

September 2013

News



Iowa Board of Pharmacy

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Prescription Monitoring Program Update

As of July 11, 2013, 4,155 prescribers have registered to use the prescription monitoring program (an increase of 24% from one year ago) and 1,885 pharmacists have registered to use the program (an increase of 44% from one year ago). Between January 1, 2012 and December 31, 2012, a total of 112,437 requests for data were submitted to the program. Between January 1, 2013 and June 30, 2013, a total of 79,111 requests were submitted. If this trend continues during the remainder of 2013, the number of requests in 2013 will increase by 41% over 2012. The program has registered 252 practitioner agents and 39 pharmacist agents as of July 11, 2013. The program is continuing to reduce the incidence of patients who utilize multiple pharmacies and multiple prescribers to obtain controlled substances in Iowa.

Iowa Board of Pharmacy Licensing and Registration Statistics – Summer 2013

Iowa-licensed pharmacists: 5,898 (3,462 residing in Iowa)
Registered, nationally certified pharmacy technicians: 4,306
Registered, uncertified pharmacy technicians (including trainees): 1,201
Total technicians: 5,507
Registered pharmacy support persons: 1,404
Pharmacist interns: 1,572
Total support staff: 8,483
Iowa pharmacies: 939
Nonresident (out-of-state) pharmacies: 617
Controlled Substances Act registrants (includes pharmacies): 16,509
Wholesalers (in state): 202
Wholesalers (nonresident): 1,294
Wholesalers (total): 1,496

Pharmacy Benefit Managers

Today, more than 210 million Americans nationwide receive drug benefits administered by pharmacy benefit managers (PBMs). It is estimated that there are fewer than 100 major

PBM companies in the United States. The Iowa Board of Pharmacy office routinely receives numerous questions about the activities of PBMs. In Iowa, PBMs are regulated by the Iowa Department of Commerce, Insurance Division. Current law resides in Iowa Code, Chapter 510B and administrative rules are located in 191 Iowa Administrative Code, Chapter 59. The law and rules have been in effect since 2007-2008. A copy of Iowa law and rules for PBMs is included as an insert to this issue of the *Newsletter*. PBMs are required to obtain the approval of the prescribing practitioner prior to requesting any drug substitution under Iowa Code §510B.6. A PBM may not substitute an equivalent prescription drug contrary to a prescription drug order that prohibits a substitution. PBMs are required to develop an internal system to record and report complaints. These requirements are contained in 191 I.A.C. 59.5(1). The Iowa Insurance Division has drafted some specific instructions for pharmacists who wish to file a complaint against a PBM, which are available online at www.iid.state.ia.us/file_a_complaint. PBMs are required to submit a summary of all complaints filed against them with the Iowa commissioner of insurance on a quarterly basis. Forty-eight PBMs are listed in the online directory of the Pharmacy Benefit Management Institute at www.pbmi.com/pbmdir.asp. None of these companies are located in Iowa. In 2012, the five largest PBMs in the US were Express Scripts of St Louis, MO; CVS Caremark of Scottsdale, AZ; Prime Therapeutics of Eagan, MN; OptumRx of Irvine, CA; and Catamaran of Lisle, IL.

Update on Epilepsy Medications

A committee of the Board met with representatives of the Iowa Epilepsy Treatment & Education Task Force on June 12, 2013. The discussion focused on the proper handling of prescriptions for brand-name products, generic products, and **branded** generic products. The advantage of having the patient's diagnosis on the prescription was also discussed. All parties agreed on the following course of action: (1) clarify, in Board rules, the difference between generics and branded generics vis-à-vis Iowa's law for drug product selection; (2) clarify the proper method for dispensing products from more

Continued on page 4



Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.


Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.

