Health Law Advisory

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Physician Licensure Discipline – Narcotics and Pain Management

Recent Nebraska disciplinary actions based on lax physician narcotic prescription practices suggest that it would be worthwhile for hospital and clinic medical staff to review their states' published guidance on pain management practices. Not only do lax narcotic prescription practices place licensure at risk, but disciplinary action short of license suspension can place physicians at risk of exclusion from managed care panels. Further, lack of vigilance can expose prescribing practitioners to suspension of DEA certificates, investigation and criminal prosecution for drug diversion, and malpractice claims by patients who suffer personal injury by overdose, misuse of drugs in combination with other drugs or alcohol, or by diversion to an individual other than the intended patient.

State licensure boards, including Iowa's and Nebraska's, have issued guidance on pain management to assist prescribing practitioners as they seek to balance patient needs for pain medications against the risks of addiction and diversion. Recent licensure investigations illustrate that boards of examiners expect licensed physicians to be aware of and adhere to the published guidelines.

The Iowa Boards of Medicine, Nursing, Pharmacy and Physician Assistants issued a Joint Statement on Pain, dated variously by the respective boards from 2007 through 2009. The Nebraska Board of Medicine and Surgery adopted Guidelines for the Use of Controlled Substances for the Treatment of Pain on June 3, 2005, outlining the Board's philosophy and analysis of individual cases involving pain management.

As a starting point, prescriptions for controlled substances must be within the context of a physician-patient relationship. Prescription of controlled substances must be based on a diagnosis and a finding of unrelieved pain.

Both states' guidance on narcotics prescription recommend the use of an agreement with pain management patients who are

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at risk of addiction, or who may intend to divert the narcotics prescribed. Sample agreements can be found on the internet. Generally, these agreements should outline the risks of addiction as well as patient responsibilities, anticipating and thwarting common schemes for drug diversion and/or abuse. For example, such agreements should call for regular appointments, including urine/serum medication level testing. The agreements should outline the circumstances under which prescriptions will be refilled or replaced (in the event of a claim of lost drugs). The patient should agree to seek pain medications only through the prescribing physician, and to fill all prescriptions through a single pharmacy. The agreement should include the reasons drug therapy may be discontinued.

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Medical record documentation should include in the history and physical the nature and intensity of the pain, current and past treatments, underlying or coexisting diseases or conditions, effect of the pain on the physical and psychological function and history of substance abuse. The medical records for pain management patients should include regular reassessment for pain levels, with diagnostic tests performed as indicated. The plan of care should include treatment objectives, and subsequent evaluations should include analysis of the patient's progress toward those objectives. Evidence should be gathered from family members and caregivers for the sake of objectivity. If progress is unsatisfactory, other therapeutic modalities should be considered.

The Nebraska guidelines direct physicians to seek consultation from other qualified physicians as necessary for additional evaluation and treatment. Pain management of patients with a history of substance abuse may require referral to an expert in pain management.

Recent disciplinary activity has emphasized that physicians cannot close their eyes to evidence of narcotic diversion or abuse. If patients confess that they have been obtaining narcotics from other physicians or repeatedly claim to have lost their narcotic supplies, physicians should suspend drug therapy. Other tell-tale signs are concerns expressed by the local pharmacist, which may signal that the patient is obtaining narcotics elsewhere, posing a threat to patient safety.

Prescribing practitioners practicing in Iowa are in a better position to monitor these risks than those in Nebraska. Iowa has implemented a State Prescription Drug Monitoring Program (PDMP), a statewide electronic database which collects designated data on substances dispensed in the state. PDMPs are intended to support access to legitimate medical use of controlled substances, while at the same time identifying and deterring drug abuse and diversion. The data can be used to identify persons addicted to controlled substances to allow intervention and proper treatment. The PDMP allows for distribution of data from the database to individuals authorized by state law to receive the information in the practice of their professions.

