



January 15, 2021

President-Elect Joseph R. Biden
Presidential Transition Headquarters
1401 Constitution Avenue NW
Washington, DC 20230

Dear Mr. President-elect,

On behalf of the Academy of Managed Care Pharmacy (AMCP), I congratulate you and Vice President-elect Kamala Harris on your historic victory. AMCP is the professional association leading the way to help patients get the medications they need at a cost they can afford. AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and economics to optimize medication benefit design and population health management, while helping patients access safe, cost-effective medications and other therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

As your administration prepares to take office on Jan. 20, AMCP looks forward to collaborating on the nation's response to the COVID-19 pandemic and on our members' priority issues. We welcome the opportunity to meet with the appropriate members of your transition team to share expertise and offer our members' perspective on urgent managed care pharmacy concerns. In the interim, we hope our recommendations will be helpful during transition planning. On behalf of our members, AMCP stands ready to assist your team in combatting COVID-19 and increasing patient access to affordable medicines, improving health outcomes, and ensuring health equity for all Americans.

Combatting COVID-19

AMCP, in partnership with representative organizations of America's pharmaceutical supply and payment chain, joined the Pharmaceutical Supply and Payment Chain (PSPC) Coalition with the singular principle that the private sector and state and federal governments must work together to facilitate Americans' reliable access to needed medications and preventatives, including vaccines, during the COVID-19 pandemic.

In October 2020, the PSPC Coalition released the [Guiding Principles for Safe and Efficacious COVID-19 Vaccine Development, Distribution, Allocation, and Mass Immunization](#), asserting that distribution must be guided by a well-coordinated national strategy aligned with existing state and local strategies for the distribution of routine vaccines. As a member of the PSPC Coalition, AMCP is committed to supporting a national strategy by amplifying public health messaging, directing patients to vaccination sites, and directly facilitating the development, distribution, and administration of the vaccine(s).

AMCP appreciates the funding for vaccine distribution efforts included in the Consolidated Appropriations Act of 2021 enacted in December. **AMCP further encourages you and your Administration to work closely with Congress to evaluate and respond to ongoing needs for supplemental funding to the Centers for Disease Control and Prevention (CDC), states, and other jurisdictions to cover operations related to the cost of planning, preparing for, distributing, facilitating administration of, and promoting awareness and education about COVID-19 vaccines.**

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Surveys by the Reagan-Udall Foundation for the U.S. Food and Drug Administration (FDA) [found](#) that health care professionals, including pharmacists, are the most trusted messengers to respond to concerns about the safety and efficacy of the COVID-19 vaccine. **AMCP encourages you and your Administration to continue to support collaboration between private sector stakeholders, the FDA and CDC, and state and other jurisdictions' public health leaders to amplify vaccine awareness and support mass immunization.**

The Rising Cost of Pharmaceuticals and Price Transparency

AMCP and our members join Americans across the country in their significant concern about the rising cost of pharmaceuticals, magnified by the COVID-19 pandemic. Costliness and high unemployment have resulted in health care being inaccessible for millions of American families and elected leaders must prioritize solving this crisis. **AMCP encourages the protection and support of managed care pharmacy tools, such as drug prior authorization and step therapy, that are essential for reducing drug prices while providing optimal care to patients.** AMCP will continue to work with elected officials and health care stakeholders to develop practical, informed, market-based solutions that make health care and prescription drugs more affordable and accessible to all Americans.

AMCP's actions promoting our three-point platform to address rising drug costs continue, despite the COVID-19 public health emergency (PHE): demonstrating the value of pharmacy outcomes; employing enhanced approaches, such as evidence-based clinical research, to coverage decisions; and fostering competition to lower costs. **AMCP urges you to support meaningful drug pricing transparency that gives patients drug pricing information that is timely, easy to access and understand, and facilitated by technology solutions.**

Most Favored Nation Model

AMCP and its members believe that a health care delivery system based on an open, competitive marketplace will provide the most value to patients and payers. We are concerned that the [Most Favored Nation \(MFN\) Model](#) introduced in Nov. 2020 is deeply anti-competitive. Requiring drug manufacturers to sell their products to Medicare at the lowest international price will likely lead to an increase in drug prices for commercial health plans, employers, and Americans, as manufacturers try to recoup lost revenue. Manufacturers would be forced to reduce spending on research, stifling innovation in the development of new medicines and related therapies.

