

July 26, 2005

Terry Witkowski  
Executive Officer  
Board of Pharmacy Examiners  
400 S.W. Eighth Street  
Suite E  
Des Moines, IA 50309-4688

**RE: Electronic Drug Database Program (ARC 4307B)**

Dear Ms. Witkowski:

Thank you for the opportunity to comment on noticed rules of the Iowa Board of Pharmacy Examiners ("Board") proposing to establish an electronic drug database program (EDDP) in the State of Iowa. The Iowa Medical Society (IMS) represents approximately 4500 Iowa physician members. The IMS core purpose is *to assure the highest quality health care in Iowa through our role as physician and patient advocate.*

**Position of the Iowa Medical Society**

The Board proposes these rules despite the fact that House File 722, a carefully negotiated bill, failed to receive final legislative approval. Further, the proposed rules reintroduce an early and significant debate by including *all* Schedules II-V controlled substances as reportable rather than *selected* controlled substances and other drugs that evidence shows are likely candidates for diversion or abuse (*see* discussion below). Finally, elimination of any role whatsoever for an advisory council of physicians and pharmacists substantially weakens a critical strength of the program as provided in House File 722 and renders the EDDP unacceptable to IMS.

For these and other reasons noted below, the IMS opposes the Board's rulemaking. Recognizing that the Board recently was awarded additional monies from the U. S. Bureau of Justice Assistance and an extension of time to March 31, 2007 for implementation of the program, IMS requests the Board to rescind this rulemaking and await legislative action to support the EDDP. In the event the Board proceeds to final adoption of the proposed rules, IMS will ask the Iowa Administrative Rules Committee to delay these rules into the 2006 General Assembly consistent with its authority under Iowa's Administrative Procedures Act, Iowa Code section 17A.8(9). Legislative airing and approval of the EDDP are essential.

Attached to these comments is the IMS position statement on implementation of a prescription drug monitoring database (now EDDP) in Iowa; that position has shaped our negotiations at all stages of discussion and debate. IMS believes the public negotiation sessions between IMS, the Board, and other interested parties netted a balanced legislative proposal consistent with this

position statement. House File 722, as passed by the House, removed IMS' objections to the EDDP. In opposing the Board's proposed rules, IMS is *not* backtracking but, rather, is remaining faithful to its position. An EDDP fully reflecting the provisions of House File 722 in its current form is acceptable to IMS.

### Comments

**Statutory authority.** IMS remains adamant in its position that statutory authority is necessary for implementation of a balanced EDDP protective of patients' rights of privacy, respectful of the physician-patient relationship, and bordered by law in granting law enforcement and government agencies access to otherwise confidential treatment information. Further, statutory provisions mandating the release of protected health information (PHI) that otherwise may not be disclosed under the federal HIPAA Privacy Rule appropriately allays HIPAA concerns expressed by challengers to House File 722 and, more importantly, provides heightened assurances to the public that confidential prescription information from their medical files will be accessed by law enforcement and state agencies through the database *only* as allowed by the General Assembly.

Legislative authority is imperative for three reasons: 1) the Iowa Administrative Code, chapter 17A, and constitutional principles underpinning the three branches of government require it; 2) the Board, as an agency of state government, cannot on its own provide certain legal assurances set forth in House File 722 and essential to an EDDP respectful of the full range of rights and interests; and 3) the public looks for and deserves the oversight of its elected representatives behind what otherwise could become a regulatory program of overuse and abuse.

*1. The Board's rulemaking must be supported by statutory authority required by the Iowa Constitution and the Iowa Administrative Procedures Act.* The Board shared with IMS the position of the Board's assistant attorney general that current statutory power of the Board to audit the supply and inventory of controlled substances in the possession of individuals authorized to possess them, Iowa Code section 124.501, is sufficient to support establishing an EDDP. A review of the language of that section, however, establishes that its ability to support this program is attenuated, at best. Article III of Iowa's Constitution vests lawmaking in the legislative branch of government and only the General Assembly can delegate that authority to a state agency. Iowa's Administrative Procedures Act, Iowa Code chapter 17A, provides statutory recognition to an agency's need for legislative authority and an affected party's right to challenge an exercise of agency authority absent appropriate delegation by the General Assembly.

Iowa Code section 124.501 empowers to Board to conduct "audits of the supply and inventory of controlled substances in the possession of pharmacists, doctors, hospitals, and health care facilities" as well as any other individual or institution authorized to possess controlled substances. That language, relating to formal Board audits of classes of otherwise regulated individuals or entities, cannot, standing alone, serve as the basis for transferring all medical record information containing prescription drug information about patients in Iowa to a statewide database. Essentially, a rule creating an EDDP says that the state, absent patient consent, will receive information about controlled substances held by patients pursuant to a lawfully issued prescription in their homes, automobiles, offices, purses, and other legitimate places. More is needed than this general audit language.

