Electronic Prescribing of Controlled Substances: Missouri BNDD’s rule allowing electronic prescribing of controlled substances became effective on July 30th. According to BNDD, the Missouri rule matches the federal DEA rule already in existence. A full copy of revised rule 19 CSR 30-1.062 is available online at http://www.sos.mo.gov/adrules/csr/current/19csr/19c30-1.pdf.

A few notes from BNDD:

1. The previous forms of transmission (writing, telephoning and faxing) are still permitted where applicable;
2. The option of electronic prescribing is a new voluntary option and is not mandatory or required;
3. The new federal rules were effective June 1, 2010. Missouri registrants may begin when they have met all the federal guidelines. Missouri will not be implementing additional requirements;
4. Prescriptions may be transmitted electronically in Schedules 2, 3, 4, and 5;
5. There are certain requirements for practitioners, pharmacies, and hospitals. Practitioners will be focusing on security and manner of transmitting. Pharmacies will be focusing on security and archiving;
6. Not all providers may be ready at the same time. A doctor may be ready to transmit, but a local pharmacy may not be ready yet to receive. It will take some time for all parties to become authorized;
7. There are medical software companies that may have an approved system in place. These companies are called “application providers.” They will have their new systems audited and reviewed by a third-party independent company. Once they have received clearance from the auditing company, these application providers will receive authorization and a certificate to begin implementing their software and hardware systems. There are similar software companies for pharmacies. These software providers and application providers cannot implement their systems until receiving approval.
8. Once the application provider has received a certificate and is authorized to begin, these providers may begin providing their systems to individual practitioners and pharmacies. The doctors should receive a certificate from the software provider that shows they are an approved provider. These software providers may also provide the practitioners with a certificate that shows the practitioners are authorized to electronically prescribe using their system.
9. What starts electronic—must stay electronic: If a practitioner transmits an electronic prescription, it shall arrive at a pharmacy and then be stored and archived electronically. The practitioner cannot transmit a prescription and then have it printed to a pharmacy fax machine. A faxed prescription arrives on paper and those require a physical and manual signature before the document is faxed.
10. Participating prescribers must undergo “identity proofing” before hitting the send/transmit button each time. Verification is required to ensure the transmission of the prescription is from the proper registrant. There are three ways to verify identity and prescribers will be required to provide any two of them:
   A. Something you know.......................a user ID or password;
   B. Something you are.........................a fingerprint scan or retina eye scan;
   C. Something you have.......................a USB device to be inserted or smartcard to swipe;
11. A prescription gets filled out with all of the information required. The prescriber must undergo two of
the identify checks above before transmitting. An assistant or employee may hold an electronic device and prepare it; however, only the registered practitioner with proper identity may transmit it. The completion of the two-factor identity code is considered part of the signature;

12. A digitally scanned in signature or a follow-up is not considered an acceptable method of identity proofing;

13. Prescriptions can only be transmitted for one patient at a time;

14. Prescriptions must be transmitted as soon as possible after identity proofing/signature;

15. If any prescription data/record is printed after transmission, the document must be labeled COPY ONLY—NOT VALID FOR DISPENSING;

16. If the transmission fails: The prescriber must be notified the transmission failed then, the prescription may be printed out for manual signature. The prescription must document the initial prescription was electronic, name of pharmacy, date and time;

17. Controlled drug records must be maintained for two (2) years;

18. Pharmacies have controls on who is allowed to access and retrieve data. Any changes or annotations must also be electronic. Receipt of a prescription is documented electronically; and

19. Pharmacy records must be backed up daily and retained electronically.

Questions regarding the revised rule or electronic prescribing of controlled substances should be addressed to BNDD at (573) 751-6321 or bndd@health.mo.gov.

