

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 05-A-23

Subject: Prescription Drug Dispensing Policies
(Resolution 237-A-22)

Presented by: Lynn Jeffers, MD, MBA, Chair

Referred to: Reference Committee G

At the June 2022 Annual Meeting, the House of Delegates referred Resolution 237-A-22, Prescription Drug Dispensing Policies, which was sponsored by the Ohio Delegation and asks that the American Medical Association (AMA) work with pharmacy benefit managers (PBMs) to eliminate any financial incentives that may exist for patients to receive a supply of medication that is greater than the physician prescribed. Resolution 237-A-22 also asks that the AMA create model state legislation to restrict dispensing a prescription drug in greater quantities than prescribed, and support legislation that supports removing financial barriers that favor dispensing of quantities greater than prescribed. This report provides background on the process of drug dispensing quantities, reviews relevant AMA policy, and makes policy recommendations.

BACKGROUND

When physicians write prescriptions and provide them to their patients, an insurance company and/or PBM may influence not only the cost of the medication, but also the amount that is dispensed to the patient¹. In certain situations, such as when a patient is taking a maintenance medication, the insurer or PBM, may be incentivized to require a 90-day supply to be dispensed, even if a 30-day supply was prescribed.² While this may not be an issue once the patient's medication and dosage are established, it can be a problem for patients and physicians when initially assessing medications, dosages, or making changes to either. When physicians write prescriptions with a set number of refills, some states allow pharmacists to dispense the total amount.² For example, a prescription for a 30-day supply of medication with two refills could result in these pharmacies dispensing the total 90-day supply at once.

PBM AND INSURER INFLUENCE ON DISPENSING QUANTITIES

To fully understand the pressures to dispense a 90-day supply it is important to understand the relationship between PBMs, health insurers, and the pharmacies that end up dispensing the medication. PBMs are considered an intermediary that works to manage prescription drug benefits for secondary entities, like health insurers. PBMs have the stated goal of working to lower drug prices through their work negotiating rebates and discounts off the list price of drugs. However, a lack of transparency and regulation into these efforts have yielded confusion and doubt as to if this goal is being met.³ Current efforts by both the Federal Trade Commission (FTC) and Congress are being made to investigate and better understand the innerworkings of PBMs in the process.⁴

The process of dispensing medication has multiple intersections between PBMs, payers, and pharmacies. PBMs pay pharmacies a drug dispensing fee and negotiate rate prices with the manufacturer, while insurers pay the PBMs fees for administrative work and dispensing fees for

1 medications. For PBMs and payers, these points of intersection may be areas where requiring a
2 larger quantity of medication to be dispensed is advantageous. For example, when a larger quantity
3 of medication is being negotiated, it gives the PBM better negotiating power and can lead to lower
4 negotiated prices or larger rebates. For both PBMs and payers, dispensing greater supplies of
5 medication can lower the dispensing costs associated with the medication. Additionally, it is not
6 uncommon for PBMs and/or health insurers to own and operate automatic dispensing facilities,
7 such as mail order pharmacies, and dispensing greater quantities of a medication can lower
8 operating costs in these settings as well.⁵ One place of major PBM reform that is promoted by the
9 National Community Pharmacist Association, is centered around the mandatory use of these PBM
10 owned mail order pharmacies that often depersonalize the process. This is especially relevant to the
11 quantity of a medication dispensed as the safeguards of both physicians and pharmacists interacting
12 with the patient are removed in the automated process used with PBM-owned mail order
13 pharmacies.⁶

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15 Overall, the insertion of payers and PBMs in the process of determining the quantity of a
16 prescription medication dispensed is opposed both by the AMA and community pharmacists, the
17 two entities that interact most directly with the patient. While there can be benefits to the
18 dispensing of a larger supply of medication, especially in the cost savings for the PBM and/or
19 payer, the decision is one that needs to be made on a patient level and under the supervision and
20 control of the prescribing physician.

21 22 POTENTIAL PATIENT RISKS OF A 90-DAY SUPPLY

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24 Among the key concerns when a patient receives a quantity of a prescription drug that is greater
25 than what was prescribed include the risk of intentional overdose. While there is not a guarantee
26 that a physician will be aware of a patient's suicide risk, there is an opportunity for assessment,
27 both formal and informal, during a medical appointment. Pharmacists' interactions with patients
28 would not typically include this type of screening process and, thus, they may not be aware of a
29 potential risk. Unfortunately, even if a risk was recognized, PBMs, who are further removed from
30 direct patient engagement, may force pharmacists to fill larger quantities without the ability to
31 apply insurance coverage at lower quantities. Currently, there are strict regulations on the quantity
32 of controlled substances that can be dispensed as these medications are often seen in suicide
33 attempts or completions.^{7,8} However, other prescription medications are not regulated at the same
34 level and may still be used in suicide attempts or completions.^{8,9}

