

## New DEA Rule Allows Single Electronic Transfer of Controlled Substance Prescriptions

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*Holland & Knight Healthcare Blog*

[Hannah Ketring Brown](#) | [Jesse C. Neil](#)

Historically, a retail pharmacy unable to fill an initial electronic prescription for Schedule II-V controlled substances could not transfer it to another pharmacy – even if the two pharmacies were affiliated and part of a larger organization. With the right safeguards in place, a retail pharmacy will now have the flexibility to transfer these initial prescriptions.

### Policy Update

The Centers for Medicare & Medicaid Services (CMS) on July 27, 2023, published a final rule to amend Drug Enforcement Administration (DEA) Regulation 21 CFR 1306.08. The amended rule will become effective on Aug. 28, 2023, and will allow for the transfer of electronic prescriptions for Schedule II-V controlled substances. The rule applies to retail pharmacies for initial filling on a one-time transfer basis only, upon request from the patient. Additionally, any authorized refills included on a prescription for a Schedule III, IV or V controlled substance may be transferred with the original prescription. The final rule specifies procedures the retail pharmacies must follow in order to provide for patient access to needed prescriptions while minimizing the potential for duplicate prescriptions or other misuse.

### Previous Procedures Caused Complications for Electronic Prescriptions

Generally, retail pharmacies may dispense a controlled substance prescription in Schedule II only pursuant to a written prescription (including an electronic prescription), except in limited emergency situations, while controlled substances in Schedules III, IV and V may be dispensed pursuant to a signed paper prescription, facsimile of a signed paper prescription, electronic prescription or oral prescription under certain conditions. Electronic prescriptions, which are becoming increasingly more common, are transmitted directly from the practitioner to the pharmacy in the form of an electronic data file.

If a paper prescription is presented to but unable to be filled by a pharmacy, the paper prescription could be returned to the patient, and the patient could take the prescription to another pharmacy. However, for electronic prescriptions, the pharmacy would need to tell the patient the prescription could not be filled, and the patient would need to call the practitioner to request that a new prescription be sent to a different pharmacy. Because this process was burdensome on pharmacies, practitioners and patients, the DEA amended the rule, seeking to strike a balance between patient access to necessary medication with protections to avoid prescription fraud and duplication.

The rule is prescription-specific. In other words, each prescription transmitted from a practitioner to a retail pharmacy may be transferred one time, upon request from the patient, regardless of whether a previous electronic prescription for a controlled substance was transferred. To successfully implement the new rules, both pharmacies and patients will have certain responsibilities.

### Patient Responsibilities

The one-time pharmacy transfer must be initiated by the patient. Additionally, the patient should confirm the ability of the new pharmacy to fill the prescription: Since a prescription can only be filled once, DEA recommends that the patient confirm the ability of the receiving pharmacy to fill the prescription before requesting the transfer.

### Pharmacy Responsibilities

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- **Ensure technology can enable transfers.** In previous rulemaking, CMS adopted SCRIPT 2017071 as the official electronic prescribing standard for prescriptions covered under Medicare Part D. If pharmacies have not already adopted the SCRIPT Standard Version 2017071, which is available to both independent and chain pharmacies, they should do so to enable the transfer of prescriptions between pharmacies.
- **Maintain the integrity of the prescription.**
  - Keep the prescription in electronic form. The prescription must be transferred from one retail pharmacy to another retail pharmacy in its electronic form. The electronic prescription may not be converted from electronic prescription to another form (e.g., facsimile) for transmission.
  - Do not alter the contents. The required contents of the prescription must not be altered during transfer between retail pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.
- **Follow documentation rules.** The transfer must be communicated directly between two licensed pharmacists. The following electronic records must be maintained for two years from the date of the transfer by the pharmacy transferring the electronic prescription as well as the pharmacy receiving the electronic prescription.
  - The transferring pharmacist must:
    - note on the electronic prescription record that the prescription has been transferred
    - add the name, address and DEA registration number of the pharmacy to which the prescription was transferred and the name of the pharmacist receiving the prescription information, and
    - record the date of the transfer and the name of the pharmacist transferring the prescription information
  - The receiving pharmacist must:
    - add the word "transfer" to the electronic prescription record at the receiving pharmacy
    - annotate the prescription record with the name, address and DEA registration number of the pharmacy from which the prescription was transferred and the name of the pharmacist who transferred the prescription, and
    - record the date of the transfer and the name of the pharmacist receiving the prescription information
- **Verify automated documentation.** If desired, instead of manual data entry, the transferring or receiving pharmacy's prescription processing software may include the information required above from the electronic prescription. The software may automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. However, the transferring and receiving pharmacists must ensure that their portion of the record is complete and accurate.
- **Ensure state law compliance.** The transfer of an electronic prescription for a controlled substance in Schedule II-V for the purpose of initial dispensing is permissible only if allowable under existing state or other applicable law.

## Further Assistance

Holland & Knight's [Healthcare Regulatory Compliance Team](#) has deep experience with the Controlled Substance Act (CSA) and DEA regulations, and offers a wealth of experience helping pharmacies and practitioners navigate these responsibilities. Reach out to the authors or another member of the team for guidance regarding this amended regulation and any other healthcare regulatory matters.

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**Hannah Ketring Brown** is an attorney in Holland & Knight's Healthcare & Life Sciences practice, where she assists with the regulatory aspects of healthcare mergers and acquisitions. Additionally, she advises healthcare clients on day-to-day operational issues such as recruitment and employment, and regulatory issues such as maintaining ongoing compliance with Stark and federal anti-kickback regulations.

615.850.8708 | [Hannah.KetringBrown@hklaw.com](mailto:Hannah.KetringBrown@hklaw.com)



**Jesse Neil** is a veteran healthcare attorney in Holland & Knight's Nashville office. Mr. Neil's background helps clients bridge two complex worlds – healthcare operations and public policy. He advises senior management and healthcare company boards regarding policy, governance and regulatory matters, and he serves as strategic counsel to healthcare providers throughout the U. S.

615.850.8910 | [Jesse.Neil@hklaw.com](mailto:Jesse.Neil@hklaw.com)