



Alaska Board of Pharmacy

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Prescription Drug Monitoring Program

*The following article was written by Brian Howes,
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On August 1, 2011, the Alaska Prescription Drug Monitoring Program will begin the mandatory collection of prescription data. The deadline was set with a primary focus of starting the flow of data into the database. If you have not registered to submit data to RelayHealth visit <https://dc.pmp.relayhealth.com/AK>.

Concerns have been expressed about statutory language that imposes disciplinary action against a “pharmacist-in-charge, pharmacist, or practitioner” who fails to submit information to the database.

This is new for all of us – start the process; help work out any bugs. The goal here is to enhance your ability, as a health care provider, to provide treatment to your patient.

Difficulties in submitting data due to personnel and/or hardware/software issues occur. Disciplinary action will be based on a “pharmacist-in-charge, pharmacist, or practitioner” failing to either submit information and/or not making any timely efforts to correct issues brought to their attention.

AS17.30.200 (e) The failure of a pharmacist-in-charge, pharmacist, or practitioner to submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist or for another licensing board to take disciplinary action against a practitioner.

Switch Data Submittal Update

This information was sent out in an e-mail on July 15, 2011: RelayHealth will not be offering the network (or “Switch”) extract for prescription drug monitoring data submission purposes. This is due to various reasons, including:

- ◆ Limited information in third-party payer claims: from a prescription drug monitoring program perspective, often there is not enough information contained in these transac-

tions to accurately identify all of the required information to note a controlled drug transaction within a prescription drug monitoring program.

- ◆ The two primary options for data collection will be batch reporting and Web entry. More information on these can be found at <http://pmp.relayhealth.com/AK>. It is also recommended that your software vendor be contacted, as they can provide details to the prescription monitoring program reporting capabilities specific to your system.

Continuing Education

The Alaska Board of Pharmacy will be participating in the CPE Monitor™ service offered by the National Association of Boards of Pharmacy® (NABP®) to electronically track approved continuing education (CE) for pharmacists and technicians. For those who enroll, the Board will be able to electronically authenticate your CE, therefore eliminating the need for paper transmissions of your approved coursework. The Board encourages readers to create their e-Profile early by going to the CPE Monitor page found in the Programs tab on the NABP Web site, and to pass the word to your colleagues and coworkers. The service will begin storing CPE data in the latter part of 2011 and is expected to be fully operational by early 2012.

Technicians: It was reported in the January 2011 *State Newsletter* that courses with a “P” designated for pharmacists would not be applied toward technician CE requirements. Since that time, the Board has determined it will accept approved courses from either the “T” technician or “P” pharmacist categories to meet technician CE requirements.

Vacant Pharmacist Board Seat

There is a currently a vacant seat on the Board of Pharmacy for a pharmacist member. Interested persons can find further information at the Office of Boards and Commissions at <http://gov.alaska.gov/parnell/services/boards-commissions.html>.



Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at www.nabp.net/programs/cpe-monitor/cpe-monitor-service in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at www.nabp.net/programs or at www.MyCPEmonitor.net. CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal

laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- ◆ Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- ◆ Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- ◆ Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- ◆ Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- ◆ Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with *Serratia marcescens* bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-



Compliance News to a particular state or jurisdiction should not be assumed (depending on the law of such state or jurisdiction.)

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts and to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at www.ismp.org.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies



This column was prepared by 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.

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription until final verification by a pharmacist had occurred.

Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for

important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning on Benzocaine Use

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. FDA also stresses that benzocaine products should not be used on children less than two (2) years of age, except under the advise of a health care provider. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurracaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at www.fda.gov.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 60 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at www.fda.gov.

Collaborative Practice Plans

When was the last time you checked the expiration date of your collaborative practice plan? Please remember it is the responsibility of the plan's primary pharmacist to submit a Collaborative Practice Application to the Juneau Board office approximately six weeks prior to the expiration date if you intend to renew it. Applications and their protocols are screened by the licensing examiner according to 12 AAC 52.240, which are referenced on the application itself. If the application does not meet regulation on initial screening, the primary pharmacist is notified and a written revision is done. Once the plan appears to meet regulations at the division level, it is forwarded to a quorum of Board members for final review and decision.

The most common reasons for rejection of an initial collaborative plan are:

1. Plan states the prescribing practitioner may authorize changes or additions to the plan. Per regulation, any modification to the written protocol must be submitted in writing and approved by the Board prior to implementation.
2. Time period for the protocol is not documented. The time period may not exceed two years.
3. Plan does not include a statement authorizing practitioners to review pharmacist decisions **every three months**.

Statutes and Regulations Projects

Projects currently being considered by the Board, but not yet in draft form, are related to automatic dispensing systems and licensing of native health care facilities. Statutorily, the Board's priorities are creating legislation for the safe dispensing and use of medical marijuana and licensing out-of-state wholesalers.

In April 2011, all licensees were issued a public notice with the proposed new regulations and changes to existing regulations. A narrative description is also available in the April 2011 Alaska Board of Pharmacy *Newsletter*. Public comments were sought and reviewed by the Board during the May 2011 Board meeting. The proposed regulations were adopted by the Board at that time and are now in final review with the Department of Law. Afterwards, they will be forwarded to Lt. Governor Mead Treadwell and become effective 30 days after his signature. They address the following:

1. *Disciplinary Reporting*, 12 AAC 52.991: The time frame in which a licensee must report disciplinary decisions/convictions to the Board will be changed to within 30 days of the decision or conviction.

2. *Prescription Order Information*, 12 AAC 52.460: Describes allowable changes to Schedule II controlled substances by a pharmacist.
3. *Reinstatement of Expired Pharmacist License*, 12 AAC 52.310: Changes application requirements for employment and license verifications so the criteria are consistent, regardless of how long the license has been lapsed.
4. *Remote Pharmacy Licenses*, 12 AAC 52.423: Incorporates the Ten Mile Rule into existing remote pharmacy regulations.
5. *Prescription Drug Monitoring Program*, 12 AAC 52.855 – 12 AAC 52.895: Describes implementation of the prescription drug monitoring program.

Statistics

The following data describes the number of new licenses issued by the Alaska Board in fiscal year 2011 and the total number of active licenses per category:

License Type	Number of New Licenses	Total Number of Active Licenses
Pharmacists	98	951
Technicians	335	1,260
Interns	172	337
Retail Pharmacies	6	129
Drug Rooms	5	27
Remote Pharmacies	0	2
Wholesale Distributors	0	23
Out-of-State Pharmacies	74	319