All Iowa pharmacies that dispense outpatient prescriptions for Schedule II, III, or IV controlled substances are required to report those prescriptions to the Iowa PDMP. Prescribers and pharmacists are permitted by password to access PDMP information regarding their patients' use of controlled substances to assist them in determining appropriate treatment options and to improve the quality of patient care.

The availability of the PDMP in Iowa is a great boon to prescribing Iowa licensees. Its availability, however, creates a presumption that Iowa physicians and other prescribing practitioners will access the database to evaluate the integrity of patients seeking narcotics. Failure to take advantage of such a valuable tool could have negative implications in an investigation of an Iowa licensee's narcotic prescription practices. ■

Barbara E. Person

HRSA Issues Additional 340B Compliance Audit Reports and Program Rules

This month, the Health Resources and Services Administration (HRSA) issued additional 340B Program compliance audit results and its final rule on the orphan drug exclusion—clarifying several matters relevant to 340B covered entities amid continuing Program expansion and scrutiny by industry stakeholders.

The federal 340B Drug-Pricing Program requires pharmaceutical manufacturers to provide substantial discounts on outpatient drugs purchased by certain safety-net providers—340B "covered entities"—in order for their drugs to qualify for Medicaid reimbursement. Covered entities are subject to the prohibitions on drug diversion (dispensing or utilizing 340B-discounted drugs for individuals who do not qualify as eligible outpatients of the provider) and duplicate discounts (obtaining both a front-end 340B discount and a back-end Medicaid rebate on the same drug).

HRSA has always had the ability to conduct audits of covered entities, but the Program historically relied on participant and manufacturer self-policing with respect to these key compliance requirements. Following significant Program growth—fueled by the 2010 expansion of 340B eligibility to rural providers, including critical access hospitals (CAHs)—and in response to congressional mandate and recommendations by Program stakeholders, the agency began systematic compliance audits in 2012.

Out of the 51 audits HRSA performed last year, it has completed and released details on 34. It found noncompliance in nearly half of these reviews, including in 9 out of 22 hospital audits. Adverse findings range from incorrect database records—e.g. inappropriately listing closed outpatient locations and terminated contract pharmacies in the OPA database—to drug diversion and incorrectly billing Medicaid in violation of the prohibition on duplicate discounts. While HRSA can require noncompliant providers to undertake remedial action and repay manufacturers for wrongfully obtained discounts, and may ultimately terminate them from the 340B Program, corrective actions and sanctions are still pending for nearly all of its deficiency findings to date.

HRSA has confirmed that we can expect escalating compliance monitoring. The agency ultimately plans to audit between 200 and 400 covered entities, with a focus on providers believed to have a higher risk of noncompliance as well as providers who are the subjects of complaints. We also expect increased independent audits by pharmaceutical manufacturers who suspect noncompliance and are authorized to review covered entities practices and recover erroneously received discounts after obtaining HRSA approval that there is "reasonable cause" to believe a provider has engaged in drug diversion or has obtained duplicate discounts.

Absent full disclosure of the audit results, we can only speculate on possible penalties and the precise tools and techniques used by auditors to determine provider compliance with 340B Program requirements. But given the current enforcement environment and concerns expressed by Program participants, manufacturers, and members of Congress, all covered entities should review existing 340B policies and processes and actively evaluate compliance with applicable Program standards on an ongoing basis.

Effective October 1, 2013, certain entities must also consider their continuing compliance with the orphan drug exclusion in accordance with the final rule published by HRSA on July 23rd.

This exclusion prevents free-standing cancer hospitals, CAHs, rural referral centers, and sole community hospitals from purchasing pharmaceuticals used to treat certain rarely occurring conditions at 340B prices in order to protect manufacturers' financial incentives to develop the drugs for rare conditions. The FDA's current orphan drug list includes over 300 well-known therapies, including Avastin, Botox and Remicade.

