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Medication Access: Policy and Practice Opportunities for Pharmacists

American College of Clinical Pharmacy

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ABSTRACT

Medication access is critical to achieving optimal patient outcomes. The 2020 Task Force on Medication Access was charged with developing an ACCP white paper on improving medication access that addresses barriers such as cost, health disparities, and utilization management practices. This white paper outlines major barriers to medication access and provides pharmacists and professional organizations with policy and practice recommendations to help reduce barriers, enhance medication access, and fulfill the goal of optimal patient outcomes.

KEYWORDS: clinical pharmacist, medication access, medication barriers

1 | INTRODUCTION

The U.S. health care system is undergoing a major shift to a value-based health care delivery model. In this model, health care providers are reimbursed on the basis of quality metrics, including patient outcomes, with the goal of providing higher-quality and more cost-effective care to patients and communities. Adequate access to health care, including medications, is a critical factor in value-based health care delivery and has been recognized as a primary aim within the Agency for Healthcare Research and Quality's National Quality Strategy.[1]

Medication access refers to the ability of patients to receive the most appropriate medication for their medical condition and improve their overall quality of life. Programs such as Medicare Part D and the Affordable Care Act (ACA) have sought to improve the accessibility and affordability of health care and medications. Despite such efforts, however, the U.S.

population continues to face significant barriers to medication access. Recently, the Pharmacy Quality Alliance and National Pharmaceutical Council published a medication access framework, which identified the most common and relevant barriers according to published studies.[2] Major barriers included access to insurance, medication affordability, health literacy, and provider attitudes and beliefs.

Limited access to medications can have widespread consequences at the patient, health care system, and population health levels. Rising medication costs have been linked to medication underuse, which may be associated with excess morbidity and mortality; decreased functional status; decreased quality of life; and increased use of health care resources.[3-5] Nonadherence is estimated to cost the U.S. health care system $100–$289 billion annually.[4]

The American College of Clinical Pharmacy's 2020 Task Force on Medication Access was charged with producing a white paper on improving medication access in alignment with the organizational vision to drive positive changes in health care through advancing clinical pharmacist roles and responsibilities to optimize pharmacotherapy. To uphold this vision, medication access barriers must be addressed to ensure patients receive optimal pharmacotherapy for the prevention and treatment of disease. The main objective of this paper is to describe major barriers and highlight important considerations for clinical pharmacists to assist in preventing, navigating, and resolving medication access challenges at the policy and practice levels. Box 1 lists the barriers addressed in this paper.

2 | BARRIERS AND CHALLENGES WITH RECOMMENDATIONS

2.1 | Utilization Management

Utilization management (UM) strategies and criteria, though intended to promote the safe

and cost-effective use of medications, may create challenges to medication access. A drug formulary, or preferred drug list, outlines drug availability and coverage within a specific health care plan or organization. These lists are developed on the basis of medical evidence and the opinions of physicians, pharmacists, and other health care professionals with expertise in the diagnosis, treatment, and prevention of health conditions. The aim is to contain health care costs for both members and insurers while optimizing patients' therapeutic outcomes.

Drug formularies are primarily created and maintained by the pharmacy and therapeutics (P&T) committees of individual pharmacy benefit managers (PBMs). PBMs can aggregate multiple insurers' members to form large networks and negotiate discounts and rebates with pharmaceutical companies, with those savings intended to be passed on to the beneficiary. However, the lack of transparency in this process results in the potential that negotiated savings are retained by PBMs rather than passed on to beneficiaries. This has led to initiatives for increased transparency and accountability in PBM practices for prescription drug pricing.[6]

In addition, there are initiatives to include transparent economic analyses in published clinical guidelines, thus raising awareness of drug costs and integrating relative value into decision-making. In general, drug costs for economic analyses are based on average wholesale price and National Average Drug Acquisition Cost, not the out-of-pocket cost the patient will pay at the pharmacy. The American College of Cardiology (ACC) and the American Heart Association (AHA) published a statement in 2014 that they would incorporate cost-effectiveness assessments into recommendations by assigning a "level of value."[7] The 2018 ACC/AHA guidelines on managing blood cholesterol define high-value interventions (less than $50,000 per quality-adjusted life-year [QALY] gained) as those that improve clinical and humanistic outcomes at a reasonable cost.[8] Care that is at a high cost for a lesser clinical and humanistic

benefit is considered low value (more than $150,000 per QALY gained). As one example, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors were categorized as low value by the 2018 guidelines. Level of assessment values for PCSK9 inhibitors and analyses of the patient subgroups most likely to benefit may further increase access to these medications.[9] Inclusion of economic and value analyses in major clinical guidelines may help PBMs place high-value medications within preferred tiers and expand access to medications that provide optimal clinical outcomes for the lowest cost. Currently, health services are largely separated from drug costs; however, linking the two and incentivizing providers to prescribe high-value medications would improve the quality of prescribing.[10] Value-based insurance design improves adherence and lowers out-of-pocket spending for drugs without significantly changing overall health care spending for patients or payers.[11]

Ideally, formulary and benefits decisions should be based on the most up-to-date clinical evidence. However, the lag time required to review the evidence, develop criteria, and secure contracts with drug manufacturers may result in the publication of outdated formularies. In addition, clinical guideline updates are not synchronized, further expanding discrepancies between clinical guideline recommendations and medication formularies. For example, the Global Initiative for Chronic Obstructive Lung Disease guidelines are published yearly. However, if the guidelines are published after the formulary development process has begun, the most recent guidelines and associated literature will not be incorporated. The transition to "living guidelines" helps reduce the lag time because these guidelines are updated real time as new literature and practice recommendations become available. For example, the American Diabetes Association Standards of Medical Care in Diabetes are now updated as new evidence becomes available. This allows for the most current clinical practice recommendations to be available at

all times during formulary development and revision.

