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*CMCS Informational Bulletin*

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**FROM:** Vikki Wachino, Director  
Center for Medicaid and CHIP Services (CMCS)

**SUBJECT: State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols.**

This guidance addresses flexibilities that states may have to facilitate timely access to specific drugs by expanding the scope of practice and services that can be provided by pharmacists, including dispensing drugs based on their own independently initiated prescriptions, collaborative practice agreements (CPA) with other licensed prescribing healthcare providers like physicians, “standing orders” issued by the state, or other predetermined protocols. These practices can facilitate easier access to medically necessary and time-sensitive drugs for Medicaid beneficiaries.

**Background**

Medicaid benefits in every state and the District of Columbia include “prescribed drugs.” In accordance with Section 1927(k)(2),(3) and (4) of the Social Security Act, in order to be covered under the Medicaid prescribed drug benefit, such drugs, including nonprescription and over-the-counter (OTC) drugs, must be prescribed by an authorized licensed health practitioner prior to being dispensed by pharmacies. This practice is consistent with the requirements of other public and private third-party payers for prescription and nonprescription drugs. When an individual with Medicaid or third-party insurance requests drugs at a pharmacy without presenting a prescription, the pharmacist may either 1) advise the individual to contact their prescribing provider to obtain a prescription, or 2) contact the individual’s provider to obtain a prescription.

However, the need to contact a provider who has knowledge of the individual’s medical circumstances may pose barriers to the initiation of drug therapy. The individual may not have established a relationship with a prescribing provider. The time required for individuals or pharmacists to contact prescribing providers for prescriptions could undermine access to, and the efficacy of, certain medications that require timely administration in order to be effective.

**Allowing Pharmacists to Dispense Drugs Prescribed Independently, or Under Collaborative Practice Agreements, Standing Orders, or Other Predetermined Protocols.**

Through laws and regulations, states establish sets of standards that dictate the scope of practice and services that may be provided by each type of licensed health practitioner in the state. The scope of practice for pharmacies and pharmacists are either authorized through legislation, or implemented by state Departments of Health and/or Boards of Pharmacy, or another governing

body authorized by the state, and in addition to drug dispensing, may enable pharmacists to provide a range of clinical services that include the initiation, modification and monitoring of a patient’s drug therapy. This scope of practice is typically tailored to meet state, jurisdiction or institution-specific public health needs related to specific diseases, conditions, epidemics, drugs or drug classes. In its definition of the authorized scope of practice for pharmacists, a state can specify that pharmacists can dispense certain drugs either 1) after independently prescribing them, or 2) after entering into collaborative practice agreements (CPA) under which the pharmacists operate under authority delegated by another licensed practitioner with prescribing authority, 3) under “standing orders” issued by the state, or 4) based on some other predetermined state authorized protocols. Forty-eight (48) states and Washington D.C. use one or more of these methods that, in effect, expand pharmacists’ scope of practice.<sup>1</sup>.

States are implementing these approaches to help address a number of national public health challenges. For example, given the opioid epidemic, these approaches can help reduce the incidence of mortality and other complications from opioid overdoses by ensuring timely access to naloxone, the opioid overdose reversal drug. Naloxone is a drug indicated for the complete or partial reversal of narcotic depression, including respiratory depression induced by opioids that include natural and synthetic narcotics, propoxyphene, methadone and certain narcotic-antagonist analgesics<sup>2, 3</sup>. The drug prevents or reverses the potential life-threatening effects of opioids, including respiratory depression, sedation, and hypotension, thereby allowing an opioid overdose victim to resume normal breathing. In cases of an opioid overdose emergency, naloxone is most effective with rapid onset of action, which requires it to be administered in a timely manner. In most states, naloxone can only be provided by prescription or medication order during the regular course of medical care, which typically starts after the ambulance first responders have arrived, or in the emergency room, at which point, precious time may have been lost. However, given the importance of timely naloxone administration, states can use their authority to define the scope of practice for pharmacists to include the ability to dispense the drug for individuals, including Medicaid beneficiaries, prior to overdose emergencies. This can help to ensure the drug is available in the community at the time of a suspected overdose, enabling the immediate initiation of this potentially life-saving drug treatment. To help ensure that naloxone is on hand for life-threatening emergencies, forty (40) states<sup>4</sup> authorize

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<sup>1</sup> National Alliance of State Pharmacy Associations (NASPA)/ National Association of Boards of Pharmacy (NABP) “Convened Meeting on Statewide Protocols for Pharmacist Prescribing” Meeting Notes, March 2016 (Accessed on October 4, 2016)

<sup>2</sup> Naloxone hydrochloride FDA-approved drug label Information. Obtained from <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=76f7eee1-d524-43a4-a868-ffa9f29638a6>

<sup>3</sup> “Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction” Obtained from <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-02-02-16.pdf>