Agencies of state government have no independent statutory or constitutional authority. Only the General Assembly can adopt laws. Agencies have power to act pursuant to authority delegated by the legislature law to them. To pass constitutional muster, “[a] legislative power can be delegated only after the legislature has established a definite policy and has fixed standards or brackets within which the administrative body may fill in the details in the exercise of its delegated power.” *Gilchrist v. Bierring*, 234 Iowa 899, 14 NW2d 724, 728 (1944).

The EDDP is a specific program providing for a significant exercise of state police powers affecting substantial rights of medical privacy. The EDDP gives blanket authority to the Board to comb private medical information in a statewide database regarding each and every citizen issued a prescription for a controlled substance and to release to law enforcement information regarding both the physician and the patient in cases where the Board, on its own motion, decides there is a suspected pattern of abuse. Citizens seeking and receiving medical care stand to be inappropriately investigated for a potential crime and falsely accused in criminal proceedings based on a state review of confidential medical information about them. Prescribing physicians similarly are at risk.

Authority of this dimension cannot be implied from a general, ill-defined grant of audit authority to the Board. See *Barker v. Iowa Dep’t. of Transportation*, 431 NW2d 348, 350 (Iowa 1988). “A statute cannot masquerade as an exercise of the police power and arbitrarily invade personal rights or private property.” *Gilchrist*, *supra* at 729. Current efforts before Congress to pass a National All Schedules Prescription Electronic Reporting (NASPER) drug monitoring program recognize the need for statutory authority bordered with standards of behavior and balancing of rights and interests and do not simply rely upon federal regulatory audit authority.

2. *The Board cannot on its own authority grant assurances essential to a balanced EDDP.*

Certain carefully negotiated provisions of House File 722, essential to a balanced and well-ordered EDDP, clearly fall outside the rulemaking authority of the Board and belong exclusively with the General Assembly. The Board recognizes that fact and in many instances either makes general reference or no reference to such provisions in its proposed rulemaking. Protections set forth in House File 722 but either missing or limited in this rulemaking include:

- *Strict* confidentiality of patient information in the database;
- Privilege and confidentiality of records of requests for information from the database by physicians and others for patient treatment purposes;
- Good faith immunity from liability for making a report of patient information to the database;
- Clarification that a physician, pharmacist or other prescriber is not duty-bound to make an inquiry of the database;
- Assurances that the EDDP will be financially supported by funding sources *other than* fees assessed on pharmacists or physicians;
- Required review of and report to the General Assembly and Governor on the effectiveness of the EDDP; and
- Assessment of penalties on entities not otherwise regulated by the Board for breach of confidentiality, unauthorized access to or release of database information, or other violations set forth in House File 722.

These provisions are critical to a successful EDDP balancing individual rights with state government oversight and enforcement for public health and safety purposes. IMS recognizes

that the Board took what steps it believed it could to address certain of these matters in its rulemaking but on points such as duty and immunity, physicians can take little comfort in such efforts unsupported by statutory authority.

3. *The public's interest is best served by legislative design of this sensitive state database program.* Treatment of human ailments and disease through a pharmaceutical course of therapy has become increasingly common. To place all Iowa citizens under potential state scrutiny for use of authorized prescription drugs demands that such a program and database of information be reviewed, designed, and authorized by the people's elected representatives. This is particularly so given the fact that the Board proposes to require that *all* scheduled controlled substances be reported into the database, including those with limited abuse potential. Further, the lack of accuracy of data within state EDDPs has been acknowledged as "troubling." Brushwood, David, "Maximizing the Value of Electronic Prescription Monitoring Programs," *Journal of Law, Medicine & Ethics*, 31 (2003) 41, 42.

Assuring legislative design and oversight of a state EDDP does nothing to diminish the concurrent interests of the people in effective detection and enforcement of diversion and abuse of prescription drugs. Statutory address of this issue fosters balance and open airing of an important public policy. Rulemaking of the dimension proposed by the Board here requires legislative authorization. The public has a right to expect no less.

**Reportable drugs.** The negotiated provisions of House File 722 addressed "selected controlled substances and other drugs" as "reportable." House File 722 also called for an advisory council of physicians, pharmacists, other prescribers and the general public that IMS understood would assist the Board with its list of reportable drugs. The proposed rules, however, define *all* Schedules II, III, IV and V controlled substances as reportable. In this regard, the rulemaking exceeds appropriate boundaries in balancing rights of privacy with police power needs for enforcement of the public good.

It is imperative that the Board's rules address "selected" drugs particularly in Schedules III, IV, and V. It is further essential that the Board's rules reinstitute some form of an advisory council to provide review and input on drugs to be reported as well as those controlled substances that, on balance, should *not* be reported. Physicians and pharmacists are well-positioned to advise the Board regarding drugs that, if reported, have a high likelihood of inappropriately identifying a patient with prescriptive authority and legitimate need for the drug as a potential abuser, particularly where law enforcement data is insufficient to establish that such a prescription drug is being abused.