PBMs often use a tier system for formulary development. Tiers dictate the coverage level for a specific drug on the basis of cost and evidence-based primary literature or clinical guidelines. A PBM P&T committee may develop additional criteria including step therapy (ST) requirements or a prior authorization (PA) process to further guide medication use.[12] Formularies may also employ quantity or days' supply limits. Finally, some drugs may be excluded from a formulary and thereby not covered under any circumstances.

The consequences of UM are important to consider from both the patient's and the provider's perspective. Delays in coverage determination or PA can result in turnaround times of up to 5 business days.[13] Under Medicare Part D, the approval or denial determination must be made within 72 hours, or 24 hours for submissions that are marked urgent or expedited. Although this is a federal mandate that provides consistency from state to state, individual state payers may have different turnaround requirements for initial coverage determinations or after an appeal.[14]

Another consideration is the added time and resources devoted to navigating the UM criteria and, if necessary, completing the PA process. This process includes gathering and submitting documentation, following up on the payer's decision, and appealing requests that are denied.[14] When health systems do not have resources and processes in place to efficiently navigate the UM criteria for individual health plans, further delays may result. Engaging pharmacy technicians and other appropriately trained support staff improves the efficiency of the PA completion process and primary adherence to the prescribed therapy.[14]

Significant variations in UM criteria among payers can also create a barrier to medication access. UM criteria and strategies may change over time in accordance with drug costs and PBM

contracts. Differences may affect patients transitioning between health plans if a chronic medication is excluded or subject to different criteria under the new plan.[15] Patients are also affected when new plans do not have access to historical claims data for the purpose of ensuring ST requirements are met. Some states have implemented legislation to restrict the requirement for ST if a medication was previously covered by another health plan.

In some cases, payers may limit the prescribing of high-cost medications to specialists.[16] Patients residing in a geographic area with limited or no access to specialists may experience treatment delays or the inability to access appropriate treatment. Payers may require submission of extensive documentation that PA criteria have been met (e.g., disease severity scores, failure of alternative treatment for a required duration, intolerance of generic or biosimilar medications, and genetic or biomarker test results). If required information is missing or the provider is unaware of the need to submit documentation, requests are denied, and subsequent delays in care may result. PA and ST requirements as UM tools can negatively affect medication adherence.[17] Many patients do not pursue coverage when an initial denial occurs, even when the use is considered clinically appropriate.

Another barrier is health care provider access to patient-specific formulary information. Formulary information can help providers select the most appropriate agent within a medication class, depending on patient-specific factors. Navigating online formularies is time-consuming and requires that providers have accurate drug plan information and working knowledge of UM tools in order to identify the most up-to-date information. Real-time benefit tools (RTBTs) aim to provide prescribers with medication pricing and preferred alternatives at the point of prescribing. These tools facilitate shared decision-making with patients regarding the out-of-pocket costs and affordability of the treatment regimen and may prevent delays in medication

access. Currently, few electronic health record (EHR) systems have comprehensive patient-specific benefits information incorporated into their prescribing software. The Centers for Medicare & Medicaid Services recently finalized a rule requiring Medicare Part D plan sponsors to implement at least one RTBT that integrates with one or more prescribers' EHR systems by January 1, 2021.[18] However, although this rule is intended to improve medication access at the point of prescribing, there is concern over standardization and interoperability across various insurance plans and EHR vendors.[19] In addition, the costs associated with implementing high-quality RTBTs may limit their usefulness. For RTBTs to be useful, they must be cost-efficient, accurate, and timely and avoid negative impacts on workflow.[10,19,20]

The barriers to medication access created by UM practices and procedures can result in delays or gaps in therapy, potentially leading to increased use of other, more costly health care interventions.[21] Table 1 lists recommendations for addressing UM barriers.