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36 A second concern regarding patients receiving quantities of prescription medication greater than
37 prescribed is the oversupply of medications. Oversupply is a concern with regard to the potential
38 for increased cost to the patient and patient stockpiling. When a prescription is dispensed at a
39 greater quantity than prescribed, a patient may not need the full 90 days. For example, if a
40 medication is new and the physician is working with the patient to establish the correct dosage
41 there may be a change in the dosage prior to completion of the full 90 days. The oversupply of a
42 prescription drug can lead to a patient stockpiling a medication, which, even when unintentional,
43 can be dangerous and should be avoided.¹⁰ In addition to the potential for a medication to be
44 stockpiled, it is possible that this oversupply could place an undue financial burden on the patient.
45 For instance, should a patient be prescribed a medication with a substantial co-pay that is only
46 covered in a 90-day supply, but that prescription is altered before completion of the 90 days, the
47 patient may be responsible for an additional, expensive co-pay. The cost of prescription
48 medications in the United States is a major barrier for many to access the care they require and
49 should be mitigated whenever possible.¹¹

POTENTIAL PATIENT BENEFITS OF A 90-DAY SUPPLY

While there are some substantial potential risks associated with dispensing larger supplies of medication than prescribed, there are some potential benefits as well. When allowed, pharmacists may be inclined or forced to dispense the larger supply due to the financial benefits and improved patient adherence to the medication regimen. Each year, a lack of medication adherence directly relates to approximately 10 percent of all health care spending in the United States⁷. Research has demonstrated that a larger supply of medication has been linked with greater medication adherence, which is especially true in patients who traditionally have the lowest levels of adherence. This improvement in adherence is explained by reduction of barriers and improvement in convenience for the patient. For example, if a patient has difficulty finding transportation to and from the pharmacy, reducing the number of trips may boost adherence. Additionally, patients report greater satisfaction with a greater supply of medication, especially for those who have multiple prescriptions. Most importantly, adherence to medications, particularly medications for chronic diseases like hypertension and diabetes, significantly improves patient outcomes and reduces health care costs.⁷

In addition to greater medication adherence, there is the added benefit of cost savings with a larger quantity of medication for the pharmacy and the patient. Prescription drug cost reduction is typically centered around a lower distribution cost, negotiated drug cost, and potential rebates.⁵ These potential advantages can lead to cost-savings to the patient, as well as a reduction in the time spent obtaining their prescriptions. However, to ensure that patients are receiving lowered costs when appropriate, but not an oversupply of medication, it is important that the decision regarding amounts of dispensed medications remain within the context of the patient-physician relationship.

RELEVANT AMA POLICY

The AMA currently has policies that address the dispensing of prescription drugs. The most directly relevant AMA policies on the topic of medication dispensing are Policies [H-120.962](#) and [H-185.942](#). Each of these policies ensure that physicians can specify the appropriate quantity of a prescription drug and that insurers must have a specific process in place when exceptions to the typically dispensed amount needs to be altered due to a medical reason. Policy H-120.962 specifically addresses mail order pharmacies and outlines when a 90-day prescription may not be appropriate; during the initialization and dose stabilization of a new medication and when changing the dosage of a long-term medication. Policy H-185.942 outlines AMA support for working with insurers to ensure that there is an exceptions process for patients that may need a higher or lower dispensed amount of a medication due to a medical necessity and supports physician ability to limit quantities of a prescription drug during initialization and dose stabilization of a new medication or if the medication may pose a risk to patients.

In addition to policies related to the dispensing of prescription medications, the AMA has policy related to limiting the overreach of pharmacists into medical decision-making. Of specific relevance, Policy D-120.934 indicates AMA's intent to prohibit pharmacy actions that are unilateral medical decisions and directs the AMA to implement policies that ensure prescriptions are dispensed by pharmacists as ordered by the physician or prescriber, including the quantity ordered. Policies D-35.981 and D-35.987 more generally establish AMA's opposition to the inappropriate practice of medicine by pharmacists. Policy D-35.981 confronts the "intrusion" of pharmacy into medical practice. Policy D-35.987 outlines the AMA's intent to study, oppose, and educate about inappropriate scope of practice expansions that would allow pharmacists to perform services that constitute the practice of medicine, including opposition to laws that would allow

pharmacists to prescribe medications or to dispense medication beyond the expiration date of the original prescription.