By definition, Schedule V controlled substances have a low potential for abuse, have currently accepted medical use in treatment, and have limited physical or psychological dependency. Iowa Code section 124.211. Senate File 169, section 1, passed by the 2005 General Assembly, tightened over-the-counter citizen access to legitimate drug products containing certain precursor Schedule V controlled substances to amphetamine and methamphetamine. While IMS did not and still does not object to Senate File 169, IMS believes that inclusion of these precursor substances as reportable to the EDDP is overly broad in reach and impact. Further, it is confusing how these substances would be reported given the exceptions set forth in section 124.212(4). Discussion and clarification on this point is necessary.

**Confidentiality.** Proposed rule 657-13.8 states that any information contained in and obtained from the EDDP is confidential medical information consistent with Iowa Code section 22.7 and section 124.504 and not a public record. Further, proposed rule 657-13.9 states that the Board will establish procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, and transmitted through the EDDP is maintained and released only as authorized by rule. These are minimal standards and IMS does not object to them. IMS, however, argues for the heightened privacy safeguards that flow from statutory language granting “strict” confidentiality protection to patient medical record information reported to and maintained in the EDDP database as set forth in House File 722. The Board cannot accord “strict” confidentiality protection to such data in its rulemaking absent the direction of the General Assembly.

IMS notes that, unlike House File 722, the Board does not afford confidentiality protection to records of requests for information from the EDDP as set forth in proposed rule 657-13.10. IMS suggests that such confidentiality be addressed similar to the provisions of House File 722.

**Advisory council.** The proposed rules are silent on a council of physicians, pharmacists, and other persons advisory to the Board on matters affecting the EDDP. Failure to include a role for an advisory council substantially compromises the ability of the EDDP to ever become a “health” program and enforces the fear that the EDDP is primarily, if not exclusively, an enforcement arm of the law and state government.

In negotiations preparatory to House File 722, the Board readily agreed that an advisory council is an important and valuable component of a well-functioning EDDP. The Brushwood article referenced by the Board in the early discussions of an EDDP encourages an “expert” committee to, among other things, “provide general policy guidance to staff, and assist with specific applications of the policy as needed.” Brushwood, *Id.* at 49. The advisory council needs to be included in this rulemaking if the Board proceeds to final adoption.

**Program review and evaluation.** Another negotiated provision of House File 722 calls for periodic program review and evaluation. While only the General Assembly can *mandate* a report, the Board, in its rulemaking, can impose upon itself the regulatory responsibility of review and evaluation of the effectiveness of the EDDP, including issuing a public report of such an evaluation and considering terminating the program if findings are inadequate to support its continuation. The proposed rulemaking, however, is silent on this issue. Such silence speaks to the need for legislation.

Program review and evaluation are essential. The Brushwood article notes:

[T]he value of these programs should not be assumed; it should be empirically examined through systematic evaluations. Not enough is yet known about electronic prescription monitoring programs to conclude how they are best designed or implemented. Anecdotes abound, but scientific data are sparse. Existing programs should conduct evidence-based evaluations, and newly developing programs should likewise incorporate evaluations into their procedures. Programmatic changes should be made to reflect what is learned about structures and processes that are associated with positive outcomes.

Brushwood, *Id* at 50. The Board's rules, if finally adopted, should specifically provide for periodic program evaluations and reports on EDDP viability and effectiveness.

**Contractor.** The proposed rules are silent on the processes and procedures the Board anticipates following in selecting a contractor to operate the database. Further, the proposed rules fail to set out duties and responsibilities of a contractor as well as standards and expectations for contractor performance. The rules also should address database security whether the responsibility of the contractor or of the Board.

**Technical comments.** Below are a few points of a more technical nature.

- Rule 13.2, definition of “nonidentifiable information.” IMS suggests to the Board that it conform its definition and practices relative to nonidentifiable information to the federal HIPAA Privacy Rule on de-identification of PHI. 45 CFR section 164.514.
- Rules 13.9(2) and 13.10(1)(b), “Court-ordered subpoenas.” IMS agrees with references in these rules to court-ordered subpoenas and warrants but suggests also adding “court order” since there could be another form of court order than the two most likely ones listed in these rules.
- Forms. In certain points throughout the rules, it would be helpful to state that forms will be developed by the Board, such as a form to be used by a person requesting information from the database about that person, rule 13.9(5), or a form for responding to a person's request for information from the database, either agreeing to or denying that request. Rule 13.10(1).

Thank you, again, for the opportunity to comment. Please do not hesitate to contact me regarding any matter set forth in this letter of comment. IMS was pleased for the Board's dedication of time and resources to reach satisfactory resolution on issues of concern that netted House File 722. We look forward to continued collaborative efforts, if possible, on this issue.

Yours truly,

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