2.2 | Specialty Pharmacy and Risk Evaluation and Mitigation Strategies

Specialty medications are high-cost prescription medications used to treat complex chronic conditions, such as cancer or immune disorders. Specialty medications contributed to 50% of all prescription costs in 2018, despite accounting for only 2.2% of the total medications dispensed.[22] Self-administered specialty medications processed through pharmacy benefits are provided through mail-order specialty pharmacies, though some will ship to a local affiliated pharmacy for pickup. The specialty distribution model was intended to maintain a higher level of control of the drug supply, provide expanded services to patients, and reduce costs associated with the supply chain; however, these intricacies have introduced a variety of access barriers.[23]

In general, “specialty tiers” have the highest copay or coinsurance, and patients may reach their out-of-pocket maximum from a single prescription fill in some cases. Payers have preferred specialty pharmacy networks, which may be difficult for prescribers and patients to determine. A patient may be responsible for an even higher copay if the medication is obtained from a nonpreferred pharmacy. Increased cost sharing has been associated with specialty medication nonadherence.[24] In one study, pharmacists integrated into specialty clinics at an academic medical center improved patient medication adherence as well as time to PA approval and specialty medication initiation through coordination of financial support.[25] Specialty hubs, or intermediaries focused on access and adherence to a specific drug or management of a disease, may aid in case management and provide support services to patients.[23]

Medications administered by a health care provider in the outpatient setting vary in cost to payers depending on the contracted percentage of charge rates, which can be significant in the setting of high-dollar specialty medications. Payers often limit their coverage to sites with favorable contract rates, such as home infusion or physician offices, and disallow coverage at hospital infusion centers. This coverage limitation can affect access to care because it dictates where a patient must travel to receive the medication. Not all patients qualify to receive medications in alternative settings and must undergo review for exception if they are to receive care at a nonpreferred site. This can disrupt access if the patient is required to switch to an alternative site that is unfamiliar.

Specialty and even some non-specialty medications are subject to additional access barriers in the form of Risk Evaluation and Mitigation Strategies (REMS). These strategies include a system of elements to ensure safe use, which may include actions for prescribers, patients, pharmacies, health care settings, infusion centers, and wholesalers to prevent, monitor,

and manage the risks associated with medication use.[26] One or more of the entities may be required to complete registration, certification, and training before the medication is prescribed, dispensed, or administered to a patient. Prescribers may need to submit documentation of patient information before enrolling in a program (e.g., laboratory results, immunization history), and patients may need to comply with education and agree to monitor for signs and symptoms of a known safety concern before enrollment is complete. Pharmacies, health care settings, and infusion centers may need to undergo site certification to assess whether prescribers and patients have completed registration requirements. Wholesalers may only be allowed to distribute to participating pharmacies or health care settings; also, they may be required to maintain adequate records for distribution and audits. The steps of individual REMS programs may vary, be cumbersome to complete, and result in delays in medication access if information is missing from one or more of the participating individuals. In addition, it may be difficult to remain knowledgeable about all medications with a REMS program. In some cases, those required to adhere to a REMS program may avoid the medication, thus affecting its access. Table 2 lists recommendations for addressing specialty pharmacy and REMS barriers.

2.3 | Affordability and Patient Out-of-pocket Costs

Prescription cost-sharing mechanisms, such as deductibles, tiered copay benefit structures, coinsurance, coverage gaps, and benefit limits, are intended to promote the appropriate and cost-effective use of medications. Although these cost-sharing methods are designed to reduce the use of unnecessary or expensive medications by incentivizing the use of lower-cost drugs, high copayments and cumulative prescription costs continue to limit their affordability, leading to patient nonadherence. A 2017 *Consumer Reports* survey found that 14%

of patients who experience increases in out-of-pocket costs stop filling their prescription medications.[27] Another survey found that almost 8% of adults do not take their medications as prescribed because of cost.[28] This varied by type of insurance coverage, with uninsured patients reporting the highest rates of cost-related nonadherence (14%); nevertheless, patients with Medicaid prescription coverage (10.4%) and private insurance coverage (6.1%) also reported nonadherence because of out-of-pocket costs.

In recent years, the United States enacted legislation to combat rising health care costs and increase the proportion of Americans with health insurance. Two significant bills, Medicare Part D and the ACA, have decreased the number of patients without prescription drug coverage; however, these reforms have resulted in a higher percentage of patients reporting financial challenges because of increased out-of-pocket prescription costs (35% in 2015 vs. 31% in 2001).[29] Even higher out-of-pocket costs are incurred during the annual Medicare coverage gap (i.e., donut hole) once the initial limit is met and before catastrophic coverage begins. Beneficiaries relying solely on Part D coverage are more likely to discontinue medications during the coverage gap than are patients with supplemental "Medigap" coverage.[30,31] Annual limits on Medicare Advantage prescription drug plans negatively affect patient adherence and result in poorer control of chronic diseases, including hypertension, hyperlipidemia, and diabetes, compared with supplemental coverage.[32]

Although the financial impact of prescription drug costs is far-reaching, low-income patients are more likely to report cost-related medication nonadherence than are patients with higher incomes.[28] Even modest copayments of $1–$5 in the low-income population have led to reductions in the use of necessary medications. Moreover, reduced access to prescriptions in the low-income population has led to more frequent emergency department visits and worse health

outcomes.[33,34]