In addition, Policies H-115.967 and H-95.945 both outline the AMA's actions to promote education, tracking, and packaging that prevents addiction, misuse, and harm. Specifically, Policy H-115.967 focuses on introducing packaging for controlled substances that is more functional for patients, improves patient adherence, and reduces the risk for misuse and abuse. Policy H-95.945 supports the permanency of and funding for the National All Schedules Prescription Electronic Reporting and state/jurisdiction Prescription Drug Monitoring Programs. Additionally, the policy outlines support for the availability of these data and the education of physicians on how to reduce the misuse of prescription drugs.

Policies H-120.943 and H-120.952 state the AMA's work to ensure that the dispensed quantity of a prescription drug is adequate for the patient, not overregulated, and not an undue burden on the physician. Policy H-120.943 outlines the requirement for a medication that is dispensed for a month and three-month supply and indicates the AMA's opposition to the arbitrary prescription limits of medication for patients with pain related to cancer or a terminal illness. Similarly, Policy H-120.952 opposes restriction to legitimate and clinically appropriate refills and encourages the implementation of a prescription refill schedule.

DISCUSSION

In weighing the potential benefits and risks of dispensing a larger supply of medication, there is no one correct answer for all patients. However, it is clear that physicians and patients should be able to work collaboratively to make the correct choice for each individual patient. Further complicating the issue are direction from PBMs and payers requiring or financially incentivizing the use of certain PBM owned mail order pharmacies that only dispense 90-day supplies of certain medications. These practices can lead to not only confusion and frustration for both physicians and patients, but also can be potentially dangerous and expensive for patients.

Although research has demonstrated benefits to dispensing 90-day supplies of medications to patients, the Council believes it is essential that the decision as to the quantity of medication dispensed is one that is made within the patient-physician relationship, not by insurers, pharmacies, or PBMs. The Council also believes that the benefits of a 90-day supply are most prevalent for maintenance medications that are stable and address chronic conditions. Although the AMA has policy to ensure that the patient is able to receive the prescribed amount of a medication, as well as policy that opposes the overreach of pharmacist practice, the Council believes that the language of existing policy can be strengthened to ensure that the quantity of a medication dispensed remains a decision made within the patient-physician relationship.

Therefore, the Council believes that the implementation of clear guidelines for physicians to indicate that a prescription should be dispensed only as written are warranted. These guidelines could follow what have been implemented in states where physicians are able to write "dispense quantity as written," "no change in quantity," or similar language to indicate the necessity of a prescription being dispensed in a specific quantity. Additionally, the Council believes that Policy H-185.942 which ensures that physicians are able to specify the quantity of a prescription dispensed, can be strengthened with the addition of PBMs as a regulated party. Finally, the Council believes that AMA policy on both ensuring the dispensing of adequate amounts of medication without undue burden on the physician or patient and restricting the influence of PBMs and payers are adequate and should be reaffirmed.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 237-A-22, and that the remainder of the report be filed:

1. That our American Medical Association (AMA) support the development and implementation of clear guidelines and mechanisms to indicate that the quantity of a prescription should be dispensed only as written using such language as “dispense quantity as written” or “no change in quantity.” (New HOD Policy)
2. That our AMA amend Policy H-185.942, to read as follows:
 1. Our AMA supports the protection of the patient-physician relationship from interference by payers and Pharmacy Benefit Managers (PBMs) via various utilization control mechanisms, including medication and testing and treatment supply quantity limits.
 2. Our AMA will work with third party payers and PBMs to ensure that if they use quantity limits for prescription drugs or testing and treatment supplies, an exceptions process must be in place to ensure that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, and that any such process should place a minimum burden upon patients, physicians and their staff.
 3. Our AMA supports interested state legislative efforts and federal action and will develop model state legislation to ensure that third party payers or PBMs that institute quantity limits for prescription drugs or testing and treatment supplies include an exceptions process so that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, including provisions such as the following.... (Amend AMA Policy)
3. That our AMA reaffirm Policy H-320.953, which defines the term “medical necessity” as referenced in the suggested amended policy H-185.942 (above) in recommendation two. (Reaffirm AMA Policy)
4. That our AMA reaffirm Policy H-120.952, which ensures that the quantity of a medication dispensed to patients is of adequate supply, not overregulated, and that receiving the medication is not an undue burden on the patient or the prescribing physician. (Reaffirm HOD Policy)
5. That our AMA reaffirm Policy D-120.934, which ensures that prescriptions must be filled as ordered, including the quantity, and that PBMs and payers restrict policies that impact patient access to prescription medications. (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

REFERENCES

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Appendix

AMA Policies Recommended for Reaffirmation or Amendment

Policy H-185.942 “Third Party Payer Quantity Limits”