ISMP Study on Targeted Mandatory Patient Counseling

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
 - ◇ fentanyl patches
 - ◇ hydrocodone with acetaminophen
 - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
 - ◇ warfarin
 - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
 - ◇ Humalog® (insulin lispro)
 - ◇ NovoLog® (insulin aspart)
 - ◇ Levemir® (insulin detemir)
 - ◇ Lantus® (insulin glargine)
 - ◇ Apidra® (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
 - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at www.ismp.org/AHRO/default.asp?link=ha.

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter*, which may be accessed in the Publications section of www.nabp.net.

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter*; accessible in the Publications section of www.nabp.net. NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABPLAW**[®] Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABPLAW** Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABPLAW** Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at www.nabp.net/programs/member-services/nabplaw/.



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than one company in a single prescription due to a drug shortage or other extenuating circumstance (ie, mixing two different generic products in the same prescription vial); and (3) educate pharmacists on the need to notify prescribers whenever a change is made in the dispensing of a patient's epilepsy medications. The Board will publish proposed changes in rules as soon as they are available and will continue to work with the members of the Epilepsy Task Force to resolve dispensing issues and ensure patient safety. A recent study in the *Journal of the American Medical Association Internal Medicine* has concluded that "changes in pill color significantly increase the odds of nonpersistence; this may have important clinical implications. Our study supports a reconsideration of current regulatory policy that permits wide variation in the appearance of bioequivalent drugs."

Source: "Variations in Pill Appearance of Antiepileptic Drugs and the Risk of Nonadherence," JAMA Intern Med. 2013; 173(3): 202-208. Background: "Generic prescription drugs are bioequivalent to brand-name versions but may not have consistent color or shape, which can cause confusion and lead to interruptions in medication use. This study sought to determine whether switching among different-appearing antiepileptic drugs (AEDs) is associated with increased rates of medication nonpersistence, which can have serious medical, financial and social consequences."

50-Year Pharmacists

The Board congratulates the following 25 Iowa pharmacists who were originally licensed in 1963, have continuously maintained their Iowa pharmacist license, and have devoted a half-century of service to the public and the profession: Thomas A. Ayres, Norman, OK; James L. Aswegan, Carlsbad, CA; Richard L. Abrahamson, Edmond, OK; Byrl D. Blackmer, Ankeny, IA; Monte R. Baugher, West Des Moines, IA; Lyman A. Berge, Peoria, IL; Robbin R. Burns, Waterloo, IA; Robert E. Bellinger, Fort Dodge, IA; Clarke H. Cordes, Lakeland, FL; David C. Dyball, Meckling, SD; James G. Dickerson, Sr, Gretna, NE; William M. Dimig, Atlantic, IA; Thomas B. Dodds, Dakota Dunes, SD; Gus T. Erickson, Clear Lake, IA; Thomas H. Hofer, Kalona, IA; Larry L. Hurst, Runnells, IA; Lamoine O. Gearhart, Ontario, OR; Shelva J. King, East Moine, IL; Kenneth R. Moorman, Atlantic, IA; Cornelius Maris, Jr, Spirit Lake, IA; Robert G. Nieland, Eldridge, IA; Richard W.

Severson, Martinez, GA; Thomas J. Sullivan, Keosauqua, IA; Paul E. Twedt, Ames, IA; and Judith A. Woolums, Ottumwa, IA.

Next Board Meeting

The Board plans to hold its next meeting on November 5-6, 2013. Administrative hearings and a closed session will be held at the Board office in Des Moines, IA, on November 5. The Board plans to meet in open session in Council Bluffs, IA, on November 6. Please contact the Board office at 515/281-5944 to confirm times and locations.

Board Web Site

Please visit the Board's Web site at www.state.ia.us/ibpe/.

Board Mission

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code §155A.2(1).

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IOWA CODE CHAPTER 510B
REGULATION OF PHARMACY BENEFITS MANAGERS

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510B.4 Performance of duties — good faith — conflict of interest.

510B.5 Contacting covered individual — requirements.

510B.6 Dispensing of substitute prescription drug for prescribed drug.

