January 2018

Oklahoma State Board of Pharmacy News

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Appreciation to Draft Rule Committee Members

The Oklahoma State Board of Pharmacy members and staff would like to express their sincere appreciation to all of the participants who provided expertise, effort, and many hours in the United States Pharmacopeia (USP) <800>, Retail Remote Medication Order Processing, Automation, and Customized Adherence Medication Package committees. Draft rules that have been approved by the Board will be posted on the Board website for comment, and a rules hearing will be held on March 6, 2018.

From the Inspector's Desk

- **18.01. Nonsterile Compounding:** A retail pharmacy may no longer provide any nonsterile compounds to physicians for "office use."
- **18.02. CDS Invoices:** When receiving controlled dangerous substances (CDS) from the wholesale distributor, the person checking in the drugs must either circle the quantity received for each drug, place a check mark by the quantity received for each drug, or make a notation that all drugs were received.
- **18.03. Compounding in Anticipation of a Prescription:** Per Drug Enforcement Administration (DEA), a retail pharmacy cannot prepare in anticipation more than a 30-day supply of a compounded preparation containing a CDS.
- **18.04. CDS Prescriptions:** In Oklahoma, a physician cannot issue multiple prescriptions to a patient for the same drug. DEA allows this, but the Oklahoma Bureau of Narcotics and Dangerous Drugs does not have a corresponding law or rule that allows it in Oklahoma. It is illegal for a prescriber to postdate a prescription. All CDS prescriptions must be dated and signed on the day when issued. If a prescriber does not want the patient to fill it that day, then he or she can put instructions on the prescription as to the date when it can be filled. The date to be filled should not exceed 30 days from the date written for Schedule II prescriptions.
- **18.05. BUDs for Nonsterile Compounded Preparations:** For water-containing or aqueous-based topical/dermal and mucosal liquid and semisolid formations, the beyond-use date (BUD) may not exceed 30 days. For aqueous-based oral formulations, the BUD may not be longer than 14 days when stored under refrigeration. Even when you add an active pharmaceutical ingredient (API) to a commercial

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National Pharmacy Compliance News

January 2018

NABPF
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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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product that has an aqueous component, the BUD should not exceed 14 days when refrigerated.

For non-aqueous formulations, the BUD may not exceed the earliest expiration date of any API or six months, whichever is earlier.

Watch the expiration dates for all ingredients used, including inactive ingredients. The BUD cannot exceed the expiration date of any ingredient used in compounding the preparation.

The USP standards listed above may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (eg, the same drug, same brands, concentration range, pH, excipients, vehicle, water content).

- **18.06. Topical Compounds in Syringes Labeled "For Oral Use":** Please do not dispense topical compounded products in syringes labeled "for oral use" unless you have covered or removed the words "for oral use." The Board has received reports of patients receiving topical medications by mouth, particularly when the person administering the medication is not the same as the person who received counseling on the prescription.
- **18.07. BUD for Repackaged Drugs:** Food and Drug Administration (FDA) recently released a repackaging guidance that changes the acceptable expiration date for repackaged medications. The guidance applies to FDA-registered repackaging firms that are repackaging solid oral dosage forms into unit-dose containers. It does not apply to solid oral dosage forms repackaged by state-licensed pharmacies, nor to other dosage forms (sterile, liquid, or topical).

  Retail and hospital pharmacies that repackage into unit dose for use within their own hospital are exempt and may continue to use a one-year expiration date or the manufacturer's expiration date, if it is less than one year.
- **18.08. CBD Oil:** According to the Oklahoma Bureau of Narcotics, cannabidiol (CBD) oil with any detectable amount of delta-9 tetrahydrocannabinol (THC) is not legal to sell. It is extremely difficult, if not impossible, to remove all THC from a natural source of CBD oil. Synthetic CBD oil is permitted if there is no detectable quantity of THC.

  The Board recommends that if a pharmacy chooses to sell CBD oil, the pharmacy should obtain a certificate of analysis or have the product independently tested for the presence and quantity of THC. There have been many reports of products that have purported to contain no THC, but have tested otherwise.

  Pharmacies dispensing CBD products containing no more than 0.3% THC must be enrolled in an FDA-approved clinical trial.

  In order for a person aged 18 years or younger to receive CBD containing no more than 0.3% THC, he or she must either be participating in a clinical trial or receive a written certification from a physician licensed in this state as having been diagnosed with Lennox-Gaustaut syndrome; Dravet syndrome, also known as severe myoclonic epilepsy of infancy, or any other severe form of epilepsy that is not adequately treated by traditional therapies; spasticity due to multiple sclerosis or paraplegia; intractable nausea and vomiting; or appetite stimulation with chronic wasting diseases. The CBD must be delivered to the patient in the form of a liquid.

