National Association of State Controlled Substances Authorities

February 20, 2024

Don't Forget to Register for Our Upcoming Webinars

NASCSA's Education Committee works throughout the year to offer programming via various webinars that are offered to members.

Our next webinar will take place **Tuesday, February 27, 20204 from 3-4 pm ET** on a timely topic of great interest to our members and partner organizations: ***"Everything You Wanted to Know About Electronic Prescribing But Were Afraid to Ask."*** To register click here.

Member states are reminded that any individual that is from a member state is permitted to attend any of our webinars as well as all sponsors so please feel free to circulate information about any of our upcoming webinars.

We have a number of other exciting webinars planned in the coming months so please make sure to reserve your space. Registration for each of the upcoming webinars is found **here**.

Note: Attendance is solely limited to members and sponsors.

We Need Your Help

Regular members are asked to submit ideas for **resolutions** to be considered at the business meeting at this year's annual conference.

Members should follow the guidelines outlined in the Bylaws (See Article XII). Proposed

Save the Date for NASCSA's Annual Conference 2024!

Mark your calendar! It's hard to believe that plans are well underway for our 40th annual conference taking place at the Hyatt Regency in downtown Greenville, South Carolina **October 28-31, 2024**. We have some exciting plans for this year's conference so check the **website** on a regular basis for updates. Conference and Hotel Registration information is already available online.

The 2025 Conference will take place October 20-23, 2025 - Renaissance New Orleans Arts Hotel - New Orleans, Louisiana so save the date!

Federal News: DEA Extends Comment Period on Disposal

The Regulatory Drafting and Policy Support Section of the US Drug Enforcement Administration is looking for additional comments on the disposal APRN published on 10-31-2023 at **88 FR 74379**. They recently extended the comment period until April 1, 2024. Below are additional details from the recent **Federal Register** publication.

On October 31, 2023, DEA published an advance notice of proposed rulemaking (ANPRM) requesting stakeholder responses to ten questions about methods and technology currently being utilized or developed to render controlled substances non-retrievable. Since publication, DEA received two requests from stakeholders for an extension of the comment period due to timeliness difficulties preparing adequate comments to the ANPRM during the holidays. One of those commenters, an association, stated that its member companies have a significant interest in this ANPRM, and requested an extension to allow them to provide timely and informative comments.

After considering these requests for additional response time, DEA is extending the comment period to allow stakeholders to prepare and submit comments. This allows sufficient time for persons to

resolutions must be submitted to the Bylaws/Resolutions Committee no later than 60 days in advance of the Business Meeting.

We Need Your News!

We would love to hear more from our members about news from your state, territory or district, or industry news of importance. Please pass this information along.

Dues Notices

Dues Notices will be sent electronically in the late spring. Please note that invoices are able to be paid securely by credit card or members can download the invoice for payment by their accounts payable department.

More information will be send in the next several months however if you have any questions please contact the office at 617-347-1455 or **kathykeough@nascsa.org**.

Have You Checked Out NASCA's Youtube Channel?

NASCSA maintains its own YouTube Channel where a select number of our webinars are uploaded several months after they take place. Quite a few webinars were recently uploaded, so please visit the YouTube channel and subscribe as well. More information is found **here**.

Industry News

Lykos Therapeutics Announces FDA Acceptance and Priority Review of New Drug Application for MDMA-Assisted Therapy for PTSD

SAN JOSE, Calif., Feb. 9, 2024 - **Lykos Therapeutics** (formerly

evaluate and consider all relevant information and respond accordingly. Therefore, the comment period is extended to April 1, 2024. Electronic comments must be submitted, and written comments must be postmarked, on or before this date. The link to submit comments can be found at **Regulations.gov**.

Surescripts Issues Advisory on E-Prescribing

February 14, 2024 - Surescripts last week issued the following Advisory to pharmacies, pharmacy computer vendors and electronic health records companies connected to their e-prescribing network:

Description: As of August 28, 2023, the electronic transfer of electronic prescriptions for controlled substances (EPCSs) between pharmacies has been allowed by the Drug Enforcement Administration (DEA) according to a new **final rule** published in July 2023. The rule states that, if allowable under existing state or other applicable law, an EPCS in schedules II-V may be transferred between pharmacies for initial filling on a one-time basis upon request from the patient. The transfer must be communicated directly between two licensed pharmacists and the prescription must remain unaltered in its electronic form.

Specific Impact: While this rule represents a critical step toward enabling the electronic transfer of EPCSs, the health information technology (HIT) industry is not yet able to support these transfers until further action is taken by the Centers for Medicare and Medicaid Services (CMS). CMS has the responsibility of designating which standard the HIT industry must use to support electronic prescribing and related transactions for the Medicare program, and this includes electronic prescription transfers. The current version of the CMS-adopted standard, which is known as SCRIPT v2017071 and was created by the National Council of Prescription Drug Programs (NCPDP), supports the electronic transfer of non-controlled substances, but updates to the standard are necessary to support transfers of EPCSs. The necessary updates have now been incorporated into SCRIPT v2022011 and later by NCPDP, but CMS has yet to finalize a new rule that allows the HIT industry to adopt this updated version of the standard (see NCPDP technical guidance in the addendum). Thus, the HIT industry is eagerly awaiting permission from CMS to proceed with implementation of the next approved version of SCRIPT in order to support transfers of EPCSs, but it is uncertain when CMS will make such an announcement. Therefore, interested stakeholders need to understand that, while DEA rules technically do allow for the electronic transfer of EPCSs, action from CMS is still needed before Surescripts and other HIT entities can make this type of electronic