510B.7 Duties to pharmacy network providers.

510B.1 Definitions.

As used in this chapter, unless the context otherwise requires:

1. “*Commissioner*” means the commissioner of insurance.
2. “*Covered entity*” means a nonprofit hospital or medical services corporation, health insurer, health benefit plan, or health maintenance organization; a health program administered by a department or the state in the capacity of provider of health coverage; or an employer, labor union, or other group of persons organized in the state that provides health coverage. “*Covered entity*” does not include a self-funded health coverage plan that is exempt from state regulation pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA), as codified at 29 U.S.C. § 1001 et seq.; a plan issued for health coverage for federal employees; or a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplemental, disability income, or long-term care, or other limited benefit health insurance policy or contract.
3. “*Covered individual*” means a member, participant, enrollee, contract holder, policyholder, or beneficiary of a covered entity who is provided health coverage by the covered entity, and includes a dependent or other person provided health coverage through a policy, contract, or plan for a covered individual.
4. “*Generic drug*” means a chemically equivalent copy of a brand-name drug with an expired patent.
5. “*Labeler*” means a person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration pursuant to 21 C.F.R. § 207.20.
6. “*Pharmacy*” means pharmacy as defined in section 155A.3.
7. “*Pharmacy benefits management*” means the administration or management of prescription drug benefits provided by a covered entity under the terms and conditions of the contract between the pharmacy benefits manager and the covered entity.
8. “*Pharmacy benefits manager*” means a person who performs pharmacy benefits management services. “*Pharmacy benefits manager*” includes a person acting on behalf of a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management services for a covered entity. “*Pharmacy benefits manager*” does not include a health insurer licensed in the state if the health insurer or its subsidiary is providing pharmacy benefits management services exclusively to its own insureds, or a public self-funded pool or a private single employer self-funded plan that provides such benefits or services directly to its beneficiaries.
9. “*Prescription drug*” means prescription drug as defined in section 155A.3.
10. “*Prescription drug order*” means prescription drug order as defined in section 155A.3.

510B.2 Certification as a third-party administrator required.

A pharmacy benefits manager doing business in this state shall obtain a certificate as a

third-party administrator under chapter 510, and the provisions relating to a third-party administrator pursuant to chapter 510 shall apply to a pharmacy benefits manager.

510B.3 Enforcement — rules.

1. The commissioner shall enforce the provisions of this chapter.
2. The commissioner shall adopt rules pursuant to chapter 17A to administer this chapter including rules relating to all of the following:
 - a. Timely payment of pharmacy claims.
 - b. A process for adjudication of complaints and settlement of disputes between a pharmacy benefits manager and a licensed pharmacy related to pharmacy auditing practices, termination of pharmacy agreements, and timely payment of pharmacy claims.

510B.4 Performance of duties — good faith — conflict of interest.

1. A pharmacy benefits manager shall perform the pharmacy benefits manager's duties exercising good faith and fair dealing in the performance of its contractual obligations toward the covered entity.
2. A pharmacy benefits manager shall notify the covered entity in writing of any activity, policy, practice ownership interest, or affiliation of the pharmacy benefits manager that presents any conflict of interest.

510B.5 Contacting covered individual — requirements.

A pharmacy benefits manager, unless authorized pursuant to the terms of its contract with a covered entity, shall not contact any covered individual without the express written permission of the covered entity.

510B.6 Dispensing of substitute prescription drug for prescribed drug.

1. The following provisions shall apply when a pharmacy benefits manager requests the dispensing of a substitute prescription drug for a prescribed drug to a covered individual:
 - a. The pharmacy benefits manager may request the substitution of a lower priced generic and therapeutically equivalent drug for a higher priced prescribed drug.
 - b. If the substitute drug's net cost to the covered individual or covered entity exceeds the cost of the prescribed drug, the substitution shall be made only for medical reasons that benefit the covered individual.
2. A pharmacy benefits manager shall obtain the approval of the prescribing practitioner prior to requesting any substitution under this section.
3. A pharmacy benefits manager shall not substitute an equivalent prescription drug contrary to a prescription drug order that prohibits a substitution.