  Pursuant to Oklahoma Statutes Title 63, Section 2-101, industrial hemp from the plant *Cannabis sativa* L. and any part of such plant, whether growing or not, with a THC concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis shall not be grown anywhere in the state of Oklahoma but may be shipped to Oklahoma.
- **18.09. Clarification of Transferring "On-Hold" CDS Prescriptions:** DEA has issued a statement allowing pharmacies to transfer "on-hold" Schedule II-V **electronic** prescriptions from one pharmacy to another if they had not been filled at the original pharmacy. However, DEA requires the transfer to be done electronically, and the electronic prescriptions for controlled substances (EPCS) software does not permit pharmacies to transmit prescriptions from one pharmacy to another. Fax transmittal is not considered to be electronic transmission. If software is changed to accommodate the requirements of EPCS, then "on-hold" CDS prescriptions may be transferred between pharmacies.

  DEA does not permit pharmacies to transfer "on-hold" CDS prescriptions that have been received by any other means of communication, including facsimile, verbal, or written.

  These requirements do not apply to the transfer of refills of CDS prescriptions. Refills may be transferred as per Oklahoma Administrative Code 535:15-3-12 and 535:15-3-12.1.

Disciplinary Actions

For more information, you may view hearing minutes at *http://ok.gov/pharmacy/Board/Minutes/index.html.*

18.10. October 4, 2017 Board Hearing

23rd Street Pharmacy, #1-6693 – Case No. 1469: Neither admits nor denies guilt on 148 counts including selling, offering for sale, or bartering or buying any professional samples, except through a program pursuant to the Utilization of Unused Prescription Medications Act; selling, offering for sale, bartering, or giving away any unused quantity of drugs obtained by prescription, except through a program pursuant to the Utilization of Unused Prescription Medications Act; failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy, including proper record keeping; failing to keep adequate records to assure that prescription drugs are legally received and/or distributed or dispensed, as appropriate; having an agreement with a prescriber that a prescription or order written by the prescriber shall only be transmitted to the registrant, licensee, or permit holder; making or filing a report or record that the registrant knows or should have known to be false; billing or charging for quantities greater than delivered; failing to establish and maintain effective controls against the diversion of prescription drugs; and failing to have a pharmacist review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness. **Five years probation until October 4, 2022. $267,000 fine.**

Thao Nguyen Thi Phan, DPh #13346 – Case No. 1470: Neither admits nor denies guilt on 154 counts including

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selling, offering for sale, or bartering or buying any professional samples, except through a program pursuant to the Utilization of Unused Prescription Medications Act; selling, offering for sale, bartering, or giving away any unused quantity of drugs obtained by prescription, except through a program pursuant to the Utilization of Unused Prescription Medications Act; failing to be a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy, including the supervision of all employees and proper record keeping; failing to keep adequate records to assure that prescription drugs are legally received and/or distributed or dispensed, as appropriate; having an agreement with a prescriber that a prescription or order written by the prescriber shall only be transmitted to the registrant, licensee, or permit holder; making or filing a report or record that the registrant knows or should have known to be false; billing or charging for quantities greater than delivered or for a brand when a generic is dispensed; failing to establish and maintain effective controls against the diversion of prescription drugs; failing to adequately review the patient record and each prescription drug order presented for dispensing for purposes of promoting therapeutic appropriateness; and misfiling a prescription. **One-year suspension from November 1, 2017, until November 1, 2018. After November 1, 2018, suspension is lifted and placed on probation for five years until November 1, 2023.**

Impaired Intern #8987 – Case No. 1475: Admitted to guilt on three counts including abusing alcohol or habit-forming drugs, or using an illegal CDS drug, or testing positive for such illegal substance or its metabolite; and violating a voluntary or Board-ordered rehabilitation program for the impaired contract. **One-year suspension until October 4, 2018, and 10-year Oklahoma Pharmacists Helping Pharmacists (OPHP) contract. May request probation after October 4, 2018, upon showing one year of compliance with OPHP and a fit-for-duty evaluation.**

Fallon Ward, Technician #9934 – Case No. 1478: Admitted to guilt on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

18.11. November 29, 2017 Board Hearing

Lisa Bennett, Technician #19621 – Case No. 1477: Found guilty on three counts including committing theft while working as a registrant. **Revoked.**

Hallandale Pharmacy, #99-8005 – Case No. 1479: Admitted to guilt on 374 counts including by failing, as a nonresident pharmacy, to make application and receive an annual nonresident pharmacy license at a fee set by the Board; failing to send Schedule II, III, IV, and V prescription records to the Oklahoma Prescription Drug Monitoring Program; dispensing a prescription drug knowing, or should have known, that the prescription was issued without a valid preexisting patient-prescriber relationship; soliciting, dispensing, receiving, or delivering a CDS through the mail without personally knowing the practitioner; failing to maintain a patient record system for patients for whom prescription drug orders are dispensed; failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy; and offering to the public, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered. **$37,400 fine.**