**IMPORTANT INFORMATION FOR VETERANS:**

Veterans taking one of the 145 professional state licensing or certification examinations required by the Department of Insurance, Finance and Professional Registration can be reimbursed for the cost of the exam. This includes costs for the:

- NAPLEX
- MPJE, and
- Preliminary Application Fee (pharmacist reciprocity candidates)

Veterans Affairs will pay for the cost of the tests, up to $2,000 for each test. Veterans Affairs will not issue reimbursement for other fees connected with obtaining a license or certification. Payment is issued after you submit the required information to the VA. The VA will reimburse regardless of the number of exams you may take, or the number of times you may take an exam.

Visit the Veterans Affairs website to learn more about how the GI Bill can pay the cost of a license or certification test or if you have questions about licensing/certification reimbursement or applying for benefits. Interested veterans can also call 888-GIBILL-1 (888-442-4551), or for the hearing-impaired call 800-829-4833. See the full list of licensing and certification exams eligible for reimbursement at [http://difp.mo.gov/licensing/documents/Veterans_DIFPApplication_Attachment.pdf](http://difp.mo.gov/licensing/documents/Veterans_DIFPApplication_Attachment.pdf).

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**Feedback**

**We’d like your feedback!**

**INSPECTION SURVEY**

The Board recently initiated a new Inspection Survey to gather feedback about the Board’s inspection process. Your inspector will provide information after your inspection on how to complete the online survey. The brief survey includes seven short questions. All responses are anonymous. Your feedback will help the Board build an effective and efficient inspection process.
ARE YOU A MANDATORY REPORTER?

Pharmacists are required by law to report abuse or neglect if the pharmacist knows or has reasonable cause to believe that such abuse or neglect has occurred or is occurring against the following individuals:

198.070, RSMo
Who does it apply to? Residents of a residential care facility, assisted living facility, intermediate care facility or skilled nursing facility.
Report made to: Missouri Department of Health and Senior Services/Missouri’s Abuse and Neglect Hotline (1-800-392-0210)

194.2475, RSMo
Who does it apply to? Clients receiving “in-home services” from an in-home services provider agency under contract with the Missouri Department of Health and Senior Services (DHSS) or with a Medicaid participation agreement.
Report made to: Missouri Department of Health and Senior Services/Missouri’s Abuse and Neglect Hotline (1-800-392-0210)

208.912, RSMo
Who does it apply to? Consumers of Personal Care: Defined as physically disabled persons determined by DHSS to be eligible to receive personal care assistance services. See definition § 208.900.
Report made to: Missouri Department of Health and Senior Services/Missouri’s Abuse and Neglect Hotline (1-800-392-0210)

565.188, RSMo
Who does it apply to? Individuals 60 years old or older that have been subjected to conditions or circumstances which would result in abuse or neglect.
Report made to: Missouri Department of Health and Senior Services/Missouri’s Abuse and Neglect Hotline (1-800-392-0210)

565.218, RSMo
Who does it apply to? Vulnerable Persons: Defined as any person in the custody, care or control of the Missouri Department of Mental Health (DMH) that is receiving services from a program operated, funded, licensed or certified by DMH. See definition § 630.005(34).
Report made to: Missouri Department of Mental Health/Division of Developmental Disabilities (573) 751-4054 ddmail@dmh.mo.gov

630.165, RSMo
Who does it apply to? Patients, residents or clients of a developmental disability facility. A “developmental disability facility” is defined as a provider or department facility licensed by the Missouri Department of Mental Health under Chapter 630, RSMo, that admits persons with an intellectual or developmental disability for residential habilitation and other services.
Report made to: Missouri Department of Mental Health/Division of Developmental Disabilities (573) 751-4054 ddmail@dmh.mo.gov

***The above statutory references are provided for informational purposes and may not include all mandatory reporting requirements. Licensees should independently review Missouri law to ensure compliance or contact the governing state agency.***

MEET OUR NEW COMPLIANCE COORDINATOR!