510B.7 Duties to pharmacy network providers.

1. A pharmacy benefits manager shall not mandate basic recordkeeping that is more stringent than that required by state or federal law or regulation.
2. If a pharmacy benefits manager receives notice from a covered entity of termination of the covered entity's contract, the pharmacy benefits manager shall notify, within ten working days of the notice, all pharmacy network providers of the effective date of the termination.
3. Within three business days of a price increase notification by a manufacturer or supplier, a pharmacy benefits manager shall adjust its payment to the pharmacy network provider consistent with the price increase.

**191 IOWA ADMINISTRATIVE CODE (IAC) CHAPTER 59
PHARMACY BENEFITS MANAGERS**

191—59.1 Purpose.

The purpose of this chapter is to administer the provisions of Iowa Code Supplement chapter 510B relating to the regulation of pharmacy benefits managers.

191—59.2 Definitions.

The terms defined in Iowa Code Supplement section 510B.1 shall have the same meaning for the purposes of this chapter. The definitions contained in 191—Chapter 58, “Third-Party Administrators,” and 191—Chapter 78, “Uniform Prescription Drug Information Card,” of the Iowa Administrative Code are incorporated by reference. As used in this chapter:

“*Clean claim*” means a claim which is received by any pharmacy benefits manager for adjudication and which requires no further information, adjustment or alteration by the pharmacist or pharmacies or the insured in order to be processed and paid by the pharmacy benefits manager. A claim is a clean claim if it has no defect or impropriety, including any lack of substantiating documentation, or no particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this chapter. A clean claim includes a resubmitted claim with previously identified deficiencies corrected.

“*Complaint*” means a written communication expressing a grievance or an inquiry concerning a transaction between a pharmacy benefits manager and a pharmacy or pharmacist.

“*Day*” means a calendar day, unless otherwise defined or limited.

“*Paid*” means the day on which the check is mailed or the day on which the electronic payment is processed by the pharmacy benefits manager’s bank.

191—59.3 Timely payment of pharmacy claims.

59.3(1)

All benefits payable under a pharmacy benefits management plan shall be paid as soon as feasible but within 20 days after receipt of a clean claim when the claim is submitted electronically and shall be paid within 30 days after receipt of a clean claim when the claim is submitted in paper format.

59.3(2)

Payments to the pharmacy or pharmacist for clean claims are considered to be overdue if not paid within 20 or 30 days, whichever is applicable. If any clean claim is not timely paid, the pharmacy benefits manager must pay the pharmacy or pharmacist interest at the rate of 10 percent per annum commencing the day after any claim payment or portion thereof was due until the claim is finally settled or adjudicated in full.

59.3(3)

Existing contracts between clients and pharmacy benefits managers shall comply with the requirement that clean claims be paid within 20 or 30 days, whichever is applicable, when such contracts are renegotiated on or after January 1, 2009, but no later than December 31, 2009.

191—59.4 Study.

On or before December 31, 2009, the commissioner will examine the feasibility of requiring a 15-day payment schedule for electronically submitted claims. The examination shall include economic impact on pharmacy benefits managers, patients, and Iowa pharmacies.

191—59.5 Complaints.

59.5(1)

Each pharmacy benefits manager shall develop an internal system to record and report complaints. This system shall include but not be limited to:

- a. Complaints from the pharmacy indicating the reason for the complaint and factual documentation to support the complaint;
- b. Contact name, address and telephone number of the pharmacy benefits manager;
- c. Contact name, address and telephone number of the pharmacy;
- d. Prescription number;
- e. Prescription reimbursement amount for disputed claim(s);
- f. Disputed prescription claim payment date(s);
- g. Plan benefits certificate.