The final rule retains the narrow interpretation of the orphan drug exclusion offered in the 2011 proposed regulation. As finalized, these covered entities are only prohibited from purchasing an orphan drug at a 340B discount when prescribed to treat the disease or condition for which it was designated as such by the FDA, and not if the drug is used for a non-orphan indication. Further, HRSA will require manufacturers

to presume that a covered entity's request for an orphan drug at a 340B price means that it satisfies this requirement and will use the drug for non-orphan treatment purposes.

HRSA's position therefore places sole responsibility to demonstrate compliance with the orphan drug exclusion with the affected covered entities. It directs providers to maintain auditable records to demonstrate compliance in the event that they develop a system to track and trace the indication for which a particular unit of a drug is utilized. If a provider is unable to satisfy this recordkeeping requirement, HRSA states that it should purchase all orphan drugs, regardless of indication, outside of the 340B Program. A covered entity's registered outpatient facilities may opt-out of 340B for purposes of orphan drug purchasing even if its parent site does not; all contract pharmacies, however, must follow the same approach as the sponsoring covered entity with respect to these purchases. Compliance with limits on orphan drug prices are subject to HRSA and manufacturer audits.

The final rule on the orphan drug exclusion takes effect October 1, 2013 and is available at http://www.gpo.gov/fdsys/pkg/FR-2013-07-23/pdf/2013-17547.pdf. ■

Whitney C. West

It's Complicated: Requests for Patient Information/Access for Research

With increasing frequency, practitioners and health professional students request patient information and/or access to patients or patients' medical records for purposes of research. The requests are particularly difficult to address in small organizations without an Institutional Review Board (IRB). They can also be difficult to handle because they may be initiated by a wide variety of persons and directed to any number of people within the organization.

Requests for access to patients and patient information demands an analysis of three things: (1) Does the proposed use amount to research, triggering regulations governing the protection of human subjects? (2) If so, how is informed consent being obtained from potential subjects? And, (3) How is the subject's authorization for use and disclosure of protected health information (PHI) under the Health Insurance Portability and Accountability Act ("HIPAA") being obtained?

Federally-funded research is regulated by the Department of Health and Human Services ("DHHS") and the Food and Drug Administration and is defined in regulations as involving human subjects and including "a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge."[1] The results do not necessarily have to be published to be research governed by regulations. All institutions performing research are encouraged to provide formal assurances that their research will comply with DHHS regulations regardless of the funding source.[2] In contrast, the HIPAA Privacy Rule applies to all covered entities.

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There are a number of urban (and perhaps rural) myths about the disclosure and use of PHI as well as the need for informed consent in research activities. This article addresses five "mythbusters" related to commonly occurring situations:

1. I'm a Member of the Medical Staff or a Student in a Clinical Rotation, So I Don't Need Permission—Right?

   Members (current or past) of a facility's medical staff are not exempt from informed consent and HIPAA authorization requirements. The fact that a medical staff member previously treated a patient or is a member of a group practice that treated the patient does not provide unfettered access to patients' records for research purposes.

   Students in clinical practicums and rotations are not exempted from informed

consent and HIPAA Privacy Rule requirements if they are conducting research. However, it can be difficult sometimes to discern between a class assignment and research. Often, it is necessary to request additional details about the project.

2. I'm Only Using De-identified Data.

   "De-identified" does not mean merely that the patient's name has been redacted or omitted. The HIPAA Privacy Rule sets out 18 identifiers that must be removed before the data is considered de-identified.[3] Very little of the data said to be de-identified by researchers actually meets this requirement.

3. Please Just Waive the Consent and Authorization Requirements.

   Waiver of informed consent and HIPAA authorization requirements is not automatic. Waiver of informed consent requirements and HIPAA authorization requirements is provided for in pertinent regulations if requested by the researcher; however, waiver requires certain factual findings by an IRB; in the case of waiver of informed consent; or, in the case of waiver of the HIPAA authorization requirement, a Privacy Board designated by the facility or an IRB acting as a Privacy Board.[4] Waiver should not be granted merely for the convenience of the researcher.

