REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-15

Subject: Emergency Prescription Drug Refills

(Resolution 201-I-14)

Presented by: Robert E. Hertzka, MD, Chair

Referred to: Reference Committee J

(Jeffrey P. Gold, MD, Chair)

At the 2014 Interim Meeting, the House of Delegates referred Resolution 201, "Short-Term Urgent Refills," which was sponsored by the Indiana Delegation. Resolution 201-I-14 asked:

That our American Medical Association (AMA) develop a policy that short-term urgent refills should be allowed once a month for certain critical medications when authorization for refill is not readily available after hours, on weekends and on holidays, and that this recommendation be sent to the Food and Drug Administration and other vested parties, and ask that the same parties generate a list of critical medications qualifying for a short-term urgent refill; and

That our AMA generate model state legislation to allow short-term urgent refills for certain critical medications as often as once a month.

This report provides background on state laws addressing emergency refills of prescription drugs; highlights the issue of emergency dispensing of Schedule II controlled substances; summarizes relevant AMA policy; and presents policy recommendations.

BACKGROUND

Many states already permit emergency refills under their state pharmacy practice acts, thereby enabling pharmacists to dispense a certain quantity of a prescription drug on an emergency basis if in the pharmacist's professional judgment, the prescription drug is critical to continue a therapeutic regimen or otherwise maintain a patient's health status. Situations under which emergency refills may be permitted under state law include when a refill is immediately needed and the prescriber cannot be reached, and when prior authorization cannot be obtained in a timely manner by the patient's health insurance plan. Some state laws also specifically address emergency prescription drug refills in the event of a state of emergency.

According to the Centers for Disease Control and Prevention, 28 states and the District of Columbia require day or hour limits for prescription drugs dispensed on an emergency basis. Twenty-two states allow emergency dispensing when a prescription drug is needed but prior authorization required by a patient's health plan has not been obtained. There is variation in the day and hour limits outlined in state law for emergency refills. For example, numerous states, including Alabama, Colorado, Florida, Kentucky, Louisiana, Mississippi, New Mexico, Rhode Island, Texas and Utah have laws authorizing pharmacists to dispense an emergency refill of up to a 72-hour supply of prescription medication if such dispensing meets all other parameters outlined in law. Other states allow for larger supplies of emergency refills, ranging from a seven-day

supply as provided for in Kansas law, to up to a 30-day supply of prescription medication as authorized in North Carolina law.³ However, the state laws of Delaware, Idaho and Montana do not specify a specific day or hour limit for emergency refills; their laws authorize pharmacists to dispense sufficient medication to maintain the prescribed treatment until prescriber authorization can be achieved.⁴

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While some states do not differentiate in their laws concerning the emergency supply allowed as a result of a state of emergency versus an individual medical emergency, other states only allow emergency refills in a state of emergency, or authorize a larger emergency supply of a prescription drug in the context of a state of emergency or in the event of a natural or manmade disaster. In states including Florida and Texas, for example, while state law permits pharmacists to dispense emergency refills of up to a 72-hour supply, pharmacists can be authorized to dispense up to a 30-day emergency refill of a prescription drug in the event of a natural or manmade disaster, or when an emergency order or proclamation of a state of emergency is declared by the governor. The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy outline model rules for refill dispensing during a state of emergency issued pursuant to a public health emergency. The model rules state that a pharmacist may dispense a prescription drug refill of no greater than a 30-day supply without prescriber authorization if certain conditions are met. The rule also explicitly states that the practitioner and pharmacist shall not incur any liability resulting from such emergency dispensing.

EMERGENCY DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES

Eleven states have laws permitting dispensing of prescription drugs on an emergency basis, with language that specifically excludes schedule II drugs. Substances in schedule II, determined to have a high potential for abuse which may lead to severe psychological or physical dependence, include methodone; oxycodone; fentanyl; morphine; codeine; hydrocodone and methylphenidate. While refills for schedule II controlled substances are prohibited, there is a mechanism allowing for the emergency dispensing of schedule II controlled substances. In the case that a prescriber is not able to provide a written prescription, a prescriber may call in a schedule II prescription to a pharmacist, who may then dispense the prescription. The prescriber must provide a written and signed prescription to the pharmacy within seven days and meet other outlined requirements in the law.

RELEVANT AMA POLICY

Policy H-120.987 advocates notification by the American Pharmacists Association (APhA) of its members that prescriptions should be refilled only on the physician's order. Policy D-35.987 opposes federal and state legislation allowing pharmacists to independently prescribe or dispense prescription medication without a valid order by, or under the supervision of, a licensed doctor of medicine, osteopathy, dentistry or podiatry; and opposes federal and state legislation allowing pharmacists to dispense medication beyond the expiration of the original prescription.