59.5(2)

A summary of all complaints as outlined in subrule 59.5(1) received by the pharmacy benefits manager shall be submitted to the commissioner on a quarterly basis within 30 days after the calendar quarter has ended.

191—59.6 Auditing practices.

59.6(1)

An audit of the pharmacy records by a pharmacy benefits manager shall be conducted in accordance with the following:

- a. The pharmacy benefits manager conducting the initial on-site audit must provide the pharmacy written notice at least one week prior to conducting any audit;
- b. Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist;
- c. When a pharmacy benefits manager alleges an overpayment has been made to a pharmacy or pharmacist, the pharmacy benefits manager shall provide the pharmacy or pharmacist sufficient documentation to determine the specific claims included in the alleged overpayment;
- d. A pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for drugs or medicinal supplies, written or transmitted by any means of communication, for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;
- e. Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the pharmacy benefits manager;
- f. The period covered by an audit may not exceed two years from the date on which the claim was submitted to or adjudicated by a managed care company, insurance company, third-party payor, or any pharmacy benefits manager that represents such companies, groups, or a department;
- g. Unless otherwise consented to by the pharmacy, an audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled during that time;
- h. The preliminary audit report must be delivered to the pharmacy within 120 days after conclusion of the audit. A final written audit report shall be received by the pharmacy within six months of the preliminary audit report or final appeal, whichever is later;
- i. A pharmacy shall be allowed at least 30 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit; and
- j. The audit criteria set forth in this subrule shall apply only to audits of claims submitted for payment after December 31, 2008.

59.6(2)

Notwithstanding any other provision in this rule, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating the recuperation of contractual penalties for audits.

59.6(3)

Recuperation of any disputed funds shall occur only after final disposition of the audit, including the appeals process as set forth in subrules 59.6(4) and 59.6(5).

59.6(4)

Each pharmacy benefits manager conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the pharmacy benefits manager. If, following the appeal, the pharmacy benefits manager finds that an unfavorable audit report or any portion thereof is unsubstantiated, the pharmacy benefits manager shall dismiss the audit report or said portion without the necessity of any further proceedings.

59.6(5)

If, following the final appeal, the pharmacy benefits manager finds that an unfavorable audit report or any portion thereof is found to be substantiated, the pharmacy benefits manager shall already have in place a process for an independent third-party review of the final audit findings. As part of the final appeal process of any final adverse decision, the pharmacy benefits manager shall notify the pharmacy in writing of its right to request an independent third-party review of the final audit findings and the process used to request such a review.

59.6(6)

Each pharmacy benefits manager conducting an audit shall, after completion of any review process, provide a copy of the final audit report to the plan sponsor.

59.6(7)

This rule shall not apply to any investigative audit which involves fraud, willful misrepresentation, abuse, or any other statutory provision which authorizes investigations relating to but not limited to insurance fraud.

191—59.7 Termination of pharmacy contracts.

59.7(1)

A pharmacy or pharmacist shall not be terminated from the network or penalized by a pharmacy benefits manager solely because of filing a complaint, grievance or appeal.

59.7(2)

A pharmacy or pharmacist shall not be terminated from the network or penalized by a pharmacy benefits manager due to any disagreement with the decision of the pharmacy benefits manager to deny or limit benefits to covered persons or due to any assistance provided to covered persons by the pharmacy or pharmacist in obtaining reconsideration of the decision of the pharmacy benefits manager.

59.7(3)

Termination of contracts between a pharmacy benefits manager and a pharmacy shall include a provision describing notification procedures for contract termination. The contract shall require no less than 60 days' prior written notice by either party that wishes to terminate the contract.

59.7(4)

If the pharmacy benefits manager has evidence that the pharmacy or pharmacist has engaged in fraudulent conduct or poses a significant risk to patient care or safety, the pharmacy benefits manager may immediately suspend the pharmacy or pharmacist from further performance under the contract provided written notice of termination is provided to the pharmacy or pharmacist.