The Board is pleased to introduce the Board’s new Compliance Coordinator- Jennifer Luebbert. Jennifer holds a Bachelors of Science in Health Science as well as a Master in Business Administration degree. Jennifer will assist the Board in conducting general consumer complaint investigations and inspecting drug distributors. Jennifer will also provide special assistance to the Board’s inspectors as needed. Welcome Jennifer!
NEW DRUG DISTRIBUTOR LICENSING RULE:

The Board recently revised 20 CSR 2220-5.020 governing drug distributor licensing. The revised rule provides a drug distributor license is not required for the following activities:

1. **Exemption:** Distributing/receiving medication for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. The amount received/transferred under this exemption cannot exceed five percent (5%) of the pharmacy’s total gross prescription sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases. **Comments:** The revised language clarifies the 5% rule for pharmacies not engaged in retail sales.

2. **Exemption:** Distributing/receiving blood components intended for transfusion.

3. **Exemption:** Distributing/receiving medication by a Missouri licensed pharmacy that does not exceed five percent (5%) of the pharmacy’s total annual prescription drug sales or, if prescriptions are not sold, five percent (5%) of the pharmacy’s total drug purchases. **Comments:** Once again, the revised rule clarifies the 5% rule for pharmacies not engaged in retail sales.

4. **Exemption:** Distributing/Receiving medication or offering to distribute/receive medication among hospitals or by a hospital to a healthcare entity under the same common control or ownership as the hospital (e.g., offsite pharmacies, clinics, surgical centers). **Comments:** “Common control or ownership” is defined as the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership, stock, voting rights, contract, or otherwise. Licensees should consult with legal counsel to determine if they meet this definition. The Board cannot provide legal advice. This exemption would not apply to entities independent/private chain pharmacies, private physician practices, public ambulance districts or governmentally owned health departments that are not under the same common control/ownership as the hospital.

Medication must be distributed from the hospital. The exemption does not apply to distributions from a clinic or ambulatory surgical center to a hospital.

5. **Exemption:** Storing or distributing drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for emergency purposes as authorized by a state or federal agency. **Comments:** This exemption applies to local, state and...

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FLU SEASON IS AROUND THE CORNER!

As a reminder, pharmacists that are immunizing by protocol must have:

- A valid and current protocol signed and dated by both the pharmacist and the authorizing physician, and
- A current Notification of Intent (NOI) on file with the Board. NOIs must be submitted annually and can be submitted online at https://renew.pr.mo.gov/pharmacy-notification-step1-pin.asp. Don’t know when your NOI expires? Expiration dates can be verified online by conducting a “Pharmacy Licensee Search” at https://renew.pr.mo.gov/pharmacy-licensee-search.asp.

Other reminders:

- Immunizing at multiple locations? Remember, your protocol must include the address of each location where you are immunizing.
- Pharmacists immunizing by protocol and administering medication by prescription order must have two NOIs on file if doing both. See the Board’s website for more information.

INSPECTION TIPS:

**DRUG STRENGTH DISPENSING ERRORS**

The Board recently reviewed multiple incidents involving dispensing errors in which patients received the wrong strength of the prescribed drug resulting in serious harm including patient death and organ rejection. One incident involved an order entry error not caught by the verifying pharmacist that most likely started with the computer system auto-populating the drug/strength field.

Pharmacists are encouraged to use all tools available in their practice to help minimize errors in the dispensing process, including DUR messages alerting to high dose or dose/age concerns. Other tools and guidance may be found at the Board’s patient safety webpage or at the Institute for Safe Medication Practices.

The Board reminds pharmacists in all practice settings that patients are relying on them.
federal facilities that are only engaged in storing/distributing medication from the Strategic National Stockpile. A drug distributor license would be required for all other distribution activities unless another exemption applies.

Local, state and federal facilities who no longer need a drug distributor license may choose to not renew in 2015.

6. Exemption: Distributing/receiving medication to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to supply delays or interruptions.
   **Comments:** This exemption only applies to medication received from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import/manufacture the specific medication. Proof of FDA authorization or registration must be maintained in the licensee’s or recipient’s records.