AMCP and its members believe that competition incentivizes health plan investments that improve patient outcomes, leading to a higher quality of care across the continuum. Marketplace competition also drives the development of new utilization management and clinical evaluation tools and strategies that help minimize misuse of medication and reduce overall prescription drug spending. **AMCP supports the recent injunction issued in federal court that halts implementation of the MFN Model and urges you to refrain from implementing policies that deter competition and to prioritize preservation of marketplace competitiveness.**

Rebate Rule

The final rebate rule ([Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees](#)) eliminating the safe harbor of the anti-kickback statute for rebates negotiated between Part D plans and drug manufacturers is concerning to AMCP and its members given the resulting increase in Medicare Part D beneficiary premiums and taxpayer costs. Ninety percent of Medicare Part D beneficiaries will pay more under the rebate rule: if premiums increase as much as the 25% suggested by the [Office of the Actuary \(OACT\)](#), the average monthly premium in 2020 would have increased from \$38.13 to \$47.66, with a proportionate increase in 2021 and future years. This

would mark the largest average premium increase in the history of the program. Further, because Part D is voluntary, it could destabilize the program if higher premiums cause healthier beneficiaries to drop coverage or never enroll.

According to the [Congressional Budget Office](#), the rebate rule will cost taxpayers \$177 billion. [OACT](#) estimated the cost to be as high as \$196 billion over 10 years, and [Avalere Health](#) estimated the cost to taxpayers to be \$400 billion over the same time. **Given these exorbitant costs to beneficiaries and taxpayers, AMCP strongly urges you and your Administration to take the necessary steps to prevent the rebate rule from taking effect and destabilizing the Medicare Part D program.**

Shifting Managed Care Pharmacy from Fee-For-Service to Value-Based Care

AMCP and our members support the shift of managed care pharmacy from fee-for-service to value-based care models where appropriate, particularly for high-cost drugs. **We encourage the removal of barriers to the expansion of value-based care models for high-cost drugs through the development of clear metrics to transfer payment for pharmaceuticals and other treatments to value-based contracts, the facilitation of data sharing and interoperability of electronic health records to evaluate outcomes while ensuring privacy protections for patients, and supporting increased patient access to pharmacists and team-based integrated care.**

Pre-Approval Information Exchange

Pre-Approval Information Exchange (PIE), a concept designed to improve patient access to emerging pharmaceuticals and devices, is a crucial effort to ensure payers have access to critical information and research-based evidence to provide timely coverage decisions and patient access when new therapies come to market. PIE allows manufacturers and health care decision-makers (HCDMs) — defined as any health care personnel, committee, or organization that uses an evidence-based process for making health care coverage and reimbursement decisions for patient populations, including, but not limited to payers, health plans, integrated delivery systems, pharmacy benefit management companies, specialty pharmacies, health insurance companies, medical groups, hospitals, hospital systems, Pharmacy and Therapeutics (P&T) Committees, health technology assessment organizations, clinical practice guideline bodies, and other organized health care systems that make or influence population-based health care decisions — to proactively share certain health care economic and scientific information about products ahead of FDA approval. Existing laws and regulations hinder the ability of pharmaceutical manufacturers to share non-promotional economic and scientific information proactively with health care decision-makers on emerging therapies. The current pipeline awaiting FDA approval offers promising but costly treatments for many chronic diseases. The need for proactive PIE communication is especially important as the health care system evolves to a value-based system rewarding quality, improved patient outcomes, and cost efficiency. Allowing proactive sharing of information between health care decision-makers and manufacturers in advance of a product's approval will expedite coverage decisions for, and patient access to, emerging therapies, including those granted breakthrough designation. PIE also allows health care decision-makers to better anticipate a new indication and properly plan for its impact on budget and expansion of patient populations eligible to receive a drug or device. PIE communication has proven essential throughout the COVID-19 PHE.