To prevent the need for emergency refill requests, Policy D-120.984 states that the AMA will work with the APhA, the National Community Pharmacists Association, and the National Association of Chain Drug Stores to streamline the process for prescription refills in order to reduce administrative burdens on physicians and pharmacists and to improve patient safety. Policy H-120.952 encourages relevant organizations, including but not limited to insurance companies and professional pharmacy organizations, to develop a plan to implement prescription refill schedule strategies so that patients requiring multiple prescription medications may reduce the need for multiple renewal requests and travel barriers for prescription acquisition. Specifically

addressing public health emergencies and disasters, Policy H-120.942 states that it is reasonable and prudent for patients with chronic medical conditions to maintain an emergency reserve of their prescription medications, and that patients with chronic medical conditions should discuss options with their physician for ensuring that they have an adequate supply of prescription medications in the event of a disaster or other potential emergency.

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DISCUSSION

While many states already permit emergency refills under their state pharmacy practice acts, the Council believes that principles are needed to guide future legislation, regulations and protocols addressing emergency refills. The Council recognizes that mechanisms to allow for emergency refills of prescription medications are necessary to prevent the interruption of a therapeutic regimen, as well as patient suffering. However, only a minimum sufficient quantity should be dispensed as an emergency refill until authorization can be obtained from a prescriber, or in the case of prior authorization, a patient's health plan. However, larger emergency supplies of prescription medications may be needed following a natural or manmade disaster, when a state of emergency or emergency order is issued. If an emergency order or proclamation of a state of emergency is declared by a state's governor, an executive order can be used to allow pharmacists to dispense up to a 30-day supply of a prescription medication, or other amount as provided for under existing state law.

Emergency refills of prescription drugs should not be a regular occurrence. It is essential for the pharmacist to inform the patient or the patient's agent at the time of dispensing that the refill is being provided without the prescriber's authorization and that authorization of the prescriber is required for a future refill. In addition, the pharmacist should notify the patient or the patient's agent of any cost-sharing responsibilities prior to dispensing. Within 72 hours of dispensing, the pharmacist should notify the prescriber of the emergency refill. As emergency refills require pharmacists to dispense prescription medication without prescriber authorization, a prescriber should not be liable for any damages resulting from an emergency refill.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 201-I-14, and the remainder of the report be filed:

That our American Medical Association (AMA) advocate the following principles to guide the dispensing of emergency refills of prescription drugs:

a) Emergency refills should only be authorized if, in the pharmacist's professional judgment, failure to refill the prescription might result in an important interruption of a therapeutic regimen that could cause patient harm.

b) Emergency refills should only be dispensed if the pharmacy is unable to readily obtain refill authorization from the prescriber; prior authorization cannot be obtained in a timely manner from the patient's health plan; or when an emergency order or a proclamation of a state of emergency is declared by a state's governor.

c) Schedule II controlled substances can be dispensed on an emergency basis as allowed under Drug Enforcement Administration protocol.

d) In general, the pharmacist may dispense a sufficient supply of the medication to maintain the prescribed treatment until prescriber authorization can be achieved.

- e) If an emergency order or proclamation of a state of emergency is issued by a state's governor, an executive order may allow pharmacists to dispense up to a 30-day supply of a prescription drug, or other amount as provided for under existing state law.
 - f) The dispensing pharmacist should notify the prescriber of the emergency refill within 72 hours of dispensing.
 - g) Emergency refills should not be a regular occurrence.
 - h) The pharmacist should inform the patient or the patient's agent at the time of dispensing that the refill is being provided without the prescriber's authorization and that authorization of the prescriber is required for a future refill.
 - i) The pharmacist should notify the patient or the patient's agent of any cost-sharing responsibilities prior to dispensing.
 - j) A prescriber should not be subject to liability for any damages resulting from an emergency refill of a prescription drug by a pharmacist. (New HOD Policy)

Fiscal note: Less than \$500.

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¹ Office for State, Tribal, Local and Territorial Support, Centers for Disease Control and Prevention. Prescription Drug Time and Dosage Limit Laws. March 2015. Available at: http://www.cdc.gov/phlp/docs/menu prescriptionlimits.pdf.

² AL PracAct 34-23-75; CO PracAct 12-42.5-120; FL PracAct 465.0275; KY BReg 201 KAR 2:175; LA BReg 2521; MS BReg 30-20-3001:XII; NM PracAct 61-11-7; RI PracAct 5-19.1-24; TX PracAct 562.054; UT PracAct 58-17b-608.

³ KS PracAct 65-1637 and NC BReg 1809.

⁴ DE PracAct 2550, ID BReg 116, MT BReg 24.174.515.

⁵ FL PracAct 465.0275 and TX PracAct 562.054.

⁶ Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. August 2015. Available at: http://www.nabp.net/publications/model-act.

⁷ Office of Diversion Control, Drug Enforcement Administration, US Department of Justice. Controlled Substances Schedules. Available at: http://www.deadiversion.usdoj.gov/schedules/.

⁸ Office of Diversion Control, Drug Enforcement Administration, US Department of Justice. Pharmacist's Manual: An Informational Outline of the Controlled Substances Act. 2010. Available at: http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm manual.pdf.