Various factors contribute to the high cost of drugs in the United States; however, the primary driver is branded products with patent protection. Branded drugs represent 10% of prescriptions but account for 70% of all drug spending in the United States.[10] Competition from generic products consistently and substantially reduces the costs of drugs. However, manufacturers often delay the entry of generic products onto the market using "product life-cycle management" strategies to extend market exclusivity. For example, drug properties like salt moieties or methods of administration can be patented and then marketed as a new branded product. In addition, unlike in most other countries, U.S. drug manufacturers have the unique ability to set their own prices for prescription drugs. Other contributors to high drug prices include a lack of transparency with how rebates and discounts are applied when offered to PBMs, off-patent sole-source medications, drug shortages, regulatory barriers, marketing costs (i.e., direct-to-consumer advertising, meals for prescribers), lack of cost-effectiveness data to support the clinical value of a new drug product, and health plan benefit structures.[10]

Drug prices are the target of many legislative initiatives at both the state and federal levels. These have largely focused on some form of legalizing drug reimportation from foreign countries, improving price transparency, allowing or mandating drug price negotiation with manufacturers, or incentivizing generic competition. Other strategies are focused on enhancing prescription drug coverage. States that expanded Medicaid under the ACA had a 19% increase in prescription use compared with states that did not expand. Increases were largest for diabetes medications, contraceptives, and cardiovascular drugs.[35] The most recent significant piece of legislation, the Patient Right to Know Drug Prices Act, reverses the "gag clause" prohibiting pharmacists from informing patients when cash prescription prices are less expensive than

insurance copays. Table 3 lists recommendations for addressing access barriers related to medication affordability and out-of-pocket costs.

2.4 | Patient Assistance Programs

Patient assistance programs (PAPs) are designed to provide patients having specific financial needs with access to brand-name drugs at reduced or no cost. This can increase medication access for eligible patients. Many pharmaceutical company programs offer free supplies of medications for a defined period, often 1 year, which may be renewable.[36] Pharmaceutical companies determine the income limits for program eligibility, often according to the Federal Poverty Guidelines or some percentage of this. Eligibility is program-specific and may vary greatly between individual company sponsors. Some programs use tiered eligibility, on the basis of income thresholds, to determine the level of assistance available. Many uninsured patients use these programs, with the annual cost to the industry estimated at $4 billion, though this figure is carefully guarded.[37]

There are several types of PAPs, each with a different structure. Typically, PAPs provide assistance in one of four ways: (1) reimbursement for the cost of the medication or a percentage of the cost upon submission of a paid receipt; (2) discount coupons redeemed at the pharmacy or medical supply company; (3) direct discounts offered by programs affiliated with a pharmacy and applied at purchase; or (4) free products shipped directly to the program participant. There are several websites and smartphone applications to help patients and providers locate available PAPs and other potential benefit programs. Table 4 lists selected examples.

However, controversy remains about the overall benefits of PAPs because of eligibility limitations and other barriers. Eligibility requirements for PAPs often lack transparency and may

require a tedious application process to continue receiving assistance.[36,38] Many of the programs require proof of U.S. citizenship and are not an option for undocumented patients.[39] In addition, the time and effort invested in obtaining approval for eligible patients may result in a financial burden to the pharmacy or health care system.[40] Despite these limitations and barriers, several centralized PAPs that use pharmacy technicians or other support staff have demonstrated significant financial benefit for both health care institutions and their patients and can help reduce the clinical workflow burden.[40,41] Table 5 lists recommendations for addressing PAP barriers.

2.5 | Over-the-counter vs. Prescription Drugs

The "switching" of medications from prescription to over-the-counter (OTC) status, according to scientific review, has provided patients with convenient and cost-effective access to a wide range of drug products. Although OTC products tend to cost less than prescription products, this is not necessarily true for patent-protected products until market exclusivity expires. The most common PBM policy response to OTC switches is either to discontinue drug coverage or encourage purchase of the OTC product by raising copayments for the equivalent prescription product (second- or third-tier coverage).[42] This often shifts the burden of drug cost to the patient. Typically, Medicare Part D and private employer-based prescription coverage do not cover the cost of OTC medications. With few exceptions (e.g., prenatal vitamins, tobacco cessation products), state Medicaid plans are not required to cover OTC products, and coverage can vary widely. OTC medications are generally eligible for reimbursement within health care plan flexible spending accounts but not employer-sponsored health care savings accounts.

The economic impact of prescription-to-OTC switches has not been widely studied. A

2013 review analyzed the results of 12 studies that used varied analytic models and included several drug categories.[43] Seventy-five percent of the models predicted cost savings for both payers and patients. Cost savings were primarily derived from lower drug prices and fewer physician visits. For second-generation antihistamines, savings included the avoidance of adverse events because of the improved safety profile over the first-generation antihistamines that were previously available OTC.[44] Most studies did not address the potential costs associated with drug misuse, adverse drug events, or suboptimal therapy.