4. The Medical Executive Committee will Approve Research.

   A medical staff committee may not act as an IRB to approve federally-funded research without applying and meeting all Department of Health and Human Services requirements of registration and obtaining a Federal-wide Assurance Number. The organization may, however, appoint a Privacy Board if it meets certain requirements.[5]

5. Locating Subjects is Exempted Because it is an Activity Preparatory to Research.

   Recruiting subjects is considered by DHHS to be research that triggers both informed consent and Privacy Rule requirements.[6] Specifically, this means that facilities may not disclose PHI to researchers who then use that information to contact potential subjects and obtain informed consent. The facility (covered entity) under HIPAA must itself obtain the potential subject's authorization to disclose his or her name to the researcher. Only when such authorization is obtained, may the facility disclose PHI unless a waiver has been granted by a Privacy Board or the IRB acting as a Privacy Board.

   The exception for "activities preparatory to research" is designed to provide researchers with limited access to the minimum necessary amount of PHI required to determine whether or not the concept of the research project is viable. The exception is very narrow and does not include identification and/or recruiting of research subjects once the concept for a study is established.[7]

Recommendations

- Designate an individual in your facility to be the central contact point for research requests. Often, the appropriate person is the HIM manager or the Privacy Officer who already has substantial background in HIPAA requirements. Any request should be directed to that individual so that the three key elements of analysis (research, informed consent and HIPAA authorization) are consistently reviewed. This person should seek the advice of legal counsel as needed.

- Be sure that Medical Staff Bylaws, Rules and Regulations and organizational policies and procedures are up to date regarding disclosure and use of PHI and access to patients for research purposes and that they do not conflict with HIPAA regulations or DHHS rules where applicable.

- Consider developing a relationship with an IRB in a larger institution for technical assistance and possible review of research requests in cases where IRB approval of research and/or waiver is required.

- Use a standard format for requests for access to patients and records and require all such requests to be in writing. Use of a form helps to assure consistent and complete information.

- Recognize that not all requests for research can be granted and not all requests for waivers should be approved. The researcher may have to modify his or her research design or method of recruiting subjects or obtaining data to be able to carry out the study in your organization.

- Understand that the organization's primary role is to protect potential subjects by making sure that applicable requirements for informed consent to participate in research and authorization for use and disclosure of PHI is properly obtained as required by current law. ■

Julie A. Knutson

1 45 C.F.R. § 46.102(e) and (f).
2 *Institutional Review Boards: A Primer,* (American Health Lawyers Association: 2007) p. 8.
3 45 C.F.R.§§ 164.514(a) and (b).
4 45 C.F. R. § 46.116; 21 C.F.R.§ 50.27.
5 45 C.F.R.§ 164.512 (i)(B); 45 C.F.R. § 46.108(b); and 21 C.F.R. § 56.108(c).
6 67 Fed. Reg. 53230-31 (August 14, 2002).
7 45 C.F. R. § 164.512(i)(I)(ii).

Upcoming Speaking Engagements

On September 17, 2013, Michael W. Chase and Andrew D. Kloeckner will present "Best Practices for Preparing Your Organization for Investigations and Audits" at the Nebraska Health Care Association Fall Convention at the La Vista Conference Center. Their presentation will begin at 3:00 p.m. ■

Health Care Group

Vickie Brady Ahlers
402.636.8230
vahlers@bairdholm.com

Michael W. Chase
402.636.8326
mchase@bairdholm.com

Alex (Kelly) M. Clarke
402.636.8204
kclarke@bairdholm.com

John R. Holdenried
402.636.8201
jholdenried@bairdholm.com

Andrew D. Kloeckner
402.636.8222
akloeckner@bairdholm.com

Julie A. Knutson
402.636.8327
jknutson@bairdholm.com

Barbara E. Person
402.636.8224
bperson@bairdholm.com

Whitney C. West
402.636.8353
wwest@bairdholm.com

All attorneys are admitted to practice in Nebraska and Iowa unless otherwise noted.

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Baird Holm

1700 Farnam St
Suite 1500
Omaha, NE 68102

402.344.0500
402.344.0588

www.bairdholm.com