TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Emergency Rule
LSA Document #13-494(E)

DIGEST

Temporarily adds provisions regarding administrative authorizations to examine controlled substances prescribing records. Effective October 25, 2013.

SECTION 1. **(a) This document establishes standards and procedures for the medical licensing board to authorize, where appropriate, the attorney general to examine a physician's records and controlled substances inventory and materials to investigate the physician's controlled substances prescribing practices and the physician's compliance with IC 25-22.5, IC 25-1-9, and 844 IAC in relation to controlled substances prescribing activities.**

(b) Nothing in this document shall be interpreted or construed to abrogate, eliminate, reduce, restrict, or replace existing provisions authorizing the attorney general to issue subpoenas or civil investigative demands to investigate possible violations of IC 25-22.5, IC 25-1-9, and 844 IAC.

SECTION 2. **(a) The definitions in this SECTION apply throughout this document.**

(b) All terms which are defined in IC 25-22.5 and IC 35-48 shall have the same meanings as they are so defined when used in this document.

(c) "Board" refers to the medical licensing board of Indiana established by IC 25-22.5-2-1.

(d) "Controlled substance" has the meaning set forth in IC 35-48-1-9.

(e) "Controlled substance registration" refers to registration required and permitted by IC 35-48-3.

(f) "OAG" refers to the office of attorney general.

(g) "Examination authorization" means an order issued by the board directing the OAG to examine records as specified in the order.

SECTION 3. **(a) The OAG may file a verified petition with the board seeking an examination authorization.**

(b) Subject to the provisions of this document, the board may issue an examination authorization if the board believes that the authorization is necessary for the OAG to conduct an investigation of a physician's controlled substance prescribing practices through review of relevant records.

(c) Examination authorizations may not be sought or issued for the purpose of unreasonably interfering with a physician's regular practice operations or for the purpose of imposing undue burden or expense on the physician.

SECTION 4. **(a) The board may designate an individual member for purposes of reviewing a verified petition filed by the OAG and issuing an examination authorization.**

(b) The board may designate an individual member for purposes of responding to a petition for modification, limitation, or discontinuance of an examination conducted pursuant to an examination authorization.

SECTION 5. **(a) The board may issue an examination authorization permitting examination of records of a physician with a controlled substance registration or a physician engaging in activities for which a controlled substance registration is required.**

(b) The OAG may petition the board for an examination authorization if the OAG has a good faith reason to believe that a physician may have violated or is likely to violate provisions of any statute or rule concerning the prescribing, dispensing, or administering of a controlled substance.

(c) A verified petition filed under this document shall include the following:
(1) facts establishing a good faith reason to believe that a violation of an applicable controlled substance prescribing, dispensing, or administrative statute or rule may have occurred or is likely to occur;
(2) an explanation of why the examination authorization is necessary to protect consumers or patients or to respond to a clear and immediate danger to public health and safety, including why issuance of a subpoena is not believed to be sufficient or appropriate under the circumstances;
(3) a description of the records or categories of records to be examined in enough specificity to allow the respondent physician to identify the documents at issue;
(4) a general description of the location or locations where the records are maintained or believed to be maintained; and
(5) a statement confirming that the request for access complies with 45 CFR 164.512(f)(1)(ii)(C).

(d) After reviewing a verified petition filed under this rule, the board may issue an examination authorization. The examination authorization shall authorize the OAG to immediately inspect and copy records maintained by the physician concerning the prescribing, dispensing, or administering of a controlled substance.

(e) A physician that is the subject of an examination authorization issued by the board pursuant to this rule shall comply with the examination authorization and cooperate with the attorney general's reasonable efforts to carry out the examination authorization.

(f) In carrying out an examination authorization, the records authorized for examination by the board shall be produced to the OAG by the respondent physician in either printed format or in electronic format as agreed upon by the parties. If the parties cannot agree as to the format of production, the respondent physician shall produce the records in printed format.

(g) The OAG may not require production of records in electronic format under subsection (f) of this SECTION if they are not created or maintained in electronic format. If records are to be produced in electronic format, the OAG may specify that they shall be produced in either native format with all software necessary to read the electronic records, or in a complete, unencrypted manner that is easily readable without the use of proprietary software.

(h) Proof of license agreement preventing a respondent physician's compliance with subsection (f) of this SECTION is to be provided at the time the OAG executes an examination authorization. Any such license agreement is subject for review as to authenticity by the OAG. If the agreement is found to be authentic and prevents a respondent physician's compliance with subsection (f) of this SECTION, the physician will not be considered noncompliant as to the electronic production of records but will, however, be required to produce the records in printed format.

(i) Provisions regarding payment for copies in the Indiana Rules of Trial Procedure are applicable to copies made pursuant to an examination authorization; however, these provisions do not prohibit the board from ordering reimbursement of costs as provided under IC 25-1-9.