Although the FDA has approved many prescription-to-OTC switches, only three first-in-class switches have occurred in the past decade.[45] In contrast, many regulatory agencies outside the United States have taken a more aggressive approach to OTC switches, including the creation of a behind-the-counter (BTC) category of medications available from an authorized health professional without a prescription.[46] The U.S. Government Accountability Office has twice studied the benefits and costs of a BTC category of medications. The first report, published in 1995, concluded that evidence was lacking to support that an expanded medication class improved public health and that pharmacists had the ability and desire to manage this service.[47] The most recent report, published in 2009, compared the OTC availability of medications in the United States with their availability in the United Kingdom, Australia, the Netherlands, and Italy.[46] Although the report acknowledged that the United States requires a prescription for more of the 86 studied drugs than the other countries, it also noted that the number of medications available strictly OTC was higher in the United States. The report cited concerns that a BTC medication class would limit the general approval of OTC medications, that pharmacies might lack the infrastructure to provide the necessary services, and that out-of-pocket costs to the patient might increase unless BTC drugs were covered by insurance. A 2011 survey showed that

pharmacy and consumer organizations generally support BTC medication access, whereas physician organizations and the pharmaceutical industry are generally opposed.[48]

In 2018, the FDA published draft guidance for the pharmaceutical industry titled "Innovative Approaches for Nonprescription Drug Products" to facilitate approval of a wider range of OTC products, including products for the treatment of chronic conditions.[49] The FDA proposed additional labeling, interactive media, and drug selection tools to address the limitations of drug fact labeling. The document also recommended self-selection studies to evaluate patient ability to apply drug fact labeling information. Of interest, this document did not acknowledge or explore the pharmacist's role and responsibility in assisting patients in the appropriate selection of OTC products. Several pharmacy organizations, including the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association, provided responses advocating for the pharmacist's role.[50,51]

The privatized structure of the U.S. health care system and the wide variety of stakeholders are likely major contributors to the lack of progress regarding improving access to OTC drugs in the United States. Another factor is the failure of U.S. regulatory agencies to recognize pharmacists as highly trained and skilled health care providers. Finally, there is a lack of scientific data supporting economic and patient outcome benefits of a third BTC class of drugs. Although expanding the availability of OTC drugs can improve patient access to medications, drug cost and lack of insurance coverage may offset this for some patients. Table 6 lists recommendations for addressing barriers related to OTC medications.

2.6 | Manufacturer Shortages

Drug product shortages are a significant barrier to medication access and pose a major

drug safety concern. According to ASHP and the University of Utah Drug Information Service, there were 306 active drug shortages and 146 new drug shortages in 2018.[52] Shortages may be the result of manufacturing quality problems, shortages of raw materials, regulatory issues, natural disasters or pandemics, supply chain disturbances, inventory practices, or lack of economic incentives.[53] Manufacturers are required to report interruptions in drug production to the FDA; however, they are not obligated to report the cause of the supply disruption or the expected time interval for resolving the problem. Drug classes commonly implicated include central nervous system and cardiovascular medications, antimicrobials, electrolytes and fluids, and chemotherapy agents.[53] Generic injectable products are particularly susceptible because of production complexity and tight profit margins, resulting in a limited number of suppliers.[46] Accordingly, it is often difficult to quickly resolve supply disruptions.

Managing drug shortages is complex. The challenge is to provide timely, safe, therapeutically equivalent, and cost-effective drug therapy. Substitution of alternative agents is common; however, these agents may be less effective or have a higher risk of adverse drug events and medication errors. Changes in how a product is ordered, prepared, or dispensed may also contribute to errors. Pharmacies may be forced to acquire drug products off-contract from unauthorized secondary distributors (i.e., gray market) or from compounding pharmacies, often at significantly inflated prices.[54] Drug products from these nontraditional sources may present risks to patients because of their questionable quality and/or unknown origin. Secondary shortages of alternative agents may be the result of unexpected demand or stockpiling. In some instances, no other suitable alternative exists. A study of oncology drugs found that shortages could lead to disruptions in treatment schedules, dose reductions to conserve remaining supply, use of less effective regimens, or missed treatments.[55]

Shortages of medications used to treat chronic diseases may require patients to accept an alternative treatment, obtain the medication through another source, ration the remaining supply, or go without treatment. Studies have also linked drug shortages to increased out-of-pocket costs.[56] These costs are attributed to switching to a more expensive brand or drug alternative and traveling farther or between multiple pharmacies to acquire the drug product.

Evidence linking drug shortages to negative patient outcomes is limited to retrospective data from patient records or self-reported anecdotes from clinician surveys. Therefore, results from these studies must be interpreted with caution because the risks of incomplete documentation and recall bias are high. Negative outcomes that have been reported as a result of drug shortages include adverse drug reactions, medication errors, drug-resistant bacterial mutations, mechanical ventilation, increased seizure frequency, new or prolonged hospitalizations, and death.[56]

ASHP has published guidelines on managing drug product shortages that focus on identifying an interdisciplinary team of key stakeholders to plan for and respond to drug shortages.[53] The drug shortage team is assigned responsibility for monitoring and gathering data; approving and procuring alternatives; modifying storage, preparation, and dispensing procedures as needed; making conservation and rationing decisions; implementing technology changes; and communicating changes to all staff. The guidelines recommend that an operational and therapeutic assessment be performed to evaluate potential impact once a drug shortage is identified. The assessment is based on shortage details, patient population affected, remaining supply availability, historical use, determination of appropriate alternatives, and estimates of alternative supplies. For severe shortages, ASHP recommends including a threat analysis for a potential delay or cancellation of surgical procedures and other treatments, including a risk

mitigation strategy for patients who are unable to be treated. This may include delaying treatments for some patients or transferring patients to facilities with remaining resources.