1. Our AMA supports the protection of the patient-physician relationship from interference by payers via various utilization control mechanisms, including medication and testing and treatment supply quantity limits.
2. Our AMA will work with third party payers to ensure that if they use quantity limits for prescription drugs or testing and treatment supplies, an exceptions process must be in place to ensure that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, and that any such process should place a minimum burden upon patients, physicians and their staff.
3. Our AMA supports interested state legislative efforts and federal action and will develop model state legislation to ensure that third party payers that institute quantity limits for prescription drugs or testing and treatment supplies include an exceptions process so that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, including provisions such as the following:
 - physicians can specify limited supplies of medications during initial trials of a medication, or if a larger quantity of medication would expose an at-risk patient to potential harm (e.g., opioids, benzodiazepines, or psychostimulants)
 - physicians can appeal adverse determinations regarding quantity limitations;
 - payers must provide an easily accessible list of all medications and testing and treatment supplies with quantity limits and the requirements for the exception process on the payer's Web site;
 - payers must indicate, what, if any, clinical criteria (e.g., evidence-based guidelines, FDA label, scientific literature) support the plan's quantity limitations;
 - physicians with specialized qualifications may not be subject to quantity limits;
 - payers cannot charge patients for an additional co-pay if an exception request for a higher medication or testing and treatment supply quantity has been approved based on medical necessity;
 - payer decisions on exception, and subsequent appeal requests, of quantity limits must be made within two working days in non urgent situations and one working day in urgent cases; and
 - physicians or patients can submit any denied appeals to an independent review body for a final, binding decision. (BOT Rep. 12, A-12; Reaffirmation: I-17)

Policy H-320.953 “Definitions of “Screening” and “Medical Necessity””

- (1) Our AMA defines screening as: Health care services or products provided to an individual without apparent signs or symptoms of an illness, injury or disease for the purpose of identifying or excluding an undiagnosed illness, disease, or condition.
- (2) Our AMA recognizes that federal law (EMTALA) includes the distinct use of the word screening in the term “medical screening examination”; “The process required to reach, with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist.”
- (3) Our AMA defines medical necessity as: Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.
- (4) Our AMA incorporates its definition of “medical necessity” in relevant AMA advocacy documents, including its “Model Managed Care Services Agreement.” Usage of the term “medical necessity” must be consistent between the medical profession and the insurance industry. Carrier

denials for non-covered services should state so explicitly and not confound this with a determination of lack of “medical necessity”.

(5) Our AMA encourages physicians to carefully review their health plan medical services agreements to ensure that they do not contain definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness.

(6) Our AMA urges private sector health care accreditation organizations to develop and incorporate standards that prohibit the use of definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness.

(7) Our AMA advocates that determinations of medical necessity shall be based only on information that is available at the time that health care products or services are provided.

(8) Our AMA continues to advocate its policies on medical necessity determinations to government agencies, managed care organizations, third party payers, and private sector health care accreditation organizations. (CMS Rep. 13, I-98; Reaffirmed: BOT Action in response to referred for decision Res. 724, A-99; Modified: Res. 703, A-03; Reaffirmation I-06; Reaffirmed: CMS Rep. 01, A-16)

Policy H-120.952 “Restriction on Prescription Refills”

1. Our AMA opposes restrictions on the legitimate, clinically appropriate refill of patient prescriptions including, but not limited to: (A) restricting refill hours to less than usual pharmacy hours; (B) restricting refills to limited pharmacies rather than all participating pharmacies; (C) restricting refills for chronic medications to a less than 90-day supply; and (D) restricting the date of refill.

2. Our AMA will encourage 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. (Res. 512, A-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 801, I-12; Modified: Sub. Res. 719, A-13; Reaffirmed: CMS Rep. 04, A-16)

Policy D-120.934 “Evaluating Actions by Pharmacy Benefit Manager and Payer Policies on Patient Care”

1. Our AMA will take steps to implement AMA Policies H-120.947 and D-35.981 that prescriptions must be filled as ordered by physicians or other duly authorized/licensed persons, including the quantity ordered.

2. Our AMA will work with pharmacy benefit managers, payers, relevant pharmacy associations, and stakeholders to: (a) identify the impact on patients of policies that restrict prescriptions to ensure access to care and urge that these policies receive the same notice and public comment as any other significant policy affecting the practice of pharmacy and medicine; and (b) prohibit pharmacy actions that are unilateral medical decisions.

3. Our AMA will report back at the 2018 Annual Meeting on actions taken to preserve the purview of physicians in prescription origination.