March 2012

New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Disciplinary Actions

Rusty Brake, PT – License PT-6972. Respondent voluntarily surrendered his pharmacy technician registration.

Timothy Donald Brown, RPh – Pharmacist applicant. Respondent entered into a stipulated agreement with the New Mexico Board of Pharmacy.

Meryl Herman, RPh – License RP-7689. Respondent entered into a stipulated agreement with the Board.

Gary Patrick Lapanne, RPh – License RP-7293. Respondent voluntarily surrendered his pharmacist registration.

Shealynn Trujillo, PT – License PT-7339. Respondent voluntarily surrendered her pharmacy technician registration.

Tamara Yazzie, PT – License PT-4152. Respondent voluntarily surrendered her pharmacy technician registration.

Corrections

After the December 2011 *Newsletter* was published, the date for the 2012 Law Update in the Silver City, NM, area was changed. The new date is:

June 27, 2012

Law Update, 7 - 9 PM

Gila Regional Medical Center

1313 East 32nd St

Silver City, NM 88061

Please mark your calendar accordingly. In addition, you can check the current Law Update schedule by going to the New Mexico Board of Pharmacy Web site.

Summary for the New CPE Requirements

Effective beginning January 1, 2013, the new continuing pharmacy education (CPE) requirements for the pharmacist renewal will take effect. All active status registered pharmacists who are applying for renewal of their New Mexico registration will need a total of 30 contact hours (3 CEUs) every two years. These 30 contact hours are divided into the following categories:

1. A minimum of 10 contact hours (1.0 CEU), **excluding the law requirement,** shall be obtained through "live programs" that are approved by Accreditation Council for Pharmacy Education (ACPE) or Accreditation Council for Continuing Medical Education.
2. A minimum of 2 contact hours (0.2 CEUs) shall be in the area of Patient Safety as applicable to the practice of pharmacy. Patient Safety is defined as the prevention of health care errors and the mitigation of patient injury caused by health care errors. These two contact hours of Patient Safety may be part of the 10 live contact hours, or may be part of the remaining contact hours you receive. As discussed below, the Topic Designator for Patient Safety is 05.
3. For all active status pharmacists that either reside or practice in New Mexico, a minimum of 2 contact hours (0.2 CEUs) of Law, as offered by the New Mexico Board of Pharmacy, is required. If the pharmacist does not practice or reside within New Mexico, then two contact hours of an ACPE-accredited course in the area of Law is acceptable. As discussed below, if a course is considered to be in the area of Law, the Topic Designator is 03.

If you are unsure whether or not the course you will be taking is considered live, the Universal Activity Number (UAN) contains a Format Designator. The Format Designator contains the letter L (live) as shown below in the fifth section, for example: 197-000-11-001-L05-P. If this course were not live, the letter designation would be H (home). The two-digit number after the L or the H is the Topic Designator. The Topic Designator is numbered 01, 02, 03, 04, or 05. The meaning of each number is:

01: Disease State/Drug Therapy

02: HIV/AIDS

03: Law (pharmacy practice)

04: General Pharmacy

05: Patient Safety

In the example above, the UAN indicates that the topic for this course was in the field of Patient Safety.

Remember, the definition of "renewal period" is continuing education programs or activities that must be completed during the 24-month time period occurring between the first day of the pharmacist's birth month and the last day of his or her birth month two years later. A pharmacist may **not** use carry over hours from a previous renewal period.

Lastly, licensees may obtain 1 contact hour (0.1 CEU) per year, in the subject area Law, by attending one full day of a regularly scheduled Board meeting, or serving on a Board-approved com-

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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 the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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mittee. If you would like to receive credit for attending a Board meeting, please let Board staff know prior to attending the meeting.

Pharmacists seeking approval of other education programs not accredited by ACPE still have the opportunity to participate in the CPD Pilot Project currently being run by the University of New Mexico College of Pharmacy.

Did You Know?

Beginning with this issue, the Board will publish articles called "Did You Know?" These articles will contain information that you think is important for people in the pharmacy profession to know, but most do not. If you have information for these articles, please contact the Board.