<sup>4, 8</sup> Alabama, Alaska, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia and Wisconsin authorize pharmacists to dispense naloxone by standing orders. California, Delaware, Massachusetts, New York and Oregon require pharmacists participate in naloxone administration programs in order to dispense the drug under

pharmacists to dispense naloxone under standing orders issued by licensed healthcare providers authorized by law to prescribe an opioid antagonist, or by the states' top medical officials, for example the state physician general., or both. Five (5) of these states require pharmacists to participate in a naloxone administration training program.<sup>5</sup>

When exercised, these flexibilities can also play an important role in facilitating the initiation of nicotine replacement therapy and other tobacco cessation treatment. Lung cancer is the leading cause of cancer death and the second most diagnosed cancer in both men and women in the United States. Although cigarette smoking is the number one cause of lung cancer, the disease can also be caused by using other types of tobacco such as pipes or cigars. In 2011, fourteen (14) percent of all cancer diagnoses and twenty-seven (27) percent of all cancer deaths were due to lung cancer. After increasing for decades, lung cancer rates are decreasing nationally, as fewer people smoke cigarettes.<sup>6</sup> In California and New Mexico; the two states that have expanded their pharmacists' scope of practice related to tobacco cessation drug therapy, pharmacists are able to initiate, modify and manage nicotine replacement and tobacco cessation drug therapy to assist patients interested in quitting cigarettes in the community setting without requiring them to contact their primary care providers for a prescription. This seamless process provides an improved patient experience, encourages adherence to the therapy, and increases the patients' chances of overcoming nicotine dependence.

These flexibilities are also instrumental to the prevention of influenza viral infections and epidemics by enabling pharmacists to administer flu-shots in community pharmacies. . Specifically, seventeen (17) states permit pharmacists to prescribe and administer flu shots independently. The remaining thirty-three (33) states and the District of Columbia permit pharmacists to administer flu-shots based on either CPAs, standing orders, prescriptions from authorized prescribers, other protocols or a combination of some of these methods. Individuals visit pharmacies requesting to receive a flu-shot, and ask the pharmacists to bill their third-party payers. The pharmacists determine the appropriate vaccine formulations, product and dosages for the specific individual based on their age, health status, health history and other health conditions, then initiate prescriptions independently or based on CPAs, standing orders or other protocols and submit the claims to the third-party payers. If covered and reimbursed by the third party, the pharmacists administer the vaccinations to the individual. If not covered, and therefore not reimbursed by the third party, the patient has the option of paying out-of-pocket for the vaccine. When covered, this process provides for seamless and timely delivery of care to patients, which is an important factor in encouraging the public to obtain a flu-shot.

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standing orders according to “Naloxone Overdose Prevention Laws” – published on <http://lawatlas.org/datasets/laws-regulating-administration-of-naloxone>. Updated through July 1, 2016 (Accessed on December 5, 2016).

<sup>6</sup> “Basic Information About Lung Cancer” – [https://www.cdc.gov/cancer/lung/basic\\_info/](https://www.cdc.gov/cancer/lung/basic_info/) (Accessed on December 6, 2016)

These flexibilities can also be used to improve access to emergency contraception. Emergency contraception is a safe and effective method to prevent pregnancies<sup>7</sup>; however, as with naloxone its efficacy is contingent on the time of administration. While certain emergency contraception pills (ECPs) may be available over-the-counter, as with all over-the-counter medications, prescriptions for ECPs are required for Medicaid as well as third-party payer reimbursement.<sup>8</sup> Generally, authorized prescribers must be contacted for prescriptions prior to beneficiaries obtaining these drugs. However, similar to the process used to ensure timely access to flu vaccines and naloxone, nine states allow pharmacists to dispense and bill third-party payers like Medicaid for ECPs using prescriptions based on either standing orders, CPAs, or expanded scope of pharmacist practice.<sup>9</sup> Like the other practices described in this bulletin, this is solely a state option, not a requirement.

## Conclusion

CMCS recognizes that states continue to look for innovative tools to address pressing public health issues, such as the opioid epidemic or preventing influenza infections. State flexibilities in expanding the ability of pharmacists to prescribe, modify, or monitor drug therapy for certain medications may be effective at helping to address such issues by improving access to care. CMCS encourages states to consider using these methods to promote access particularly to those drugs that can help address priority public health issues.

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<sup>7</sup> “Emergency Contraception - The Facts” – <https://www.hhs.gov/opa/sites/default/files/emergency-contraception-fact-sheet.pdf> (Accessed on January 4, 2017)

<sup>8</sup> FDA News release. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm> (Accessed on January 5, 2017)

<sup>9</sup> Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington according to the “Emergency Contraception State Laws” published by the National conference of State Legislators on <http://www.ncsl.org/research/health/emergency-contraception-state-laws.aspx> (Accessed on June 17, 2016)