New CMS Rules for Part D, Prescriptive Authority, and Prescriber Verification

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Out-of-state prescriptions:

**Missouri:**
Out-of-State Practitioners: Pursuant to Section 195.060.1, RSMo, Missouri pharmacies may in good faith dispense controlled drug prescriptions from out-of-state practitioners, as long as the prescriptions were written in compliance with the laws of the applicable state.

OR:
(1) A prescription written by a practitioner licensed in a state or territory of the United States, other than Oregon, may be filled only if the pharmacist called upon to fill such prescription determines, in the exercise of professional judgment:
(a) That it was issued pursuant to a valid patient-practitioner relationship; and
(b) That it is authentic.

**Minnesota:**
Minnesota pharmacies may legally fill or refill, providing refill authorizations exist, prescriptions from prescribers practicing in any state. If the prescription is for a controlled substance in Schedule II, III or IV, the practitioner must be licensed to prescribe controlled substances by the state in which the prescription is issued and have a current federal Drug Enforcement Administration registration number. Schedule II prescriptions, or course, cannot be refilled.

**California:**
Prescription for Controlled Substance Issued in Another State for Delivery to Patient in Another State; Dispensing by California Pharmacy
(a)(1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

For the purposes of discussion, the legal definition found for a Resident is:

Resident means one of the following:
(1) An individual who participates in an approved GME program, including programs in osteopathy, dentistry, and podiatry.
(2) A physician who is not in an approved GME program, but who is authorized to practice only in a hospital, for example, individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. For purposes of this subpart, the term resident is synonymous with the terms intern and fellow.

2. http://www.phcybrd.state.mn.us/faq.htm
Use of a hospital DEA:

Section 1301.22 Exemption of agents and employees; affiliated practitioners.
(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.
(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.
(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:
(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;
(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;
(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;
(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;
(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and
(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

NPPES Taxonomies do not imply prescriptive authority:

“The Healthcare Provider Taxonomy Codes and code descriptions that health care providers select when applying for NPIs may or may not be the same as the categorizations used by Medicare and other health plans in their enrollment and credentialing activities. The Healthcare Provider Taxonomy Code or code description information collected by NPPES is used to help uniquely identify health care providers in order to assign them NPIs, not to ensure that they are credentialed or qualified to render health care”

CMS Proposed 2015 Rules:

30. Enrollment Requirements for the Prescribers of Part D Covered Drugs (§ 423.120(c)(5) and (6))

To improve our ability to oversee the Medicare Part D program, we are proposing to implement section 6405(c) of the Affordable Care Act effective January 1, 2015. This section provides the Secretary with authority to require that prescriptions for covered Part D drugs must be prescribed by a physician enrolled under section 1866(j) of the Act (42 U.S.C. 1395cc(j)) or an eligible professional as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w–4(k)(3)(B)).

We are proposing in revised 42 CFR 423.120(c)(5) and new (6) that a prescriber of Part D drugs must have: (1) An approved enrollment record in the Medicare FFS program (that is, original Medicare); or (2) a valid opt-out affidavit on file with a Part A/ Part B Medicare Administrative Contractor (A/B MAC) for a prescription to be eligible for coverage under the Part D program.

To help ensure that Part D drugs are prescribed only by qualified prescribers, we are proposing that physicians and eligible professionals enroll in the Medicare program in order to prescribe covered Part D drugs. We are proposing an enrollment deadline of January 1, 2015, which would provide physicians and eligible professionals with at least 6 months after the publication of a final rule to initiate and complete the Medicare enrollment process for the purposes of prescribing covered Part D drugs.


• Whether there are diagnoses to support the indications for which the drugs were prescribed;
• Whether there are instances where the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit);
• Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses;
• The number and type(s) of disciplinary actions taken against the physician or eligible professional by the licensing body or medical board for the state or states in which he or she practices, and the reason(s) for the action(s);
• Whether the physician or eligible professional has any history of "final adverse actions" (as that term is defined under § 424.502);
  • (4) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or
  • (5) An exclusion or debarment from participation in a Federal or State health care program.
• The number and type(s) of malpractice suits that have been filed against the physician or eligible professional related to prescribing that have resulted in a final judgment against the physician or eligible professional or in which the physician or eligible professional has paid a settlement to the plaintiff(s) (to the extent this can be determined);
• Whether any State Medicaid program or any other public or private health insurance program has restricted, suspended, revoked, or terminated the physician or eligible professional's ability to prescribe

medications, and the reason(s) for any such restriction, suspension, revocation, or termination;
• Any other relevant information provided to CMS. In determining whether a physician or eligible professional has a pattern or practice of prescribing that fails to meet Medicare requirements, CMS would consider the following factors, including whether the physician or eligible professional –
1. Has a pattern or practice of prescribing without valid prescribing authority;
2. Has a pattern or practice of prescribing for controlled substances outside the scope of the prescriber’s DEA Certificate of Registration;
3. Has a pattern or practice of prescribing drugs for indications that were not medically accepted—that is, for indications neither approved by the Food and Drug Administration (FDA) nor medically accepted under 1860D-2(e)(4) of the Act – and whether there is evidence that the physician or eligible professional acted in reckless disregard for the health and safety of the patient.

CMS is proposing to revise our regulations governing the release of Part D data to expand the release of unencrypted prescriber, pharmacy, and plan identifiers contained in prescription drug event (PDE) records, as well as to make other changes to our policies regarding release of Part D PDE data.
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