MAPS Public Benefit Corporation) ("Lykos"), a company dedicated to transforming mental healthcare, announced that the U.S. Food and Drug Administration ("FDA") has accepted its new drug application ("NDA") for midomafetamine capsules ("MDMA") used in combination with psychological intervention, which includes psychotherapy (talk therapy) and other supportive services provided by a qualified healthcare provider for individuals with post-traumatic stress disorder ("PTSD"). The FDA has granted the application priority review and has assigned a Prescription Drug User Fee Act ("PDUFA") target action date of August 11, 2024. If approved, this would be the first MDMA-assisted therapy and psychedelic-assisted therapy. To read the full press release click **here**.

Blog Posting of Interest: Marijuana: Top Ten Reasons for Descheduling, Rescheduling (or Not)

Given the Interest in the Topic of Marijuana descheduling, members may be interested in viewing a recent blog post on the topic by Larry Houck, JD, from our sponsor Hyman, Phelps & McNamara. To read the post click **here**.

Sponsor Spotlight: BizTek Innovations

BizTek Innovations continues to be a proud sponsor of NASCSA and its annual conferences. We support the

prescription transfer a reality.
Technical Addendum: The following questions and responses can be found in NCPDP's **SCRIPT Implementation Recommendations** (see pages 58-59):

5.1.1 With the July 2023 DEA final rule regarding the Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances between Pharmacies for Initial Filling (21 CFR Part 1306), can a prescription be electronically transferred using the NCPDP SCRIPT Standard Version 2017071?

NCPDP Response: SCRIPT Standard Version 2017071 does not support the electronic transfer of controlled substance prescription information. However, prescriptions for non-controlled substances can be electronically transferred between pharmacies using the SCRIPT Standard Version 2017071.

The amended regulations to allow the transfer of electronic prescriptions for schedules II-V controlled substances between registered pharmacies for initial filling, upon request from the patient, on a one-time basis requires SCRIPT Standard Version 2022011 or later. The information that must be recorded to document (e.g., digital signature component in MedicationPrescribed) the transfer of EPCS between pharmacies is not present in prior versions of the SCRIPT Standard.

5.1.2 Are there additional RxTransfer features found in SCRIPT Standard Versions 2022011 or later that are advantageous for the electronic transfer of controlled substance prescription information?

NCPDP Response: Yes, in addition to incorporating missing data elements such as the digital signature component in MedicationPrescribed for electronic prescriptions for controlled substances (EPCSs), RxTransfer in SCRIPT Standard Versions 2022011 or later will allow pharmacies to initiate transfers of prescriptions to other pharmacies (i.e., "push" transactions) as well as the currently supported use case of requesting them from other pharmacies (i.e., "pull" transactions). An example of when a "push" RxTransfer transaction might be useful would be when a pharmacy has received an EPCS but does not have the medication in stock. In this case, the pharmacy could use a "push" RxTransfer transaction to send the prescription to a pharmacy that does have the medication in stock, so the patient receives his or her medication as soon as practicable.

DEA's Announces 2nd Annual Supply Chain Conference

efforts that the NASCSA staff and members devote to bringing stakeholders together in collaboration to curtail abuse, misuse and diversion of controlled substances.
BizTek provides a wide variety of secure IT solutions to its customers. We offer a cost-effective, easy to use Prescription Drug Monitoring Solution. Focus on accuracy and integrity of controlled substance data is a core component of our overall data management process. We are committed to providing innovative integration solutions that will optimize the functionality of current state and federal systems.

Drug Diversion Misuse Brochure Available

The drug diversion misuse brochure produced by Scripps Safe that lists commonly misused controlled substances as well as non-federally scheduled drugs is now available online **here**.

Purpose: The conference provides a venue in which representatives from the supply chain industry, their affiliated associations, and DEA can engage in discussions concerning existing federal regulations, issues requiring regulatory changes, clarification of DEA policy, and the development of initiatives to reduce diversion of pharmaceutical controlled substances while ensuring an adequate and uninterrupted supply.

Who: DEA registered manufacturers, distributors, pharmacists, importers, and exporters.
When: April 30 - May 2, 2024
Where: Little Rock, Arkansas [A virtual component will be offered for those who are unable to attend in person.]

Topics: DEA is soliciting relevant topics of discussion from registrants. Please email your suggestions to **ODLL@dea.gov** no later than **Friday, February 16th**.

Break Out Sessions: Registrants interested in participating in a breakout session to discuss Quota or Import/Export issues with DEA staff are requested to submit a request to **ODLL@dea.gov** no later than **Friday, April 5th**.

Please note: There is no fee to attend this conference. To ensure in-person participation is available to all interested registrants DEA is requesting that no more than 3 persons per DEA registration number plan to attend in-person. Additional participants are welcome to attend virtually. Participants not registering in advance will not be permitted to attend the conference. In the past, there was confusion as to whether private practice attorneys or consulting firms may or may not attend DEA-sponsored conferences for industry. If these individuals or firms represent registrants or their affiliated associations on an "as-needed basis", *DEA does not view them as employees of a registrant or an association, but as paid consultants*. As such, they are not eligible to attend these types of conferences.
More information will be forthcoming as details are finalized.

NASCSA in the Media

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