same could be set forth in this rule by describing those acts the physician must perform to assure a proper level of supervision, such as, but not necessarily limited to, assuring that the pharmacist is "authorized"; entering into and abiding by community practice protocol or hospital practice protocol consistent with these rules; being available to the pharmacist; regularly reviewing notes of the pharmacist as may be appropriate to the course of drug therapy; and responding in a timely fashion to an inquiry or concern of the pharmacist. Assurance that the physician remains responsible for direction of the overall care of the patient is established in proposed rule 13.4.

Prior approval by the BME and BPE of community practice protocol agreements.

Subrule 13.4(2)(a) requires prior submission of a written community practice protocol agreement reached by a principal supervising physician and a pharmacist for approval by both the BME and the BPE. IMS believes that the requirement for prior approval should be stricken from the rules. The proposed collaborative practice rules are clear on what should go into a collaborative practice protocol agreement.

Certainly the physician and pharmacist should be required to keep a signed copy of their written agreements in their respective files for purposes of inspection and/or audit by either of the boards. Prior approval, however, is administratively burdensome for both the boards and the physician and pharmacist. More importantly, filing and obtaining approval of both boards will require time that delays effective implementation of the collaborative protocol even though the patient has been apprised of and consented to the defined collaborative arrangement upon leaving the physician's office. Waiting for approvals and follow-up notifications of those approvals could substantially impede the hoped-for effectiveness of the collaboration.

Medicaid rules recognize physician-pharmacist collaboration in managing patients at high risk for medication related problems. Ia. Admin. Code r. 441-78.47. Those rules require that a copy of pharmaceutical case management records be maintained on file in each provider's facility and be made available for audit by the department upon request. Ia. Admin. Code r. 78.47(2)(a). Those rules do not require prior approval by the Medicaid program. A similar approach is appropriate here.

IMS requests that the prior filing/approval requirement of proposed subrule 13.4(2)(a) be stricken. In the same way, the requirement that the BPE be notified in the event a collaborative drug therapy management protocol is amended or terminated, r. 13.4(2)(f), should be stricken.

Community practice protocol – therapeutic substitutions. Subrule 13.4(2)(b)(4)(1) gives the supervising physician authority to authorize therapeutic substitutions by an authorized pharmacist within a class of drugs or with generic drugs. This rule addresses a sensitive arena of pharmaceutical delegation. Clarity on what is and what is not allowed is essential. Terminology is key.

Iowa Code section 155A.32 allows a pharmacist to select a drug product with the same generic name and demonstrated bioavailability as the drug prescribed but does not authorize further therapeutic substitutions. IMS policy states that pharmaceutical and therapeutic substitution by pharmacists is appropriate only after consultation with and approval by the prescribing physician. IMS policy supports the concept that pharmacists employed by and dispensing in a hospital may exercise professional judgment by selecting drugs from a formulary in a hospital, providing that such selection applies *only* to hospital inpatients and the formulary is determined by a P & T committee consisting of physicians and pharmacists. AMA policy recognizes that the methodology for approval of bioequivalency and therapeutic equivalence has yet to be fully resolved.

In this regard, IMS asks for a review of terminology employed by proposed rule 13.4(2)(b)(1) to assure common understanding of what “therapeutic substitution” is “within a class of drugs or with generic drugs.” IMS also suggests a need for reference to professional standards that may exist in this area to guide community physicians and pharmacists in developing and implementing community practice protocol.

Community practice protocol – lab testing. Subrule 13.4(2)(b)(4)(2) allows a supervising physician to authorize an authorized pharmacist to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management. This rule in its proposed form is very broad. Iowa law is not clear on what types of lab tests are appropriately performed by a pharmacy and/or pharmacist, if any at all.

At a minimum this subrule should be amended to include at the end of the sentence the following: “... and are within the scope of the pharmacist’s license and training to perform.” IMS believes the better approach, however, is to strike this rule in its entirety until greater direction can be provided by the BME and the BPE on the appropriate scope of pharmacy lab testing. Pharmacists are not licensed physicians or trained medical pathologists; as such, the proposed rule should not invite practice acts that otherwise are not authorized.

Community practice protocol – malpractice liability coverage statement. Subrule 13.4(2)(b)(4)(16) requires the supervising physician to certify that the physician has sought and received a commitment from the physician’s professional liability carrier that

drug therapies initiated under a community practice protocol will be covered for professional liability purposes. While the intent of this subrule may be well-intentioned, what it will accomplish is not clear. IMS questions the workability of this proposed regulatory requirement. In addition, no similar provision is required for the authorized pharmacist.

In some ways, the proposed rule seems to be placing a measure of responsibility on professional liability carriers for determining the appropriateness of a collaborative agreement. If collaboration is authorized by law or regulation, generally carriers will cover it. Seeking prior review by professional liability carriers also may delay effective implementation of the agreement, particularly in cases where the nature of the agreed-to collaboration is fairly routine and accepted in both medical and pharmacy practice. The subrule, itself, places the physician at risk in the event the physician does not contact the physician's carrier and the carrier later denies coverage because the physician failed to meet this regulatory requirement, a very tough penalty, indeed.

IMS asks that this subrule be stricken. If not stricken, IMS believes the rule needs to be rewritten to *suggest*, but *not* require, that both the supervising physician and the authorized pharmacist consult their respective professional liability carriers if a collaborative agreement under consideration is of a level of complexity or in an area of practice uncertainty that the carrier may be able to provide a risk assessment and suggestions on how to best shape the collaborative arrangement or may advise against entering into the arrangement.

Collaborative drug therapy management *only* under a written protocol. Questions likely will arise relative to the nature of ordinary physician-pharmacist interactions relative to drug therapies that commonly have been conducted absent written protocol. There may be a need for the proposed rules to generally reference types of drug therapy management activities that now occur between physicians and pharmacists that may not need written protocol. For instance, there may be incidental or routine or "standing order" pharmaceutical services now commonly provided by community pharmacists at the direction of community physicians.

BPE coordinating rules. IMS recognizes that the BPE also will adopt rules regulating participation of pharmacists in collaborative relationships with physicians for purposes of patient drug therapy management. Those rules are important to a fair understanding of the regulatory impact of physician-pharmacy collaboration. The BME's proposed rules recognize that certain matters (i.e., training requirements for an "authorized" pharmacist) are appropriately addressed by the BPE. In that regard, IMS reserves its ability to file comments on the BPE's rules that may call for further consideration of some aspect of the BME's proposed rules. Further, IMS prefers final adoption of the BME rules close in time with final adoption of parallel BPE rules.

Implementation delay. Final rules on collaborative practice will impact existing relationships between physicians and pharmacists on co-management of a patient's drug

therapy in both the community practice and hospital settings. IMS believes that time should be given for physicians and pharmacists to become familiar with final rules of both boards before enforcement of the particulars of the rules would occur. IMS would ask the BME and the BPE to coordinate on an effective implementation or enforcement date that allows reasonable time for the professional societies to inform their membership of the rules and to clarify, in concert with the BME and BPE, questions that might arise as well as time for physicians, pharmacists, hospitals, and other non-hospital settings to adjust current practices and protocol consistent with the newly adopted requirements of the BME and BPE.

Thank you, again, for this opportunity to comment. IMS remains committed to working with the BME, BPE, the Iowa Pharmacy Association and others to assure that the final collaborative drug therapy management rules are clear in their requirements, workable, free from unduly burdensome procedures, faithful to physician-driven patient care, and focused on quality health care services and patient safety.

Yours truly,

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