ASHP, together with other health care organizations, has proposed various regulatory, legislative, and marketplace actions to address ongoing shortages of critical medications in the United States.[57] ASHP also suggests developing a list of drugs critical for emergency response and prioritizing these drugs for contingency or redundant production plans and transparency of raw material sources. Other high-priority actions include incentivizing increased production of vulnerable drugs by streamlining regulations, harmonizing global regulatory requirements, and enacting legislation that requires manufacturers to proactively notify the FDA of any changes in production that may lead to a shortage. Many of these provisions were recently enacted with the Coronavirus Aid, Relief, and Economic Security Act.[58] Table 7 lists recommendations to address manufacturer shortages.

2.7 | Health Disparities and Social Determinants of Health

Medication access is affected by a wide variety of environmental factors and social determinants of health. Major barriers include health literacy, citizen status, cultural influences and personal beliefs, and access to pharmacies.

Health literacy is defined as the degree to which an individual can obtain, communicate, process, and understand basic health information and services in order to make appropriate health decisions.[59] Health literacy has been identified as an integral component of the social determinants of health.[60] Health literacy is multifaceted and often influenced by cultural barriers, ethnicity and race, education, and overall health status.[61,62] Low health literacy and language barriers may contribute to medication nonadherence and inability to access medications if

patients do not understand the need for medications and preventive care or cannot successfully navigate the health care system.[63,64] A 2006 study of health literacy found that only 12% of adults were "proficient," whereas 36% were described as either "basic" or "below basic."[65] Lower average health literacy was associated with advanced age (65 and older) and adults who spoke languages other than English before starting school.[65] However, even individuals with normal to high overall literacy may be unable to comprehend and interpret written health-related information or instructions.[62] Health care providers must take an active role in identifying low health literacy and improving patient communication. Several standardized tools exist (e.g., REALM-R, Newest Vital Sign) that can be administered in a clinical setting in under 3 minutes.[66] Interventions to address low health literacy include provision of easy-to-understand written materials (fifth-grade reading level and below), use of pictographs, and use of the "teach-back" method.[66,67]

Undocumented patients face unique barriers to medication access such as limited access to public assistance, lack of employer-sponsored insurance plans, and fear of deportation. With lack of insurance and distrust of the U.S. health care system, undocumented immigrants tend to receive fewer preventive care interventions and screenings and reduced access to treatment measures.[39,68,69] When undocumented immigrants do receive care, it typically comes from emergency Medicaid, which offers minimal coverage for medications, or safety net clinics and charitable services with potentially limited pharmacy formularies.[70,71] Immigrants are more likely to obtain medications outside the United States, share medications with family and community members, use complementary and alternative medicine, and participate in alternative healing practices. Some immigrant communities have resorted to creating alternative pharmacies in flea markets and selling "leftover" prescription medications and medications obtained from

bordering countries.[72]

Access to medication requires access to a pharmacy. It is estimated that up to 100 million Americans may be living in *pharmacy deserts*.[73] This term is used to describe areas with relatively poor pharmacy access, which leads to a limited ability to acquire prescription medications. Medically underserved areas and minority populations are often the most affected, with fewer pharmacies offering around-the-clock access, lower rates of home delivery in areas with higher percentages of patients with disabilities, and fewer pharmacies located in non–English-speaking communities.[74]

Urban pharmacy deserts disproportionately affect minority communities. One study identified that more than 1 million people in Chicago, Illinois, reside in pharmacy deserts and that this number is increasing because of a growing number of pharmacy closures.[73,75] Another study conducted in Baton Rouge, Louisiana, found more pharmacies located in densely populated minority areas; however, these areas still had lower overall access because of the large population served.[76]

Because access to rural medical care is hindered by physician shortages, hospital closures, and transportation challenges, pharmacies are ideally positioned to provide a regular point of contact between patients and the health care system.[77] Unfortunately, rural communities have been disproportionately affected by the increase in independent pharmacy closures (16.1%, 2003–2018).[78] This can partly be attributed to the initiation of Medicare Part D in 2006, which has lower reimbursement rates.[79] When analyzing pharmacy deserts in Pennsylvania, every county in the state had a pharmacy desert, with most deserts found in rural communities.[80] Pharmacy deserts in rural areas further exacerbate the challenges already faced by these communities related to access to care and require attention.

Table 8 lists recommendations to address health disparities and social determinants.