Our first "Did You Know?" article is regarding a pharmacy audit. Recently an independent retail pharmacy was audited by a pharmacy benefits manager. The audit looked at all Suboxone® prescriptions that were dispensed within a certain time period. All Suboxone prescriptions prescribed for narcotic maintenance therapy that did not contain both the prescriber's Drug Enforcement Administration (DEA) X identification number and the prescriber's DEA registration number, were rejected for payment.

Did You Know: According to the DEA, Suboxone prescriptions must have the DEA registration number plus the "X" identification number written on the prescription.

From the DEA

By Randall Bencomo, Diversion Investigator, DEA

Prescription Requirements

A prescription is an order for medication that is dispensed to or for an ultimate user. A prescription is not an order for medication that is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. **The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number.** The prescription must also include:

1. drug name
2. strength
3. dosage form
4. quantity prescribed
5. directions for use
6. number of refills (if any) authorized

A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature.

The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. In addition, **a corresponding responsibility rests with the pharmacist who fills the prescription.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription within the meaning and intent of the Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Schedule II Substances

Schedule II controlled substances require a written prescription that must be signed by the practitioner. There is no federal time limit within which a Schedule II prescription must be filled after being signed by the practitioner.

While some states and many insurance carriers limit the quantity of controlled substances dispensed to a 30-day supply, there are no specific federal limits to quantities of drugs dispensed via a prescription. For Schedule II controlled substances, an oral order is only permitted in an emergency situation.

Refills

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited (Title 21 U.S. Code §829(a)).

The previous excerpts were extracted from the DEA online *Practitioner's Manual.* For more detailed information or if you wish to download the *Practitioner's Manual* and print it, it can be accessed at the following Web site: *www.deadiversion.usdoj.gov/pubs/manuals/.*

Questions in reference to registration issues should initially be directed to the El Paso Field Division registration clerk via phone at 915/932-6014 or via fax at 915/832-6225, unless they have referred you to the Albuquerque office for a specific situation. You can also find most of your answers at the aforementioned Web site.

Adverse Drug Events

1. Patient A was prescribed Soma® 350 mg but picked up patient B's Xanax® 0.5 mg instead. Patient A and B are father and son with the same first and last names. Error was discovered by the son after father had taken one dose of the incorrect medication. No serious adverse effect was reported. Pharmacist recommends asking "What is your address?" instead of reading address to patient, then asking him or her to verify with "yes" or "no."
2. A patient with an order for hydrocodone/APAP 5/325 was mistakenly given hydrocodone/APAP 10/325 for one dose. No significant adverse effects were noted. The medication administrator stated that he or she overlooked the names of the residents and gave the wrong drug. No recommendation for improvement was provided by the responsible party.
3. Patient was prescribed trazodone 100 mg to be taken in the evening. Upon electronic prescription entry, the technician entered the prescription to be taken in the morning. This entry error was not caught by the pharmacist. Patient reported lightheadedness and drowsiness leading to a fall and subsequent back injury. The mistake was attributed to poor/illegible handwriting on the prescription hard copy. Pharmacist recommends calling on any unclear/illegible prescriptions, and counseling on all new prescriptions.