   The transaction must be limited to the period of shortage and to the drug that is unavailable/in short supply.

   FDA maintains an online drug shortage list at [http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm](http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm). The Board recommends maintaining proof of the shortage (e.g., a printout from FDA’s list).

7. Exemption: Distributing/receiving medication between a Missouri licensed pharmacy and a non-resident pharmacy that does not hold a Missouri license. The total amount of medication distributed/received cannot exceed five percent (5%) of the pharmacy’s total annual prescription drug sales.
   **Comments:** The Missouri pharmacy must maintain:
   
   a. Proof the non-resident pharmacy has a current pharmacy license in the state or territory where the drug is shipped/distributed from; and

   b. An invoice record which documents the name and address of the non-resident pharmacy, the date of sale, purchase, transfer, or trade, and the name, strength, and quantity of the drug received.

   Records must be maintained for two (2) years.

The revised rule became effective on May 30, 2015. Licensees should review the entire rule to ensure compliance. *Caution: BNDD/DEA licensure and record requirements still apply. Other states may have additional licensure requirements for Missouri pharmacies shipping into their state.*

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**GOLD CERTIFICATES**

The following pharmacists will receive gold certificates in honor of maintaining a license with the Board for 50 years. Congratulations to those who have served the public for 50 years as a pharmacist!

**William Boone**

**Eules Hively**

**Harry Tishk**

**Robert Bilzing**

**Dominick R. Caleca**

**Sylvan Cohen**

**James Cradock**

**Diane Erdman**

**Leonard Kaye**

**Richard Miller**

**Patrick Potter**

**Jerome Gershman**

**Mary Lee**

**Robert Andes**

**James T. Brown**

**John Carter**

**Raymond Cordes**

**Jon Eberhardt**

**William Fitzpatrick**

**John McMullin**

**Michael Milsark**

**Melvin Taylor**

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**IT'S RENEWAL TIME**

Pharmacy and Drug Distributor renewals were mailed in early August. Avoid delays, renew early! Remember, PIC changes,
COUNTERFEIT BOTOX FOUND IN THE UNITED STATES, FDA WARNS

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors’ offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as “Botulinum Toxin Type A” instead of “OnabotulinumtoxinA.” The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug’s manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients’ health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA’s Office of Criminal Investigations. More information is available on the FDA website at www.fda.gov/Drugs/DrugSafety/ucm443217.htm.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP’s VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

SEVEN PERSISTENT SAFETY GAFFES IN COMMUNITY/AMBULATORY SETTINGS THAT NEED TO BE RESOLVED!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP National Pharmacy Compliance News readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled “Offer” In Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an “offer” to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, “Do you have any questions?” or told to “Please sign here.” They may not even know what to ask. This means that, with few exceptions, pharmacies in
states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit www.ismp.org/communityRx/tools/ambulatoryhighalert.asp. ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

• In “NDC Directory,” pharmacists demonstrate how to use this quick, easy, online resource.
• In “FAERS,” pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications’ drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

• MUCINEX FAST-MAX Night-Time Cold & Flu;
• MUCINEX FAST-MAX Cold & Sinus;
• MUCINEX FAST-MAX Severe Congestion & Cough; and
• MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.
Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at www.fda.gov/Safety/Recalls/ucm444028.htm.

**Pharmacists Are Performing More Patient Care Activities, National Survey Indicates**

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the 2014 National Pharmacist Workforce Survey. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, www.aacp.org.

**Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL**

INTERPOL has issued a global alert for a drug known as 2,4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The “Orange Notice” warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at www.interpol.int/News-and-media/News/2015/N2015-050.

**HHS Announces New Interactive Training on Safe Opioid Use**

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, “Pathways to Safer Opioid Use,” also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at http://health.gov/hcq/training.asp#pathways.