SECTION 6. **(a) Every examination authorization issued under this document shall be in writing and include the following:**
(1) Requirements for the OAG to execute the authorization during the normal business hours of the physician's practice, unless a narrower time frame is specified by the board.
(2) Requirements for the OAG to execute the authorization within ten (10) business days of issuance, unless otherwise specified by the board.
(3) Procedures that shall be followed by the OAG in conducting the examination to avoid unreasonable and unnecessary interference with the operation of the physician or the health care provider for which the physician works.
(4) Notice to the physician of the physician's rights, including:
(A) The right to be present and observe the examination and copying by the OAG, and the right to make an accounting of records examined and copied by the OAG.
(B) The right to continue to conduct its health care practice without unreasonable and unnecessary interference by the OAG during the examination.
(C) The right to consult with legal counsel in relation to rights specified in this rule and other applicable rights and remedies.

(D) The right to petition the board for an order directing the OAG to modify, limit, or discontinue an examination conducted pursuant to this document if the physician believes that the examination is being carried out in a manner that is unreasonable or oppressive.
(5) Notice to the physician that failure to cooperate with the examination authorization and that destruction, alteration, or removal of records that are the subject of the examination authorization may result in administrative sanctions by the board.
(6) Requirements for the OAG to preserve the integrity of the physicians' original records.

(b) If the OAG has knowledge that the physician who is the subject of an examination authorization issued under this rule has retained an attorney to provide legal counsel in relation to pending consumer complaints that are being investigated, the OAG shall provide notice to the attorney upon execution of the examination authorization; however, the physician's representation by legal counsel shall not delay the physician's requirement to immediately comply with SECTION 5(e) of this document.

SECTION 7. **(a) A physician may file a petition with the board requesting that the board:**
(1) modify the terms or scope of the examination authorization that the board previously issued;
(2) limit the terms or scope of an examination authorization that the board previously issued; or
(3) direct the OAG to discontinue an examination being conducted pursuant to an examination authorization that the board previously issued.

(b) In a petition filed under subsection (a) of this SECTION, a physician shall set forth reasons why the examination authorization should be modified, limited, or discontinued.

(c) Unless the board issues a temporary stay, the OAG's ability to continue conducting an examination pursuant to an examination authorization is not limited or affected during the pendency of the board's review of a petition by a physician under subsection (a) of this SECTION.

(d) The board may order the modification, limitation, or discontinuance of an examination authorization if the board finds that the physician has demonstrated any of the following:
(1) the OAG has exceeded the scope or terms of the examination authorization;
(2) the OAG has carried out the examination authorization in a manner that unreasonably interferes with the operation of the physician; or
(3) that the examination is no longer necessary for the OAG to conduct an investigation of a physician's controlled substance prescribing practices.

(e) An order modifying, limiting, or discontinuing an examination authorization shall not be construed to require the OAG to return or disregard information and copies of records properly obtained pursuant to the examination authorization before its modification, limitation, or discontinuance. However, the OAG may not use records obtained by exceeding the scope of an examination authorization in a disciplinary proceeding involving the licensee. Records improperly obtained shall be returned to the physician or destroyed by the OAG based on agreement of the parties.

SECTION 8. **(a) The board may consider failure to comply with an examination authorization issued under this rule as a violation of IC 25-1-9-4(a)(3) when a physician who is the subject of an examination authorization issued by the board pursuant to this rule:**
(1) fails to comply with the examination authorization; or
(2) refuses to comply with the examination authorization.

(b) The board may take action under subsection (a) of this SECTION after a hearing if:
(1) the OAG has brought a disciplinary action against the physician seeking sanctions under IC 25-1-9; or
(2) the board has issued an order requiring the physician to show cause why the board should not impose disciplinary sanctions against the physician under IC 25-1-9.

SECTION 9. **(a) An examination authorization issued by the board pursuant to this document shall not be considered to constitute "agency action" or "final agency action" as those terms are defined in IC 4-21.5-1-4 and IC 4-21.5-1-6 of the Administrative Orders and Procedures Act.**

(b) The board has discretion to schedule a hearing to consider a petition for an examination authorization filed by the OAG. Nothing in this document shall be construed or interpreted to require a hearing or to provide a physician with hearing rights in relation to a petition filed by the OAG.

(c) The board has discretion to schedule a hearing to consider a petition filed by a physician under SECTION 7(a) of this document. Nothing in this document shall be construed or interpreted to require a hearing or to provide a physician with hearing rights in relation to a petition filed by the physician.

(d) A petition for judicial review of an examination authorization under IC 4-21.5-5 may not be filed by a physician before:
(1) all other available administrative remedies have been exhausted; and
(2) the board takes action to impose disciplinary sanctions against the physician under IC 25-1-9.

SECTION 10. **(a) Records relating to the following are subject to the confidentiality provisions, limitations, and exceptions in IC 25-1-7-10:**
(1) verified petitions requesting issuance of an examination authorization;
(2) examination authorizations issued by the board;
(3) petitions filed by physicians under SECTION 7(a) of this document; and
(4) orders issued by the board modifying, limiting, or terminating examination authorizations under SECTION 7(e) of this document.

(b) Hearings held under SECTION 9 of this document are subject to IC 5-14-1.5, the open door law.

LSA Document #13-494(E)
Filed with Publisher: October 25, 2013, 8:50 a.m.

Posted: 10/30/2013 by Legislative Services Agency
An html version of this document.