Alishia Nuckolls, Technician #21320 – Case No. 1480: Found guilty on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Bryan Cassil, Technician #22928 – Case No. 1481: Admitted to guilt on three counts including possession of a CDS without a valid prescription and abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite. **Revoked.**

Ylan Pham, Technician #14968 – Case No. 1482: Found guilty on three counts including committing theft while working as a registrant and abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite. **Revoked.**

Alyssa Cox, Technician #17854 – Case No. 1483: Admitted to guilt on four counts including committing theft while working as a registrant; abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite; and possession of a CDS without a valid prescription. **Revoked.**

Catlyn Larsen, Technician #14387 – Case No. 1484: Admitted to guilt on three counts including abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite. **Revoked.**

Trever Blanco, Technician #22589 – Case No. 1485: Admitted to guilt on four counts including committing theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Rebecca Lindsey, Technician #19775 – Case No. 1486: Neither admits nor denies guilt on four counts including unlawfully distributing, dispensing, transporting with intent to distribute or dispense, or possessing with intent to manufacture, distribute, or dispense a CDS; and committing theft while working as a registrant. **Revoked.**

Kevin Dominguez, Technician #18966 – Case No. 1487: Found guilty on three counts including possession of a CDS without a valid prescription and forging or increasing the quantity of drug in any prescription, or presenting a prescription bearing forged, fictitious, or altered information or possessing any drug secured by such forged, fictitious, or altered prescription. **Revoked.**

Ralph's Family Pharmacy, Inc, #1-6280 – Case No. 1488: Neither admits nor denies guilt on five counts including failing to establish and maintain effective controls against the diversion of drugs; failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy, including the establishment of policies and procedures for safekeeping of pharmaceuticals, the proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs, and the supervision of all employees as they relate to the practice of pharmacy; and failing to implement and follow a written drug diversion detection and prevention policy. **$1,428.60 fine.**

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Ralph Abercrombie, DPh #9832 – Case No. 1489: Neither admits nor denies guilt on seven counts including failing to establish and maintain effective controls against the diversion of drugs; failing, as pharmacy manager, to be responsible for all aspects of the operation related to the practice of pharmacy, including the establishment of policies and procedures for safekeeping of pharmaceuticals, the proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs, and the supervision of all employees as they relate to the practice of pharmacy; and failing to implement and follow a written drug diversion detection and prevention policy. **$3,571.50 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required continuing education (CE) in the calendar year 2018 for a total of 23 hours of CE. All CE required to renew his license shall be live during the calendar year 2018.**

St Francis Hospital – Cancer Center Pharmacy, #2-6630 – Case No. 1490: Admitted to guilt on one count and neither admits nor denies guilt on three counts including failing to have a pharmacy manager who was responsible for all aspects of the operation related to the practice of pharmacy; failing to have a pharmacy manager who worked sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager; and failing to have a director of pharmacy who is responsible for the safe and efficient purchasing, acquisition, monitoring, distribution, control, security, and accountability of all drugs. **$5,000 fine.**

Kevin Doherty, DPh #15976 – Case No. 1491: Admitted to guilt on one count and neither admits nor denies guilt on three counts including failing to be a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy; failing to be a pharmacy manager who worked sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager; and failing to be a director of pharmacy who was responsible for the safe and efficient purchasing, acquisition, monitoring, distribution, control, security, and accountability of all drugs. **$5,000 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required CE in the calendar year 2018 for a total of 23 hours of CE. All CE required to renew his license shall be live during the calendar year 2018.**

Impaired DPh, #13361 – Case No. 1492: Admitted to guilt on seven counts including failing to participate in a rehabilitation program for the impaired as required by the Board; possessing dangerous drugs without a valid prescription; failing to establish and maintain effective controls against the diversion of drugs; violating a Board order or agreed order; violating a voluntary or Board-ordered rehabilitation program for the impaired contract; and committing theft while practicing pharmacy. **Indefinitely suspended.**

Calendar Notes

The Board will meet on **Wednesday, January 17, 2018,** and **Tuesday, March 6, 2018.** The Board will be closed **Monday, January 15** for Martin Luther King, Jr Day; and **Monday, February 19** for Presidents' Day. Future Board dates will be available at *www.pharmacy.ok.gov* and will be noted in the April *Newsletter.*

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem, and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574 ext. 5773. All calls are confidential.

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