

	2014	2015	2016	Oct-16
Administrative Filings	52	33	15	1
Criminal Filing/Felony	0	3	0	0
Letter of Concern	146	98	100	2
Referred to Diversion	2	0	1	0
PR/Outreach	4	1	2	0
Cases Received	567	666	402	23
Case Assigned	555	659	400	23
Closed Cases	595	624	504	28
Citations Issued	60	64	28	1
Pharmacy Inspections	335	316	262	10
Pharmacy Alerts	261	220	240	8
Dr. Shopper Letters	571	1251	2751	0

NOTES: Pharmacy Group

Administrative Action

Pharmacy did not list the time the inventory was conducted on the annual inventories in 2011, 2012, and 2013, and did not conduct the inventory with the required period for 2014 and 2015. The Pharmacy failed to record the offer to counsel. The Pharmacy failed to provide to the Division an accounting for and securing medications removed from the system but that remain unused and securing medications removed from the system that are wasted or discarded. The Pharmacy personnel did not receive all necessary training for compounding and those present could not say they had read USP 795 within the last year. The Pharmacy will stop compounding until all personnel have completed training to comply with USP 795 requirements. Personnel could not provide the Division inspector the SOPs on site for non-sterile compounding. The Pharmacy did not document items on the Master Worksheet or the Compounding formulation record.

Citation Issued

Unlicensed Individual was contacted via telephone and agreed to sell HCG to a Division Investigator. A package was delivered to the Division containing HCG purchased from the unlicensed individual. HCG requires a prescription to be written by a licensed prescriber and further be dispensed by a licensed pharmacy. The individual has been engaging in the practice of a pharmacy by obtaining and selling HCG without a license. The individual was issued a Citation with a \$5,000 fine, and a Cease and Desist Order.



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MEMORANDUM

DATE: August 9, 2016

TO: Utah Board of Pharmacy and Utah Division of Occupational and Professional Licensing

FROM: Matt Higley, PharmD, BCPS; Shannon Saldaña, PharmD, MS, BCPP; Intermountain Healthcare Pharmacy Services

SUBJECT: Pharmacist DEA registration and controlled substance prescribing

Background: The Utah Pharmacy Practice Act (Utah Code 58-17b) permits collaborative pharmacy practice, whereby a pharmacist agrees to work in conjunction with a practitioner(s) under a protocol; "Collaborative pharmacy practice agreement" means a written and signed agreement that provides for collaborative pharmacy practice for the purpose of drug therapy management. A collaborative pharmacy practice agreement for the treatment of outpatients with Attention-Deficit/Hyperactivity Disorder has been approved within Intermountain Healthcare. An Intermountain Healthcare pharmacist is pursuing a DEA registration to prescribe controlled substances in Schedule II (stimulant medications) under the practice agreement. The online application halts, with the message, "Either your State does not allow those with your MLP [Mid-Level Practitioner] degree to handle any Schedules, or The Drug Enforcement Administration has not completed its review of your State's MLP legislation. We cannot process a registration without any available schedules to select." The DEA recognizes seven states that permit pharmacists to prescribe controlled substances: California, Massachusetts, Montana, New Mexico, North Carolina, Ohio, and Washington. Idaho is currently under review by DEA for inclusion on this list.

A pharmacist in Montana had the same experience with the DEA registration. This pharmacist advised that the state board (with licensing authority) agreed pharmacists in Montana could prescribe controlled substances, which they communicated to the DEA. The DEA subsequently updated the Mid-Level Practitioner Controlled Substance Authorization for Pharmacists in Montana to reflect authority to "administer, procure, dispense, and prescribe (Pharmacy Practice Agreement)" substances in Schedules 2, 2N, 3, 3N, 4, 5. The pharmacist completed the application and secured a DEA registration.

Assessment: In the Utah Controlled Substances Act (Utah Code 58-37-2(1)(II)), "Prescription" means an order issued: (i) by a licensed practitioner, in the course of that practitioner's professional practice or by collaborative pharmacy practice agreement; and (ii) for a controlled substance or other prescription drug or device for use by a patient or an animal.' The Utah Controlled Substances Act Rule (Utah Administrative Code R-156-37-301(1)(a)) states, "Consistent with the provisions of law, the Division may issue a controlled substance license to manufacture, produce, distribute, dispense, prescribe, obtain, administer, analyze, or conduct research with controlled substances in Schedules I, II, III, IV, or V to qualified persons. Licenses shall be issued to qualified persons in the following categories: (a) pharmacist."

Pharmacist controlled substance prescribing in all seven states is under an agreement with a licensed prescriber. Some states have stipulations for any collaborative practice agreement but most – Idaho, Massachusetts, Montana, North Carolina, and Washington – do not detail in their state law additional requirements to obtain a DEA registration or prescribe controlled substances (see Table 1). California requires a pharmacist to obtain a DEA registration prior to initiating or adjusting a controlled substance therapy. New Mexico, Massachusetts, and Ohio require a state controlled substance registration (Ohio has exceptions for hospital pharmacists). New Mexico and Ohio have regulations specifically around obtaining a DEA registration above that of a collaborative practice agreement. New Mexico requires 0.2 CEU (2 contact hours) per renewal period in the subject area of responsible opioid prescribing practices. Ohio requires a review of controlled substances database reports prior to adding or modifying a controlled substance therapy. Utah has a similar recommendation in state law now. Ohio also requires the pharmacists to notify the board of pharmacy within five business days, if they are no longer permitted to prescribe controlled substances under a collaborative practice agreement.