59.7(5)

Termination of a contract between a pharmacy benefits manager and a pharmacy or pharmacist or termination of a pharmacy or pharmacist from the network of the pharmacy benefits manager shall not release the pharmacy benefits manager from the obligation to make payments due to the pharmacy or pharmacist for services rendered before the contract of the pharmacy or pharmacist was terminated.

59.7(6)

Independent third-party review of termination decision. The pharmacy or pharmacist may request an independent third-party review of the final decision to terminate the contract between the pharmacy benefits manager and the pharmacy or pharmacist by filing with the pharmacy benefits manager a written request for an independent third-party review of the decision. This written request must be filed with the pharmacy benefits manager within 30 days of receipt of the final termination decision.

These rules are intended to implement Iowa Code chapters 17A and 514L and Iowa Code Supplement chapter 510B.

INSTRUCTIONS TO PHARMACISTS FOR FILING A COMPLAINT WITH THE IOWA INSURANCE DIVISION

1. Have you used your pharmacy benefits manager's (PBM) complaint and appeal process to resolve your dispute?

Iowa Code Chapter 510B requires all PBMs to develop an internal system for adjudication of complaints and settlement of disputes between a PBM and a licensed pharmacy. Before the Iowa Insurance Division (IID) may accept a complaint regarding a pharmacy issue, you must exhaust the complaint and appeals process provided by your PBM. If problems remain unresolved after participating in the appeal process, you may submit a complaint to the IID for assistance.

2. Network Policy Contract. If any of your Network Policy Contract provisions are central to your complaint, please provide the applicable contract language.

3. Provide the following information regarding your complaint.

- Your name, telephone number, and e-mail address
- Pharmacy name and address
- PBM's full name
- Pharmacy Services Administration Organization (PSAO) (if applicable)
- Insurance company's full name
- Prescription number
- Date of service
- Reason for complaint
 - Each complaint should include one problem that involves one PBM. If there are multiple examples of a specific problem that involves one PBM, you may include all examples in one complaint. Please provide a thorough explanation of your problem and document it with examples.
 - Provide examples for each problem and include documents that support your position. It is not necessary to provide a narrative for each individual example.

Information the IID obtains in the course of an investigation is confidential. See Iowa Code, Section 505.8. If the insurance commissioner determines that it is necessary or appropriate in the public interest or for the protection of the public, the insurance commissioner may share information with other regulatory authorities or may publish information concerning violations of Iowa insurance law. If you feel the information you are providing to the IID should not be released under the discretionary authority of the insurance commissioner, clearly identify the documents or information and assert the privilege asserted. See Iowa Code, Section 22.7.

THE ROLE OF THE IOWA INSURANCE DIVISION IN REVIEWING PHARMACIST'S COMPLAINTS AGAINST PHARMACY BENEFIT MANAGERS

The IID regulates and supervises the business of PBMs in Iowa, pursuant to Iowa Code Chapter 510B and Iowa Administrative Code 191-59.

If this matter involves a dispute, we request you set forth your position including the relevant facts, contract language, and documents as described above that you feel would be helpful in our review.

- By accepting your complaint, we have not made any assumptions about the validity of the complaint or the truth of your complaint.
- In handling this complaint, the IID does not represent any party to the dispute. We represent the state of Iowa in enforcing the relevant insurance laws and do not represent private parties.
- In making our decision, we rely on the information provided to us by the pharmacy, the PBM, the insurer, and other relevant parties to the complaint.
- In situations where it appears that a violation of Iowa insurance law has occurred, the Iowa insurance commissioner has the authority to issue administrative orders, hold administrative hearings, suspend or revoke TPA Certificate of Administration, and to impose monetary penalties.

The Iowa Insurance Division makes an independent evaluation of each matter received. We review PBM responses for the reasonableness of the actions taken, compliance with all applicable statutes and regulations, compliance with all contract provisions, and identification of appropriate actions taken to resolve this complaint.

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