2.8 | Pharmacists' Knowledge, Attitudes, and Confidence

Barriers to medication access may be the result of conflict between a pharmacist's personal beliefs and values and the intended purpose of a medication. The dispensing of oral contraception may conflict with religious or personal views on sexuality and fetal rights. In one study, pharmacists were apprehensive about dispensing medical abortifacients and emergency contraception, and some believed they should have the right to refuse to dispense medications when used for indications that opposed their moral beliefs.[81] Although a 2019 review seemed to show improving access to emergency contraception, it was still unavailable in around 31% of encounters. In addition, pharmacy staff provided inaccurate information regarding federal regulations, drug mechanism, and drug administration, which contributed to reduced access. Personal objections from pharmacy staff accounted for around 9% of encounters, and store policy counted for an additional 10%. Inadequate stocking of emergency contraceptives also accounted for a significant lack of access (21%).[82] However, even states with widely stocked emergency contraception show barriers to access. Despite high rates of availability, a Colorado study showed limitations to rates of access to emergency contraception because of BTC status and proof-of-age requirements.[83] Other commonly refused medication classes include erectile dysfunction drugs, infertility drugs, and treatments for medically assisted suicide.[81] There is also reluctance to treat patients with opioid and other substance use disorders because of stigmatization by prescribers and pharmacists. Attitudes toward substance use disorders are also reflected in pharmacists' willingness to provide nonprescription access to syringes.[84] The perceived conflict between preventing infections and facilitating illegal drug use creates mixed

feelings among pharmacists; however, support for nonprescription sales generally increases when laws support the practice.[85]

Another barrier is associated with the increasing responsibility and liability of expanded pharmacy practice. Some pharmacists may lack the knowledge or confidence to perform certain tasks or engage in difficult discussions. Data analyses show that pharmacists may feel uncomfortable initiating a discussion about human papillomavirus vaccination with parents of minors or feel they lack adequate educational materials to share.[86] A study assessing pharmacists' perceptions of readiness to prescribe hormonal contraception found that many pharmacists felt they needed more training on switching between hormonal contraceptive products and selecting a regimen on the basis of the patient's personal circumstances.[87]

Despite recent measures to enhance access to naloxone as a harm reduction strategy (e.g., pharmacist prescribing protocols, standing orders, nonprescription access), the dispensing of naloxone has not been widely optimized.[88] Small, emerging studies exploring pharmacists' attitudes toward dispensing are mixed.[89-91] One study found that naloxone is inconsistently offered to patients receiving higher opioid doses.[92] Other factors that prevent pharmacists from becoming engaged in naloxone dispensing include drug cost, patient refusal, insurance barriers, difficulty determining which patients are at risk of opioid overdose, and keeping naloxone stocked.[90-95]

The increased liability associated with opioid dispensing also creates a barrier. Pharmacists have a responsibility corresponding to that of prescribers to ensure prescriptions have a legitimate medical need. Pharmacists must clear "red flags" that raise suspicion before they dispense medication in an effort to prevent opioid misuse and/or abuse.[96,97] Pharmacists and pharmacies have been the target of litigation in opioid-related deaths.[98,99] The fear of liability

related to opioids has resulted in some pharmacies limiting their opioid inventory or refusing to accept new opioid prescriptions.[100,101] Restrictive policies may also be the result of legal settlements.[102-104] Limited access to opioids can negatively affect patients who require opioids for legitimate purposes and patients who are being treated for substance use disorders. Table 9 lists recommendations for addressing barriers related to pharmacist knowledge, attitudes, and confidence.

3 | SUMMARY

Medication access is a critical factor in optimizing patient health care outcomes. Potential barriers to medication access are widespread and complex. Pharmacists are in a unique position to improve medication access through enhancing clinical practice and advocating for policy changes.

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Box 1. Barriers to Medication Access
Utilization management practices
Specialty pharmacy requirements
Risk Evaluation and Mitigation Strategies (REMS)
Patient out-of-pocket costs
Patient assistance program requirements
Over-the-counter drug status
Manufacturer shortages
Health disparities
Health care provider attitudes

Table 1. UM Recommendations

Policy Recommendations: ● Support legislation to facilitate continuation of therapy and insurance coverage for patients transitioning between payers ● Recommend timely revision of UM criteria as new evidence becomes available ● Recommend inclusion of clinical pharmacists on payer clinical review boards to assist with development of UM criteria
Practice Recommendations: ● Recommend transparent economic analyses in clinical guidelines for selected medications ● Recommend integration of drug costs into value-based reimbursement models to engage providers in cost-effective prescribing ● Support implementation and use of "living guidelines," which are updated as new literature becomes available ● Recommend the use of electronic PA processes to speed turnaround time and improve communication ● Designate resources and establish processes to efficiently navigate the UM criteria for individual health plans by appropriately trained support staff ● Improve provider access to medication formularies, UM criteria, and prescription drug costs with the assistance of accurate and efficient RTBTs

PA = prior authorization; RTBT = real-time benefit tool; UM = utilization management.

Table 2. Specialty Pharmacy and REMS Recommendations

Policy Recommendations: ● Support revision of site-of-care program policies to allow the use of hospital outpatient settings if patients cannot receive treatment at home or travel to alternative sites ● Recommend outcomes-based studies to establish the effectiveness of REMS programs and justify the need for continued use ● Recommend the inclusion of all stakeholders in REMS program development to facilitate operationalization and avoid unintentional barriers
Practice Recommendations: ● Recommend intermediaries (e.g., clinical pharmacists, hub case managers) to help patients navigate the complexity of specialty medication access and distribution

REMS = Risk Evaluation and Mitigation Strategies.