Request: Most states that allow pharmacists to prescribe controlled substances and obtain a DEA registration do not impose additional requirements above the collaborative practice agreement. We therefore believe Utah could allow a pharmacist to obtain their DEA registration without changing state law or rules. If pharmacists may be authorized to prescribe controlled substances by collaborative pharmacy practice agreement in Utah, it is requested that this be communicated to the DEA, along with a request to the DEA to update the Mid-Level Practitioner Controlled Substance Authorization for Pharmacists in Utah to reflect their authority to prescribe (by Collaborative Pharmacy Practice Agreement) substances in Schedules 2, 2N, 3, 3N, 4, and 5. If regulations are required, we are willing to help write those using the other states as an example.



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Table 1

		State Pharmacist Prescribing Model	State Law for Pharmacist DEA Registration or Controlled Substance Prescribing
Utah	Status is "no" but might need further review of state law by DEA	Yes – Collaborative Practice Agreement (CPA)	No specific state requirements
California	2, 2N, 3, 3N, 4, 5 Prescribe Only	Yes	"Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration." (California Code Chapter 9, Division 2, Section 4052.6)
Idaho	No under review	Yes – Collaborative Practice Agreement (CPA)	No specific state requirements for prescribing controlled substances or registering with DEA other than following collaborative agreement regulations
Massachusetts	2, 2N, 3, 3N, 4, 5 Prescribe only Institutional pharmacist only, No Retail	Yes – Collaborative Practice Agreement or (CDTM) Agreement	No specific state requirements for prescribing controlled substances or registering with DEA other than following collaborative agreement regulations
Montana	2, 2N, 3, 3N, 4, 5 Administer, Procure, Dispense & Prescribe (Pharmacy Practice Agreement)	Yes – Collaborative Practice Agreement (CPA)	No specific state requirements for prescribing controlled substances or registering with DEA other than following collaborative agreement regulations
New Mexico	2, 2N, 3, 3N, 4, 5 Administer & Prescribe	Yes – Under guideline or protocol	<p>A pharmacist clinician requesting a controlled substance registration to prescribe controlled substance in Schedule II or Schedule III shall be trained in responsible opioid prescribing practices.</p> <p>A pharmacist clinician with a controlled substance registration to prescribe controlled substances listed in Schedule II or Schedule III shall complete a minimum of 0.2 CEU (2 contact hours) per renewal period in the subject area of responsible opioid prescribing practices.</p> <p>A pharmacist clinician may prescribe controlled substances provided that the pharmacist clinician: (a) has obtained a New Mexico controlled substances registration and a drug enforcement agency registration, and (b) prescribes controlled substances within the parameters of written guidelines or protocols established under these regulations and Section 3, A. of the Pharmacist Prescriptive Authority Act.</p>

			(New Mexico Code 16.19.4.17)
North Carolina	2, 2N, 3, 3N, 4, 5 Prescribe Only	Yes – Clinical Pharmacist Practitioner (CPP) Agreement	No specific state requirements for prescribing controlled substances or registering with DEA other than following collaborative agreement regulations.
Ohio	2, 2N, 3, 3N, 4, 5 Administer, Prescribe and Dispense	Yes – consult agreement	<p>A pharmacist managing a patient's outpatient drug therapy pursuant to a consult agreement shall request and review an OARRS report covering at least a one-year time period, including a border state's information when the pharmacist is practicing in a county bordering another state if that state's information is available, prior to any of the following:</p> <p>(a) Adding a controlled substance drug to a patient's drug therapy; or</p> <p>(b) Adjusting a controlled substance drug's strength, dose, dosage form, frequency of administration or route of administration.</p> <p>A pharmacist authorized to prescribe controlled substances pursuant to paragraph (C)(1)(a) of this rule shall comply with all of the following:</p> <p>(a) Maintain a valid controlled substance prescriber registration issued by the state board of pharmacy by submitting an application in a manner prescribed by the board.</p> <p>(i) A pharmacist shall be required to renew their controlled substance prescriber registration in accordance with a renewal schedule adopted by the board. A controlled substance prescriber registration shall be deemed void if a pharmacist does not renew their registration in accordance with the renewal schedule adopted by the board.</p> <p>(ii) A pharmacist shall be required to notify the board, in a manner prescribed by the board, if they are no longer authorized to prescribe controlled substances pursuant a consult agreement. Notification shall occur within five business days. A controlled substance prescriber registration shall be deemed void if the pharmacist no longer has a valid consult agreement authorizing the prescribing of a controlled substance. Failure to obtain or maintain a valid controlled substance prescriber registration prohibits a pharmacist from prescribing controlled substances.</p> <p>(iii) A pharmacist applying for a controlled substance registration shall be an Ohio licensed pharmacist in good standing. The pharmacist shall not be the subject of any current board disciplinary action or have a restricted license. In determining whether to grant a registration, the board may consider any previous disciplinary action.</p> <p>(iv) The board may deny a registration if the applicant fails to meet any of the required qualifications or if the board finds that issuing a controlled substance registration presents a danger to public safety. (Ohio Administrative Code 4729-29-02)</p>
Washington	2, 2N, 3, 3N, 4 & 5 Prescribe Only	Yes – Collaborative Drug Therapy Agreement	No specific state requirements for prescribing controlled substances or registering with DEA other than following collaborative agreement regulations