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4. Patient was prescribed hydroxyzine 50 mg, but was dispensed metoclopramide 10 mg that was prescribed for someone else. No significant adverse events were reported. Error was attributed to not verifying the home address upon pick up of the prescription. No recommendation for improvement was provided by the pharmacist.
5. Patient was prescribed phentermine 37.5 mg, but was dispensed metformin 500 mg that was prescribed for another patient with the same last name. Patient reported non-specific symptoms of "not feeling right." Error was attributed to not verifying the home address upon pick up of the prescription. Pharmacist recommends that address, date of birth, or phone number should be verified prior to dispensing medication.
6. Patient was prescribed hydroxyzine 25 mg, but was dispensed phenytoin 100 mg that was prescribed for another patient with the same last name. Patient took eight capsules before error was discovered. Patient reported confusion and agitation upon taking the incorrect medication. Error was attributed to not verifying the home address upon pick up of the prescription. Pharmacist recommends counseling on all new prescriptions to avoid this type of error.
7. Patient was prescribed Lasix® 20 mg, but was dispensed lisinopril 20 mg. Patient took eight capsules before error was discovered. Marked edema of the patient's lower extremities was noted as a result of the mix up. Error was attributed to not verifying the home address upon pick up of the prescription. Pharmacist recommends counseling on all new prescriptions to avoid this type of error.
8. Patient was prescribed gabapentin 300 mg, venlafaxine 37.5, and venlafaxine 150 mg. Patient received prescriptions meant for another patient, including prednisone 20 mg and spironolactone 25 mg. The patient took one dose of both incorrect medications and reported upset stomach. The pharmacist responsible was terminated.
9. Patient was prescribed Klonopin® 0.25 mg to be given twice daily, but was dispensed clonazepam 0.5 mg to be given twice daily. No adverse reactions were reported. Pharmacist attributes error to Klonopin 0.25 not being commercially available. Pharmacist recommends to double-check work before dispensing.
10. Patient was prescribed porcine thyroid 150 mg to be compounded, but was dispensed a compound of progesterone 150 mg. The incorrect medication was taken for a number of weeks before patient reported feeling sick. Symptoms included bloating, constipation, nausea, fatigue, and headache. Patient was admitted to emergency room with TSH > 100. Pharmacist recommends staff education on medication dispensing errors.
11. Patient was prescribed doxycycline 50 mg with directions of two capsules per day. Patient was dispensed doxycycline 100 mg with the directions noted above. Patient informed pharmacy that she stopped taking the medication after two weeks due to stomach upset. Error was attributed to filling the prescription in haste 10 minutes prior to closing. Pharmacist recommends double-checking the prescription prior to dispensing and counseling on all new medications.
12. A prescriber called in a prescription for Pepcid® suspension for a pediatric patient. The pharmacist on duty did not indicate units on the dose to be given. When the medication was filled, the directions read 3.5 mL four times daily instead of what the physician intended, which was 3.5 mg four times daily. Patient was admitted to the intensive care unit due to renal failure. Pharmacist recommends that all verbal orders must be verified if any section of the order is unclear.
13. Patient was given a flu vaccination in her left arm and a pneumonia vaccination in her right arm on the same day. Patient returned to the pharmacy a day later to report significant allergy symptoms including deep tissue erythema in the right arm. Her physician later determined this to be the result of an allergy to the vaccine. No recommendation for avoidance of this reaction was given by the pharmacist.
14. A dog was prescribed phenobarbital 15 mg but was dispensed phenobarbital 60 mg. The error was caught after the dog ingested one dose of medication. No significant adverse drug event's were reported; however, the dog did have its stomach pumped. The error was attributed to a product verification scale being overridden. Pharmacist recommends that scale not be overridden by a technician without pharmacist approval.
15. Patient was prescribed warfarin 2 mg with directions for two tablets **the** night prior to surgery. The prescription was processed for warfarin 2 mg with directions for two tablets **every** night prior to surgery. The patient took the medication every night for two weeks. At the time of surgery, INR of 4 was noted, however surgery was performed without complication. Pharmacist recommends triple checking all warfarin prescriptions.
16. Patient was prescribed Lamisil® 250 mg but was dispensed Lamictal® 250 mg. After taking the medication for 10 days, the patient reported a major allergic reaction and was eventually admitted to the emergency room for treatment. The pharmacist recommends profile review prior to dispensing and counseling for all new medications.

Disclaimer: The suggestions are made by the pharmacist submitting the Significant Adverse Drug Event Report. The New Mexico Board of Pharmacy may not necessarily agree with these suggestions.

Web Page

The New Mexico Board of Pharmacy Web page has gone through a conversion process. To access the new Web page, visit *www.rld.state.nm.us/boards/Pharmacy.aspx*. Please make a new bookmark for your computer. The old Web page address will forward to the new address until May 1, 2012.

When you enter the above address, you will be taken to a page with links on the left-hand side of the screen. You must first click on the link titled "Individual Boards and Commissions." This link is directly below the link called Overview.

After clicking "Individual Boards and Commissions," all the boards under the Regulation and Licensing Department will expand out. You must then click on the link titled "Pharmacy."

The *New Mexico Board of Pharmacy News* is published by the New Mexico Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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