Table 3. Affordability and Out-of-pocket Cost Recommendations

Policy Recommendations:

- Support legislative initiatives aimed at controlling drug prices through transparency, increased competition, and price negotiation
- Support enhanced Medicare Part D coverage that minimizes the impact of coverage gaps and annual limits for beneficiaries
- Support Medicaid expansion in states not currently participating

Table 4. Selected PAP Websites and Tools

Program	**Description**
Medication Assistance Tool https://medicineassistancetool.org/	Free online database that helps low-income, uninsured patients get free or low-cost, brand-name medications through PAPs and drug discount cards
NeedyMeds https://www.needymeds.org/	Free online database that helps low-income, uninsured patients get free or low-cost, brand-name medications through PAPs, state assistance, drug discount programs, and free or low-cost medical care Site also has information on thousands of programs to help consumers through the application process
Rx Assist Patient Assistance Program Center https://www.rxassist.org/	Free online database that helps low-income, uninsured patients get free or low-cost, brand-name medications through PAPs and drug distance cards
National Council on Aging https://www.ncoa.org/centerforbenefits/	Website offering information about health care, medication, and general assistance programs for low-income older adults and people with disabilities (Medicare Part D Extra Help/Low-Income Subsidy, Medicare Savings Programs, Medicaid, SNAP, Low-Income Home Energy Assistance Program, SSI, State Pharmaceutical Assistance Programs, local

	transportation assistance, tax relief, etc.)
Rx Outreach: The Nonprofit Pharmacy https://rxoutreach.org/	Mail-order pharmacy for patients with little or no health insurance coverage at ≤ 400% FPL. Patients must provide documentation of eligibility. Patients pay listed prices for medications, with some provided at no cost
GoodRx https://www.goodrx.com/	Website and phone app for locating the lowest prices and coupon/discounts for medications at nearby pharmacies. There have been recent concerns regarding GoodRx and data privacy[†,‡]
ScriptSave WellRx https://www.wellrx.com/	Website and phone app for locating the lowest prices and coupon/discounts for medications at nearby pharmacies

[†]Consumer Reports. GoodRx saves money on meds – it also shares data with Google, Facebook, and others. Available from www.consumerreports.org/health-privacy/goodrx-shares-users-health-data-with-google-facebook-others/. Accessed November 15, 2020.

[‡]GoodRx. GoodRx and data privacy. Available from www.goodrx.com/blog/goodrx-data-privacy/. Accessed November 15, 2020.

FPL = Federal Poverty Level; PAP = patient assistance program.

Table 5. PAP Recommendations

Practice Recommendations:
● Recommend that pharmacies and health care organizations implement centralized workflow processes for PAP and incorporate technical personnel ● Provide educational resources to the public on sources of medication assistance

Table 6. OTC vs. Prescription Drug Recommendations

Policy Recommendations:

- Recommend updated analysis of economic and patient outcomes related to OTC switches by a task force composed of relevant stakeholders, including pharmacists
- Provide funding for pilot projects to study economic and patient outcomes related to creation of a behind-the-counter drug category
- Support expanded coverage options for OTC medications

OTC = over the counter.

Table 7. Manufacturer Shortage Recommendations

Policy Recommendations: ● Support enhanced FDA communication with health care organizations and pharmacies during supply disruptions ● Support enhanced FDA authority to incentivize production of vulnerable medications, and implement controlled importation to meet demand when shortages exist
Practice Recommendations: ● Support practice standards establishing drug shortage teams within health care organizations ● Recommend development of collaborative management strategies among health care organizations to ensure equitable allocation of limited resources during critical shortages

Table 8. Health Disparities and Social Determinant Recommendations

Policy Recommendations: ● Develop a position or policy statement by pharmacy organizations outlining the commitment to serve undocumented patients ● Advocate for the expansion of clinics and pharmacies that provide access to affordable health care services and medication regardless of a patient's documented status
Practice Recommendations: ● Incorporate formal assessments of health literacy into pharmacy practice sites ● Use methods to overcome low health literacy, including written patient literature that does not exceed a fifth-grade reading level and that includes pictographs ● Provide pharmacist continuing education in cultural competency and health literacy ● Involve pharmacists in expansion of the patient safety net by enhancing access to needed services such as vaccinations, health screenings, and management of chronic diseases ● Increase the availability of medication delivery services, including use of mail-order pharmacies, to increase medication access for older patients and patients with disabilities

Table 9. Pharmacists' Knowledge, Attitudes, and Confidence Recommendations

Policy Recommendations: ● Advocate for regulations that protect patient access to care and respect pharmacists' personal and professional rights ● Advocate for reduced barriers for prescribing and dispensing of naloxone by pharmacists
Practice Recommendations: ● Develop plans to ensure patients are offered alternatives when personal values conflict with medication dispensing ● Provide continuing education and tools to enhance pharmacists' level of cultural competence ● Provide education and training on appropriate use of opioids and best practices for facilitating access for appropriate patients with pain and mitigating the risk of opioid misuse or abuse ● Enhance student pharmacist opportunities to practice communicating in uncomfortable situations and with diverse patient populations (broad definition of diverse) ● Enhance organizational training for pharmacists in accordance with scope of practice changes