AMCP urges your support of legislation codifying current regulatory safe harbors that allow for proactive information exchange between manufacturers and health care decision-makers. Such a legislative safe harbor will allow for sharing truthful and non-misleading clinical and economic information about medications and devices in the pipeline, as well as new uses of approved products, before FDA approval.

Managed Care Pharmacy Strategies

AMCP and our members support the use of managed care tools and strategies such as drug prior authorization, step therapy, tiered formularies, medication therapy management (MTM), and preferred pharmacy networks in public and private programs, including Medicare Part D, Medicare Part B, and Medicaid. Managed care pharmacy tools and strategies improve patient outcomes and reduce health care costs, as demonstrated by the Medicare Part D program, which the Congressional Budget Office (CBO) originally [estimated](#) to cost \$400 billion over 10 years, but [was actually 30% less than expected](#).

Provider Status

As highly trained, essential clinicians, pharmacists receive more training and education on medication and its administration than any other role in health care, rendering pharmacists uniquely qualified to significantly expand patient access to needed care and contribute to improving public health. Pharmacists are also the nation's most accessible healthcare professionals, with 90% of Americans living within five miles of a community pharmacy. Unfortunately, major barriers restrict pharmacists from fully utilizing their expertise, including those necessary to support the COVID-19 response.

Currently, pharmacists are not eligible to participate in Medicare. As a result, direct reimbursement for pharmacist services is not available, undermining access to essential services, such as COVID-19 testing and vaccine administration, in pharmacies. This lack of direct reimbursement impacts the financial sustainability of pharmacists' services and limits the ability of pharmacists to practice at the top of their license. Further, because the Centers for Medicare & Medicaid Services (CMS) does not directly oversee pharmacists under Medicare, the agency often inadvertently excludes pharmacists during rulemaking.

To address this issue, AMCP supports the [Pharmacy and Medically Underserved Areas Enhancement Act](#), which would allow pharmacists to deliver care within their scope of practice to patients in federally defined medically underserved communities. This access is particularly vital to meeting patient and community needs during the COVID-19 PHE. **AMCP urges your support of the passage of this legislation in the 117th Congress.**

Pharmacist Reimbursement under Medicare Part B for COVID-19 and Influenza Testing and Vaccinations

AMCP and its members believe that pharmacists should be authorized to receive reimbursement under Medicare Part B for testing and vaccination of COVID-19 and influenza. While many states have authorized pharmacists to administer COVID-19 tests and the Department of Health & Human Services (HHS) issued guidance authorizing certain pharmacists to order and administer COVID-19 vaccinations, a nationwide strategy is essential to reduce strain on the health care system. However, neither recent state nor HHS authorizations allow pharmacists to receive Medicare Part B reimbursement for these services provided to Medicare beneficiaries. Authorizing reimbursement under Part B is critical to ensuring that pharmacists have the necessary resources to treat the highest possible number of patients. **AMCP urges you to protect Medicare beneficiaries and reduce strain on America's healthcare system by authorizing pharmacists to receive reimbursement under Medicare Part B for COVID-19 and influenza testing and vaccinations. Furthermore, AMCP encourages the engagement of managed care organizations and professionals in the safe, efficient, and equitable allocation and distribution of COVID-19 tests and vaccines, especially to vulnerable, at-risk populations.**

Utilization Management Flexibility

Utilization management tools, such as drug prior authorization and step therapy, play an important role in managing the safety and costs of patients' medication. These tools are **not** designed to save money at the expense of patient care, nor are they intended to restrict the practice of medicine or frustrate providers. AMCP supports the appropriate suspension of utilization management tools, including prior authorization, to ensure

that patients have safe access to care and treatment during the COVID-19 PHE. However, **AMCP urges the support of health plans' flexibility to use these managed care tools beyond the COVID-19 PHE. Doing so has the potential to reduce medication costs, errors, and patient harm, while increasing quality of care.**

AMCP is happy to meet with members of your transition team and/or Administration to discuss how we can collaborate to combat COVID-19 and help get patients the medicines they need at a price they can afford. We look forward to working with you to strengthen our healthcare system, improve patient outcomes, reduce costs, and ensure equitable care for all Americans.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan A. Cantrell".

Susan A. Cantrell, RPh, CAE
Chief Executive Officer